

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Agitation; Insomnia; Nausea; Nervousness	Escitalopram Oral Drops	S	Unknown	5 Mg, Unk	Not Reported				
	Escitalopram Oral Drops	S	Unknown	10 Mg, Unk	Not Reported				
	Lorazepam	C	Unknown	0.5	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13426933	DIRECT					41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13426935	DIRECT	Y				41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue; Product Substitution Issue	Escitalopram			S			3 MTH	Not Reported
	Citalpram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13426965	DIRECT	Y	HO			48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13312964	NON-EXPEDITED			US-INCYTE CORPORATION- 2017IN001573		19 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Off Label Use	Jakafi			S	Oral	10 Mg, Bid		Incyte
	Jakafi			S	Oral	10 Mg, Qd		Incyte
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

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Cholecalciferol	C	Not Reported
Clobetasol	C	Not Reported
Dexamethasone	C	Not Reported
Docusate Sodium	C	Not Reported
Emla /00675501/	C	Not Reported
Prednisone	C	Not Reported
Metoprolol Succinate	C	Not Reported
Tacrolimus	C	Not Reported
Bactrim Ds	C	Not Reported
Ativan	C	Not Reported
Hydromorphone	C	Not Reported
Oxycodone	C	Not Reported
Neurontin	C	Not Reported
Albuterol /00139501/	C	Not Reported
Cetirizine	C	Not Reported

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12-Apr-2017	13384351	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1018730			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Overdose; Sopor	Escitalopram			S	Oral	270 Mg, Total		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Carbolithium			S	Oral	5 Df, Total		Mylan
	Etiltox			S	Oral	9 Df, Total		Mylan

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12-Apr-2017	13433018	EXPEDITED (15-DAY)		HO	FR-SA-2017SA060547		82 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Melaena; Peptic Ulcer Haemorrhage	Plavix			S	Oral			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Intravenous (not otherwise specified)	Dosage Form: Owder And Solution For Parenteral Use		Not Reported
	Seroplex			S	Oral			Not Reported
	Aciclovir			C	Unknown			Not Reported

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	Levetiracetam		C	Unknown				Not Reported	
	Augmentin		C	Unknown				Not Reported	
	Lovenox		C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13433599	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1714221US		83 YR	Male	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S		Unk		Allergan	
	Olanzapine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13437968	NON-EXPEDITED			US-SA-2016SA088124			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Head Discomfort	Allegra Allergy 24 Hour			S	Unknown			Not Reported	
	Vyvanse			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13438863	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2017-009096			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Prednisolone			S	Unknown			Bausch And Lomb	
	Tramadol			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Palexia Sr			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13075118	EXPEDITED (15-DAY)		DE, OT	US-WEST-WARD PHARMACEUTICALS		4 DAY	Male	USA

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CORP.-US-H14001-16-03

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy Neonatal; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Neonatal Cardiac Failure; Neonatal Multi-Organ Failure; Vertical Infection Transmission	Progesterone			S	Transplacental			Hikma	
	Ondansetron			S	Transplacental			Hikma	
	Escitalopram			S	Transplacental			Hikma	
	Sertraline			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13387827	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1712393US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Meilax			S	Oral			Not Reported	
	Rize			C	Oral	Unk		Not Reported	
	Sepazon			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13438251	EXPEDITED (15-DAY)			US-LUNDBECK-DKLU2027595		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Contraindication To Medical Treatment	Lexapro Film-Coated Tablets			S	Oral	Unk		Forest	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13441351	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-031208		16 YR	Male	USA

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Drug Ineffective; Prescribed Overdose	Abilify			S	Unknown	25 Mg, Qd		Bristol Myers Squibb	
	Escitalopram			S	Unknown			Not Reported	
	Lithium /00033702/			C	Unknown			Not Reported	
	Infliximab Recombinant			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13442011	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1675823US		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Hyponatraemia	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Metoprolol			S	Oral	23.75 Mg, Qd		Not Reported	
	L-Thyroxin			C	Oral	For Years		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13442030	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1714325US		82 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cerebral Ischaemia; Coma; Melaena; Peptic Ulcer Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Plavix			S	Oral	75 Mg, Qd		Not Reported	
	Aspegic [Acetylsalicylate Lysine]			S	Intravenous (not otherwise specified)	250 Mg, Single		Not Reported	
	Novorapid			C	Unknown			Not Reported	
	Aciclovir			C	Unknown	750 Mg, Q8hr		Not Reported	
	Levetiracetam			C	Unknown	500 Mg, Bid		Not Reported	
	Augmentin			C	Unknown	1 G, Q8hr		Not Reported	
	Metformin			C	Unknown	1000 Mg, Tid		Not Reported	
	Coversyl			C	Unknown	5 Mg, Qd		Not Reported	
	Repaglinide			C	Unknown			Not Reported	

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Lovenox			C		Unknown		4000 lu, Qd		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13442386	DIRECT		HO, OT			45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation;	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Lundbeck	
Catatonia; Dysphonia;	Amitriptyline			C				Not Reported	
Fine Motor Skill	Rizatriptan Benzoate			C				Not Reported	
Dysfunction; Gait	Chlordiazepoxide			C				Not Reported	
Disturbance;	Ventolin			C				Not Reported	
Hypoaesthesia;	Extra Virgin Coconut Oil			C				Not Reported	
Palpitations; Paraesthesia;	Apple Cider Vinegar Tablets			C				Not Reported	
Tremor	Multi Vitamin			C				Not Reported	
	Omega Fish Oil			C				Not Reported	
	Krill Oil			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin B-12			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2017	13442078	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017004678			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Dizziness;	Escitalopram			S	Oral	2 Df, Qd		Macleods	
Dyspnoea; Hypersomnia;									
Musculoskeletal Stiffness;									
Vision Blurred									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2017	13447218	DIRECT		HO, LT			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional	Escitalopram 5mg			S	Oral	Quantity:1 Tablet(S);		Camber	

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State; Dehydration; Hallucination; Insomnia; Palpitations; Paranoia; Speech Disorder	Clonazepam Vitamin D Nos Vitamin B12	S C C	Oral	Quantity:1 Tablet(S);	Mylan Not Reported Not Reported

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15-Apr-2017	12193187	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR- APL-2016-02992			Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Dizziness; Drug Ineffective; Gingival Disorder; Headache; Hypersensitivity; Mental Disorder; Nausea; Suicidal Ideation	Escitalopram Aurobindo Tablets			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13259140	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2017024583		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Sounds Abnormal; Intentional Product Misuse; Intentional Underdose; Product Dose Omission; Rales	Incruse Ellipta Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Qd		Glaxosmithkline
	Escitalopram Oxalate Tablet			S	Oral	20 Mg, Qd		Glaxosmithkline
	Escitalopram Oxalate Tablet			S	Oral	10 Mg, Bid		Glaxosmithkline
	Ceftin			C				Glaxosmithkline
	Aspirin Low Dose			C				Glaxosmithkline
	Atorvastatin Tablet			C				Glaxosmithkline
	Furosemide Tablet			C				Glaxosmithkline
	Pantoprazole Tablet			C				Glaxosmithkline
	Azithromycin			C				Not Reported
	Prednisone			C				Not Reported
	Clonazepam			C				Not Reported
	Verapamil Cr			C				Not Reported

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17-Apr-2017	13446057	EXPEDITED (15-DAY)		OT	DE-HETERO LABS LTD-1065411		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Small For Dates Baby	Escitalopram			S	Transplacental			Hetero	
	Buprenorphine			S	Transplacental			Not Reported	
	L-Thyroxin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13447452	EXPEDITED (15-DAY)		HO, OT	FR-ASTELLAS- 2017US014405		39 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemolytic Anaemia	Vesicare			S	Oral	Unk Unk, Unknown Freq.		Astellas	
	Tysabri			S	Intravenous (not otherwise specified)			Not Reported	
	Fampyra			S	Oral	Unk Unk, Unknown Freq.		Not Reported	
	Baclofen			S	Oral	Unk Unk, Unknown Freq.		Not Reported	
	Gabapentin			S	Oral	Unk Unk, Unknown Freq.		Not Reported	
	Escitalopram			S	Oral	Unk Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13447713	DIRECT	Y	OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Crying; Depression; Dizziness; Fatigue; Fear; Irritability; Nausea; Product Substitution Issue; Withdrawal Syndrome	Escitalopram 10mg			S	Oral			Not Reported	
	Escitalopram Oxylate			S	Oral			Not Reported	
	Paxil Cr			C				Not Reported	
	Zoloft			C				Not Reported	
	Celexa			C				Not Reported	
	Cymbalta			C				Not Reported	
	Prozac			C				Not Reported	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447872	DIRECT	Y	LT			14 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Intentional Overdose; Intentional Self-Injury	Escitalopram 10mg			S	Oral			Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13448254	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2017M1022991			Unknown	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S	Oral	2 - 0 - 0		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13449360	EXPEDITED (15-DAY)		HO	FR-SA-2017SA067641		43 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Reaction With Eosinophilia And Systemic Symptoms	Mianserin Hydrochloride			S	Oral			Not Reported	
	Stilnox			S	Oral			Not Reported	
	Lamictal			S	Oral			Not Reported	
	Lamictal			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Xanax			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13449372	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1714802US		61 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Agitation; Asthenia; Drug Abuse; Overdose; Restlessness	Escitalopram Oxalate Unk	S	Oral	20 Tablets, Overdose	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	12554650	EXPEDITED (15-DAY)		OT	DE-FRI-1000086029		59 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortitis	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Ramipril			C	Oral	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13450835	EXPEDITED (15-DAY)		OT	NZ-APOTEX-2017AP010087			Male	NZL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome Neonatal; Nystagmus; Optic Atrophy	Apo-Allopurinol			S	Oral	Unk		Apotex
	Apo-Gabapentin			S	Oral	Unk		Apotex
	Apo-Escitalopram			S	Oral	Unk		Apotex
	Clonidine			S	Oral	Unk		Not Reported
	Mercaptopurine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13455241	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1714784US		31 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13455243	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1714793US		76 YR	Male	CAN

FDA Adverse Event Reporting System

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Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram Oxalate - Bp			S		10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13455339	EXPEDITED (15-DAY)		HO, LT	AT-ALLERGAN-1714783US			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Myoclonus; Partial Seizures	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Cefepim Mip			S	Intravenous (not otherwise specified)	1 Df, Tid		Not Reported	
	Trittico Retard			S	Unknown	100 Mg, Qd		Not Reported	
	Trittico Retard			S	Unknown	0-0-0-1		Not Reported	
	Tradolan Tropfen			S	Unknown	10 Drops, Daily		Not Reported	
	Neurontin			C	Unknown			Not Reported	
	Lovenox			C	Unknown	0-0-1		Not Reported	
	Thyrex			C	Unknown			Not Reported	
	Temesta (Lorazepam)			C	Unknown			Not Reported	
	Spiroon			C	Unknown	1/2-0-0		Not Reported	
	Novalgine (Metamizole Sodium)			C	Unknown	30-30-30		Not Reported	
	Antiflat			C	Unknown			Not Reported	
	Concor			C	Unknown	1-0-1		Not Reported	
	Lasix			C	Intravenous (not otherwise specified)	1-0-0, 1m Kh		Not Reported	
	Multivit B			C	Intravenous (not otherwise specified)			Not Reported	
	Nexium			C	Unknown	1-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13404787	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-MACLEODS PHARMACEUTICALS			Unknown	USA

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US LTD-
MAC2017004623

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram Oxalate			S	Transplacental	Unk		Macleods
	Sertraline			S	Transplacental	Unk		Not Reported
	Ondansetron			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13456957	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017162430		43 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Xanax			S	Oral	0.5 Mg, 3x/Day		Pfizer
	Lamictal			S	Oral	50 Mg, Daily		Not Reported
	Lamictal			S		150 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported
	Mianserin Hydrochloride			S	Oral	30 Mg, 1x/Day		Not Reported
	Stilnox			S	Oral	10 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13457905	EXPEDITED (15-DAY)		HO	TW-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016R1-111410		46 YR	Male	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Restless Legs Syndrome	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Lithium			S	Unknown	600 Mg, Daily		Sun

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	Quetiapine		S	Unknown	100 Mg, Daily		Sun		
	Quetiapine		S		150 Mg, Daily		Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13458571	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP010261		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram Apotex			S	Unknown	10 Mg Per Day		Apotex	
	Escitalopram Apotex			S	Unknown	20 Mg Per Day		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	6067238	EXPEDITED (15-DAY)		HO	PHBS2006US08567		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Pressure Increased; Chest Pain; Confusional State; Dizziness; Fall; Flushing; Hallucination; Headache; Heart Rate Increased; Hyperventilation; Lethargy; Muscle Rigidity; Pallor; Pharyngeal Erythema; Pyrexia; Serotonin Syndrome; Tremor	Methylphenidate			S	Unknown	20 Mg, Qd (10 Mg, 2 Doses)		Novartis	
	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported	
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported	
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Lamotrigine			C	Unknown	125 Mg, Bid		Not Reported	
	Lamotrigine			C	Unknown	150 Mg, Bid		Not Reported	
	Lamotrigine			C	Unknown	50 Mg, Bid		Not Reported	
	Trazodone			C	Unknown	100 Mg, Qhs		Not Reported	
	Trazodone			C	Unknown	100 Mg, Qhs		Not Reported	
	Mirtazapine			C	Unknown	15 Mg, Qhs		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13191868	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20170124350			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Sudafed		Y	S	Unknown			Not Reported	
	Sudafed			S	Unknown			Not Reported	
	Latuda			S	Oral			Not Reported	
	Latuda			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Abilify			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13385274	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1712267US		77 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage; Drug Interaction; Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Plavix			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13459843	NON-EXPEDITED		OT	US-JNJFOC-20170308278		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia; Off Label Use; Product Use In Unapproved Indication	Risperidone			S	Oral			Not Reported	
	Risperidone			S	Oral			Not Reported	
	Pristiq			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Paroxetine			S	Unknown			Not Reported	
	Lithium Carbonate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13460396	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-32341		31 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S	Oral	1 Df, Two Times A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13461664	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2017GSK054759		43 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Incorrect Dose Administered	Lamictal			S	Oral	50 Mg, Qd		Glaxosmithkline	
	Lamictal			S	Oral	150 Mg, Unk		Glaxosmithkline	
	Seroplex			S	Oral	10 Mg, 1d		Glaxosmithkline	
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported	
	Mianserine			S	Oral	30 Mg, 1d		Not Reported	
	Stilnox			S	Oral	10 Mg, 1d		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13461836	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK054032			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stress	Wellbutrin			S		Unk		Glaxosmithkline	
	Lexapro			S		Unk		Not Reported	
	Xanax			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13463272	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715102US		82 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Disturbance In Attention; Dysarthria; Gastrointestinal Ulcer Haemorrhage; Hypercapnia; Hypotension; Myoclonus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Olanzapine Mylan			S	Oral			Not Reported	
	Ciprofloxacin Mylan			S	Oral	500 Mg, Bid		Not Reported	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Cardensiel			C	Unknown			Not Reported	
	Losartan			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Neurontin			C	Unknown			Not Reported	
	Letrozole			C	Unknown			Not Reported	
	Xgeva			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13463275	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1715269US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Defaecation Urgency; Rectal Discharge; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Lorazepam			S	Oral			Not Reported	
	Imuran			C	Oral			Not Reported	
	Imuran			C	Oral			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13423986	EXPEDITED (15-DAY)		HO, OT	CN-ALLERGAN-1713808US		33 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Promyelocytic Leukaemia; Leukopenia; Myelodysplastic Syndrome; Nasopharyngitis; Off Label	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Alprazolam			C	Unknown	Unk		Not Reported	

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Use

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13466307	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001999		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram /01588502/			S	Oral	Unk Unk, Unknown		Not Reported
	Diphenhydramine			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13468338	EXPEDITED (15-DAY)		HO, OT	FR-INDIVIOR LIMITED- INDV-100536-2017		25 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Drug Dependence; Drug Dependence; Drug Dependence; Product Use Issue; Substance Abuser; Suicide Attempt; Toxicity To Various Agents	Subutex 8mg Tablet			S	Unknown	8 Mg, Bid		Reckitt Benckiser
	Cocaine			S	Unknown	Unknown		Not Reported
	Cannabis			S	Unknown	Unknown		Not Reported
	Seresta			S	Oral	50 Mg: 1 At Noon And 2 When Going To Sleep		Not Reported
	Seresta			S	Oral	600 Mg, Unk		Not Reported
	Seroplex			S	Oral	15 Mg: 1 When Waking Up		Not Reported
	Seroplex			S	Oral	60 Mg, Unk		Not Reported
	Haldol /00027401/			S	Oral	5 Mg: 1 At Noon And 2 When Going To Sleep		Not Reported
	Haldol /00027401/			S	Oral	60 Mg, Unk		Not Reported
	Largactil /00011901/			S	Oral	100 Mg, 1 When Going To Sleep		Not Reported
	Largactil /00011901/			S	Oral	400 Mg, Unk		Not Reported
	Parkines Lp			C	Unknown	5 Mg: 2 When Waking Up		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13468795	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715461US		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Drug Dependence; Substance Abuser; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Seresta			S	Oral	600 Mg, Unk		Not Reported	
	Seresta			S	Oral			Not Reported	
	Subutex			S	Unknown			Not Reported	
	Haldol			S	Oral	60 Mg, Unk		Not Reported	
	Haldol			S	Oral			Not Reported	
	Largactil			S	Oral	400 Mg, Unk		Not Reported	
	Largactil			S	Oral			Not Reported	
	Cannabis			S	Unknown			Not Reported	
	Cocaine			S	Unknown	15 Mg, Unk		Not Reported	
	Parkinane Lp			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2017	13470063	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001951		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Oxycodone Hcl			S	Oral	Unk Unk, Unknown		Vintage	
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	11523981	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-592946ISR		72 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Apathy; Confusional State; Daydreaming; Dizziness; Dysphagia; Dysstasia; Hypercalcaemia; Hyperparathyroidism Primary; Malaise; Parathyroid Disorder; Somnolence; Tremor	Escitalopram 10 Mg Teva, Filmomhulde Tabletten Metformine Amlodipine Enalaprilmaleaat Acetylsalicylzuur Metoprololtartraat Crestor Losartan Omperazol Divisun Novomix	S C C C C C C C C C C	Oral	10 Milligram Daily;	Ivax
				2 Dosage Forms Daily; In The Morning And At Night	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13404791	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2017004624			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Escitalopram Oxalate			S	Unknown	Unk, (Final Trimester)		Macleods	
	Ondansetron			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	Unk,For The Initial Two Trimester		Not Reported	
	Progesterone			S	Unknown	High Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13472078	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001857		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besylate Tablets			S		Unk, Unknown, Ingst+Par		Vintage	
	Tamsulosin Hcl			S		Unk Unk, Unknown, Ingst+Par		Par	
	Enalapril			S		Unk Unk, Unknown, Ingst+Par		Not Reported	

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Escitalopram /01588502/	S	Unk Unk, Unknown, Ingst+Par	Not Reported
Insulin	S	Unk Unk, Unknown, Ingst+Par	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13472189	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-001872		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besylate Tablets			S		Unk Unk, Unknown, Ingst+Unk		Vintage	
	Escitalopram			S		Unk Unk, Unknown, Ingst+Unk		Not Reported	
	Ethanol			S		Unk Unk, Unknown, Ingst+Unk		Not Reported	
	Drug, Unknown			S		Unk Unk, Unknown, Ingst+Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13473654	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1715452US		43 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Lamictal			S	Oral	150 Mg, Qd		Not Reported	
	Lamictal			S	Oral	50 Mg, Qd		Not Reported	
	Xanax			S	Oral	1.5 Mg, Tid		Not Reported	
	Mianserine			S	Oral	30 Mg, Qd		Not Reported	
	Stilnox			S	Oral	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13476371	DIRECT		DS			52 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Escitalopram			S	Oral			Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13477547	DIRECT	Y	LT, OT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral			Not Reported	
	Carbamazepine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13479718	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715644US		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Kardegic			S	Oral	160 Mg, Qd		Not Reported	
	Pravastatine			C	Oral			Not Reported	
	Xanax			C	Oral			Not Reported	
	Dafalgan			C	Oral			Not Reported	
	Duotrav			C	Ophthalmic			Not Reported	
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C	Unknown			Not Reported	
	Uvedose			C	Unknown			Not Reported	
	Perindopril			C	Unknown			Not Reported	
	Chondrosulf			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13482670	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002504		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Clonazepam	S	Oral	Unk Unk, Unknown	Par
	Bupropion Hcl XI	S	Oral	Unk Unk, Unknown	Par
	Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
	Amfetamine/ Dextroamfetamine	S	Oral	Unk Unk, Unknown	Not Reported
	Ethanol	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13483306	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2017-01917		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	Unk		Lupin	
	Escitalopram			S	Unknown	20 Mg, Per Day		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13485044	EXPEDITED (15-DAY)		OT	PHHY2017AU058369		71 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Orthostatic Hypotension; Spinal Cord Disorder	Exforge			S	Unknown			Novartis	
	Atorvastatin			S	Unknown			Not Reported	
	Pradaxa			S	Unknown			Not Reported	
	Temazepam			S	Unknown			Not Reported	
	Nexium			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Diamicron			S	Unknown			Not Reported	
	Zanidip			S	Unknown			Not Reported	
	Lorcaserin			S	Unknown			Not Reported	
	Micardis			S	Unknown			Not Reported	
	Adalat			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13486655	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-01983			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13486681	NON-EXPEDITED			US-APOTEX- 2017AP008423		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Chills; Confusional State; Dizziness; Drug Interaction; Dysstasia; Gait Disturbance; Hallucination; Heart Rate Increased; Tremor; Vision Blurred	Trazodone Hydrochloride			S	Oral	1 Df, Qd		Apotex	
	Trazodone Hydrochloride			S				Apotex	
	Lexapro			S	Oral	1 Df, Qd		Not Reported	
	Lisinopril			C	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13488291	NON-EXPEDITED			US-009507513- 1704USA011963		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Remeron			S	Oral			Merck	
	Escitalopram			S				Not Reported	
	Escitalopram			S				Not Reported	
	Pregabalin			S				Not Reported	
	Pregabalin			S				Not Reported	

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27-Apr-2017	10138717	EXPEDITED (15-DAY)		OT	FR-FRI-1000066843		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Fluctuation; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Novorapid			C	Subcutaneous	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13420943	EXPEDITED (15-DAY)		CA, DE, DS, HO, LT, OT	US-TORRENT-00002648		4 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S				Unknown	
	Sertraline			S				Unknown	
	Progesterone			S				Unknown	
	Ondansetron			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13420944	EXPEDITED (15-DAY)		OT	US-TORRENT-00002649			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S				Unknown	
	Sertraline			S				Unknown	
	Escitalopram			S				Unknown	
	Progesterone			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13454834	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2017M1023676			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Off Label	Baclofen			S	Oral			Not Reported	

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Use; Toxicity To Various Agents; Unresponsive To Stimuli	Metoprolol	S	Oral							Not Reported
	Escitalopram	S								Not Reported
	Perindopril	S								Not Reported
	Colchicine	S								Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13455769	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2017M1023679			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Poisoning Deliberate; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Paracetamol			S				Not Reported
	Dextropropoxyphene			S		Mylan		
	Valpromide			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13490376	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US07374			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Apathy; Condition Aggravated; Libido Decreased; Sedation	Topiramate			S	Unknown	Unk		Invagen
	Topiramate			S	Unknown	50 Mg/Day		Invagen
	Topiramate			S	Unknown	100 Mg/Day		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	30 Mg/Day		Invagen
	Risperidone			S	Unknown	2 Mg/Day		Cipla
	Fluoxetine			S	Unknown	20 Mg/Day		Cipla

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13490893	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-762349ROM		41 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Off Label Use; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram	S	Unknown	Ivax
	Baclofen	S	Oral	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Dextropropoxyphene	C	Unknown	Not Reported
	Valpromide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13491600	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE41631		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Haematuria; Hyperkalaemia; Limb Discomfort; Myalgia; Testicular Cyst; Testicular Pain	Inexium			S	Oral			Astrazeneca	
	Escitalopram			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Pravastatin			C	Oral			Not Reported	
	Pregabalin			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13492224	NON-EXPEDITED			US-PFIZER INC-2017175034		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Treximet			S		Unk		Not Reported	
	Tramadol Hydrochloride			S		Unk		Not Reported	
	Amitriptyline Hcl			S		Unk		Not Reported	
	Lunesta			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13492433	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170424871			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia; Obesity	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperidone			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13495316	DIRECT		HO			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Impaired Driving Ability; Memory Impairment; Road Traffic Accident	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Omeprazole			S	Oral	Quantity:1 Capsule(S);		Not Reported	
	Vitamin C			C				Not Reported	
	Calcium			C				Not Reported	
	Multivitamin			C				Not Reported	
	Vitamin D3			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13435709	EXPEDITED (15-DAY)		OT	ES-MYLANLABS- 2017M1022724			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	10mg/Day; Later Doubled The Dose		Not Reported	
	Escitalopram			S	Unknown	20mg/Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13485677	EXPEDITED (15-DAY)		OT	US-SUNOVION-2017SUN001759		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Intentional Self-Injury; Suicide Attempt	Latuda			S	Oral	20 Mg, Unk		Sunovion	
	Clonidine			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13494479	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002354		41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Tramadol			S	Oral	Unk Unk, Unknown		Par	
	Baclofen Tablets			S	Oral	Unk Unk, Unknown		Vintage	
	Clonazepam			S	Oral	Unk Unk, Unknown		Par	
	Hydrocodone Bitartrate / Acetaminophen			S	Oral	Unk Unk, Unknown		Vintage	
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13495365	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2017-002387		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Doxepin			S	Oral	Unk Unk, Unknown		Par	
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage	
	Hydrochlorothiazide Tablets			S	Oral	Unk Unk, Unknown		Vintage	
	Cetirizine Hydrochloride Syrup			S	Oral	Unk Unk, Unknown		Vintage	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	

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Hydrocodone	S	Oral	Unk Unk, Unknown	Not Reported
Olmesartan	S	Oral	Unk Unk, Unknown	Not Reported
Famotidine	S	Oral	Unk Unk, Unknown	Not Reported
Pregabalin	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13421802	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-137513			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown	Unk		Natco Pharma
	Sertraline			S	Unknown	For The Initial Two Trimester		Sun
	Escitalopram			S	Unknown	For The Final Trimester		Not Reported
	Progesterone			S	Unknown	High-Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13473653	EXPEDITED (15-DAY)		HO	DE-ALLERGAN- 1715475US		74 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Head Titubation; Prescribed Overdose; Syncope; Tremor	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan
	Ergenyl			C	Unknown	In The Evening		Not Reported
	Dilatrend			C	Unknown			Not Reported
	Atorvastatin			C	Unknown	(1 In The Evening)		Not Reported
	Marcumar			C	Unknown			Not Reported
	Common Salt			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Trenantone			C	Unknown	3 Months Injection		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Remergil		C	Unknown		Trenantone			Not Reported
	Cymbalta		C	Unknown		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13500412	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1716660US		70 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia Oral; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13181847	NON-EXPEDITED			US-IMPAX LABORATORIES, INC-2016-IPXL-01502		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Feeling Jittery; Labelled Drug-Food Interaction Medication Error; Pain; Therapeutic Response Shortened; Tremor	Rytary			S	Oral	Three Capsules 195 Mg At Five To Six Hours Intervals Four Times A Day		Impax	
	Rytary			S	Oral	3 Capsules Of 195 Mg And One Capsule Of 95 Mg (Four Capsules)		Impax	
	Rytary			S	Oral	48/75mg/195 1 Capsule Four Times A Day Every 5-6 Hrs		Impax	
	Gabapentin			S	Unknown	100 Mg, Three Times Daily		Not Reported	
	Gabapentin			S	Unknown	Unk, Dose Reduced		Not Reported	
	Synthroid			S	Unknown	0.88 Mg, Once A Day In The Morning		Not Reported	
	Lexapro			S	Unknown	Two Tablets -One Tablet Of 5 Mg And The Other One Of 10 Mg Once In		Not Reported	

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Senna	C	Unknown	The Morning	Not Reported
Centrum Silver	C	Unknown	8.6 Mg, Two Tablets At Night	Not Reported
Vitamin D3	C	Unknown	One Tablet With Food In Afternoon	Not Reported
Vitamin B12	C	Unknown	2000 Lu Units	Not Reported
Aleve	C	Unknown	1000 Units	Not Reported
Aleve	C	Unknown	220 Mg, Once A Day	Not Reported
Aleve	C			Not Reported
Aleve	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13468283	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715469US		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Focal Dyscognitive Seizures	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13502221	EXPEDITED (15-DAY)		DE	FR-ACCORD-050958		53 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram			S		Drug Packs		Accord
	Metoprolol			S		Drug Packs		Accord
	Perindopril/Perindopril Erbumine			S		Drug Packs		Not Reported
	Colchicine			S		Drug Pack		Not Reported
	Baclofen			S		Drug Pack		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13502252	EXPEDITED (15-DAY)		OT	ES-ZYDUS-014703		73 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Angle Closure Glaucoma;	Escitalopram	S	Unknown	Zydus Pharm
Chorioretinal Folds;	Escitalopram	S	Unknown	Zydus Pharm
Choroidal Detachment;				
Choroidal Effusion;				
Choroiditis; Headache;				
Myopia; Visual Acuity				
Reduced				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13503401	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX-2017AP011426		21 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Serotonin Syndrome	Apo-Desvenlafaxine Mr			S	Oral	500 Mg, Unk		Not Reported	
	Apo-Escitalopram			S	Oral	100 Mg, Unk		Apotex	
	Apo-Mirtazapine			S	Oral	870 Mg, Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	12940543	NON-EXPEDITED			US-JNJFOC-20161103011			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Weight Gain; Gynaecomastia	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported	
	Risperdal			S	Oral	Varying Dose Of 0.50mg ; 1.00mg.		Not Reported	
	Risperdal			S	Oral			Not Reported	
	Lexapro			S	Unknown	At Bed Time		Not Reported	

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Lexapro			S	Unknown	At Bed Time			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13507143	EXPEDITED (15-DAY)		OT	TW-CIPLA LTD.- 2017TW07824			Unknown	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Hypertriglyceridaemia; Somnolence	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla	
	Fenofibrate			S	Unknown	200 Mg, Daily For 7 Days		Cipla	
	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla	
	Fenofibrate			S	Unknown	200 Mg, Qod		Cipla	
	Carvedilol			S	Unknown	Unk		Cipla	
	Escitalopram			S	Unknown	Unk		Invagen	
	Venlafaxine			S	Unknown	37.5 Mg, Qd		Cipla	
	Venlafaxine			S	Unknown	75 Mg, Qd		Cipla	
	Clopidogrel			S	Unknown	Unk		Cipla	
	Famotidine			S	Unknown	Unk		Not Reported	
	Sennosides			S	Unknown	Unk		Not Reported	
	Levocetirizine			S	Unknown	Unk		Not Reported	
	Zopiclone			S	Unknown	Unk		Cipla	
	Mirtazapine			S	Unknown	Unk		Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13510103	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS- 2017M1025934			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cushing'S Syndrome; Depression; Drug Abuse; Steroid Withdrawal Syndrome	Dexamethasone			S	Oral			Not Reported	
	Escitalopram			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2017	13332681	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1709321US		38 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Abuse	Escitalopram Oxalate Unk			S	Oral	18 Df, Single		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2017	13514240	NON-EXPEDITED			US-ABBVIE-16P-163-1625572-00			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Major Depression; Panic Attack; Tinnitus	Creon			S	Oral	1 Each Meal		Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Venlafaxine			S	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Percocet			C	Unknown			Not Reported	
	Aspirin			C	Unknown			Not Reported	
	Loratadine			C	Unknown			Not Reported	
	Multivitamin			C	Unknown			Not Reported	
	Vitamin E			C	Unknown			Not Reported	
	Calcium With Vitamin D3			C	Unknown			Not Reported	
	Calcium With Vitamin D3			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13313311	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1709137US		32 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Rib Fracture	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

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Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
Depas (Etizolam)	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13517871	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1674498US		45 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety Disorder; Pyrexia; Sexual Dysfunction; White Blood Cell Count Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13518153	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717257US		1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Neonatal Respiratory Distress	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan
	Paroxetine Base			S	Transplacental	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	11003288	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2015001678			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angle Closure Glaucoma; Choroidal Effusion; Extra Dose Administered; Headache; Visual Acuity Reduced	Escitalopram 10mg Tablet			S	Unknown	10 Mg, Qd		Macleods
	Escitalopram 10mg Tablet			S	Unknown	20 Mg, Qd (Three Days Before Onset The Dose Was Doubled At 20 Mg)		Macleods

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08-May-2017	13521864	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-33616		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Off Label Use; Overdose; Toxicity To Various Agents; Unresponsive To Stimuli	Metoprolol			S	Unknown			Aurobindo	
	Perindopril			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Not Reported	
	Baclofen			S	Unknown			Not Reported	
	Colchicine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13521891	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-33747		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Poisoning Deliberate; Toxicity To Various Agents; Unresponsive To Stimuli	Paracetamol			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Not Reported	
	Dextropropoxyphene			S	Unknown			Not Reported	
	Baclofen			S	Unknown			Not Reported	
	Valpromide			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13522751	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1717675US		93 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Coumadine			S	Oral	2 Mg, Qd		Not Reported	
	Levothyrox			C	Oral	25 Mg, Qd		Not Reported	
	Temesta (Lorazepam)			C	Oral	0.5 Mg, Qd		Not Reported	

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08-May-2017	13523087	EXPEDITED (15-DAY)		OT	ES-SA-2017SA078189		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Aubagio			S	Oral			Not Reported	
	Amantadine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13524339	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1717677US		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Erythema; Feeling Hot	Escitalopram Oxalate - Bp			S	Oral	10 Mg Once Every 2 Days On Even Days		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg Once Every 2 Days On Uneven Days		Allergan	
	Puregon [Follitropin Beta]			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13524340	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717669US		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2017	13526271	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00002720		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation;	Quetiapine			S				Unknown	

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Treatment Noncompliance	Fluoxetine	S	Unknown
	Lithium	S	Unknown
	Aripiprazole	S	Unknown
	Guanfacine Er	S	Unknown
	Escitalopram	S	Unknown
	Sertraline	S	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13532507	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-767720ROM		53 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Off Label Use; Overdose; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Unknown			Ivax
	Perindopril			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Colchicine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13532740	EXPEDITED (15-DAY)		OT	DK-ELI_LILLY_AND_COMP ANY-DK201705000143			Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affect Lability; Compulsions; Dental Caries; Derealisation; Dry Mouth; Headache; Irritability; Mouth Swelling; Mucosal Inflammation; Oral Pain; Pain In Jaw; Periodontitis; Restlessness; Toothache	Cymbalta			S	Oral	30 Mg, Unknown		Eli Lilly And Co
	Cymbalta			S	Unknown	60 Mg, Qd		Eli Lilly And Co
	Cymbalta			S	Unknown	60 Mg, Bid		Eli Lilly And Co
	Akarin			S	Oral	Unk, Unknown		Not Reported
	Cipralext /01588501/			S	Oral	Unk, Unknown		Not Reported
	Efexor			S	Oral	Unk, Unknown		Not Reported
	Medikinet /00083801/			C	Oral	Unk, Unknown		Not Reported
	Ritalin			C	Oral	Unk, Unknown		Not Reported

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10-May-2017	13532976	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE48842		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Headache; Status Epilepticus	Xeroquel			S	Oral			Astrazeneca	
	Xeroquel			S	Oral			Astrazeneca	
	Seroplex			S	Oral			Not Reported	
	Stilnox			S	Oral			Not Reported	
	Lysanxia			S	Oral			Not Reported	
	Forlax			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13533449	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1027621			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Abnormal; Electrocardiogram Qrs Complex Prolonged; Hypotension; Tachycardia	Acetaminophen\Caffeine\Propoxyphene			S	Oral	32 Df, Once		Mylan	
	Izalgi 500 Mg/25 Mg, Gélule			S	Oral	16 Df, Once		Mylan	
	Alprazolam			S	Oral	30 Df, Once		Not Reported	
	Escitalopram			S	Oral	14 Df, Once		Not Reported	
	Tramadol			S	Oral	30 Df, Once		Not Reported	
	Laroxyl			S	Oral	Unk, Once		Mylan	
	Prazepam			S	Oral	40 Df, Once		Mylan	
	Skenan			S	Oral	14 Df, Once		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13534689	DIRECT	Y	HO			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Mental Status Changes; Seizure	Escitalopram			S	Oral			Not Reported	

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10-May-2017	13535048	DIRECT		DS			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Substitution Issue	Escitalopram			S				Not Reported	
	Lexapro			C				Not Reported	
	Metformin			C				Not Reported	
	Levemir Flextouch			C				Not Reported	
	Novolog Flexpen			C				Not Reported	
	Benazepril-Htz			C				Not Reported	
	Pioglitazone			C				Not Reported	
	Alprazolam			C				Not Reported	
	Atorvastatin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13535103	DIRECT		DS			34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Temporomandibular Joint Syndrome	Escitalopram			S				Not Reported	
	Allergy Shots			C				Not Reported	
	Vitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13441013	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-030887			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Abilify			S	Unknown			Bristol Myers Squibb	
	Latuda			S	Oral	Unk		Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Sudafed /00076302/			S	Unknown			Not Reported	

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11-May-2017	13443147	EXPEDITED (15-DAY)		OT	US-TORRENT-00002664		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Electrocardiogram Qt Prolonged	Methimazole			C				Unknown	
	Warfarin			C				Unknown	
	Propranolol			C				Unknown	
	Iloperidone			S				Unknown	
	Olanzapine			S				Unknown	
	Bupropion Hydrochloride			S				Unknown	
	Escitalopram			S				Unknown	
	Amitriptyline			S				Unknown	
	Mirtazapine			S				Unknown	
	Lorazepam			S				Unknown	
	Alprazolam			S				Unknown	
	Quetiapine			C				Unknown	
	Clonazepam			C				Unknown	
	Trazodone			C				Unknown	
	Haloperidol			C				Unknown	
	Valproic Acid			C				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13535070	EXPEDITED (15-DAY)		HO, LT, OT	BR-ASTRAZENECA-2017SE49153		67 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foreign Body Aspiration; Heart Rate Decreased; Hypotension; Loss Of Consciousness; Stupor; Suicide Attempt	Seroquel			S	Oral	25.0mg Once/Single Administration		Zeneca	
	Lexapro			S	Oral	20.0mg Once/Single Administration		Not Reported	
	Alprazolam			S	Oral	1.0mg Once/Single Administration		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13537409	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1718597US		56 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Headache; Status Epilepticus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S	Oral	600 Mg, Qd		Not Reported
	Lysanxia			S	Oral	Unk		Not Reported
	Stilnox			S	Oral	Unk		Not Reported
	Forlax			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13537410	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1718417US		23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Anger; Cognitive Disorder; Depression; Hallucination; Hospitalisation; Mental Disorder; Panic Attack; Physical Assault; Product Dose Omission; Tobacco User	Lexapro			S	Oral	10 Mg, Bid		Allergan
	Lexapro			S	Oral	20 Mg, Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	12884918	EXPEDITED (15-DAY)		HO, LT, OT	PL-PFIZER INC-2016496618			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Overdose; Toxicity To Various Agents	Ramipril			S	Unknown	Unk		Pfizer
	Donepezil Hcl			S	Endocervical	Unk		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer
	Dextromethorphan Hbr		Y	S	Unknown	Unk		Unknown
	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Acetylsalicylic Acid			S	Unknown	Unk		Pfizer

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Sertraline Hcl	S	Unknown	Unk	Pfizer
Olanzapine	S	Unknown	Unk	Not Reported
Zolpidem Tartrate	S	Unknown	Unk	Pfizer
Topiramate	S	Unknown	Unk	Not Reported
Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
Simvastatin	S	Unknown	Unk	Not Reported
Valsartan	S	Unknown	Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Escitalopram Oxalate	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Metformin Hcl	S	Unknown	Unk	Not Reported
Indapamide	S	Unknown	Unk	Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Morphine Hcl	S	Unknown	Unk	Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Hydroxyzine	S	Unknown	Unk	Not Reported
Sulpiride	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Omeprazole	S	Unknown	Unk	Not Reported
Lamotrigine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13538091	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2017US06841			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dizziness;	Gabapentin			S	Oral	100 Mg, Unk		Invagen
Dizziness; Drug	Gabapentin			S	Oral	400 Mg, Unk		Invagen
Ineffective; Feeling								
Abnormal; Gait								

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Disturbance; Pain	Gabapentin	S	Oral	300 Mg, Qd	Invagen
	Escitalopram	S	Unknown	20 Mg, At Dinner Time	Invagen
	Escitalopram	S			Invagen
	Zaleplon	S	Unknown	10 Mg, Unk	Cipla
	Buspirone	S	Unknown	15mg In The Morning And 30mg At Night	Not Reported
	Buspirone	S	Unknown	30mg In The Morning And 30mg At Night	Not Reported
	Buspirone	S	Unknown	15mg In The Morning And 30mg At Night	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13541088	EXPEDITED (15-DAY)		HO, OT	GXBR2017US001623		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Gastroesophageal Reflux Disease; Hyperhidrosis; Hypovitaminosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Tremor	Phentermine Hydrochloride Capsules Usp			S	Unknown	Unk Df, Unk		Novartis
	Ampyra			S	Oral	10 Mg, Q12h		Not Reported
	Baclofen			S	Oral	10 Mg, Tid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Aspirin			C	Unknown	Unk Df, Unk		Not Reported
	Celebrex			C	Unknown	Unk Df, Unk		Not Reported
	Oxycontin			C	Unknown	Unk Df, Unk		Not Reported
	Oxycodone			C	Unknown	Unk Df, Unk		Not Reported
	Levemir			C	Unknown	Unk Df, Unk		Not Reported
	Spiroglactone			C	Unknown	Unk Df, Unk		Not Reported
	Zyrtec			C	Unknown	Unk Df, Unk		Not Reported
	Movantik			C	Unknown	Unk Df, Unk		Not Reported
	Ambien			C	Unknown	Unk Df, Unk		Not Reported
	Cholecalciferol			C	Unknown	Unk Df, Unk		Not Reported
	Clonidine			C	Unknown	Unk Df, Unk		Not Reported

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	L-Methylfolate	C	Unknown	Unk Df, Unk	Not Reported
	Lisinopril	C	Unknown	Unk Df, Unk	Not Reported
	Maalox	C	Unknown	Unk Df, Unk	Not Reported
	Premarin	C	Unknown	Unk Df, Unk	Not Reported
	Pantoprazole	C	Unknown	Unk Df, Unk	Not Reported
	Multi Vitamin	C	Unknown	Unk Df, Unk	Not Reported
	Lipitor	C	Unknown	Unk Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13541295	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1718909US		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Noctamide			S	Oral	Unk		Not Reported	
	Risperdal			S	Oral	2 Mg, Qd		Not Reported	
	Akineton L.P.			S	Oral	4 Mg, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	11155085	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-98357		35 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rabbit Syndrome	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported	
	Clonazepam			C	Unknown	0.5 Mg, Qd (Night)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	12210677	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-021366		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective	Abilify	S	Unknown	Unk	Bristol Myers Squibb
	Lexapro	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	12341624	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-034246		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Bipolar Disorder; Depression; Dizziness; Drug Ineffective; Dry Mouth; Mania; Rash	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Oral	2.5 Mg, Qd		Bristol Myers Squibb
	Carbamazepine			S	Unknown	600 Mg, Qd (200mg Tablet In The Morning And Two 200mg Tablets In The Evening)		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Prozac			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	12369161	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2016-05962		84 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Syncope; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown			Aurobindo
	Levofloxacin			S	Unknown			Aurobindo
	Sulpiride			S	Unknown			Not Reported
	Solifenacin			S	Unknown			Not Reported
	Amiodarone			S	Intravenous (not			Not Reported

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	Simvastatin	C	otherwise specified)	Unknown	Not Reported
	Acenocoumarol	C	Unknown	Unknown	Not Reported
	Furosemide	C	Unknown	Unknown	Not Reported
	Candesartan	C	Unknown	Unknown	Not Reported
	Digoxin	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	12516513	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2016-08402		84 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Solifenacin			S	Unknown	Unk		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulpiride			S	Unknown	Unk		Not Reported
	Digoxin			S	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Acenocoumarol			C				Not Reported
	Simvastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	13472018	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00006385		31 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Dizziness; Dyspnoea; Hypersomnia; Musculoskeletal Stiffness; Vision Blurred	Escitalopram			S				Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	13547047	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1719628US		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Use Disorder; Sopor	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan	
	Xanax			S	Oral			Not Reported	
	Depakin			C	Oral			Not Reported	
	Zarelis			C	Oral			Not Reported	
	Dobetin (Cyanocobalamin)			C	Intramuscular			Not Reported	
	Eutirox			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13509480	EXPEDITED (15-DAY)		HO	PHHY2017IT062339		51 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg, Unk		Not Reported	
	Xanax			S	Oral	0.25 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13548729	EXPEDITED (15-DAY)		OT	TW-APOTEX-2017AP008767		71 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akinesia; Bradykinesia; Cognitive Disorder; Cognitive Disorder; Drug Intolerance; Extrapyramidal Disorder; Gait Disturbance; Hallucination, Visual; Hypokinesia; Illusion; Muscle Rigidity; Parkinsonism; Progressive	Paroxetine			S	Unknown	25 Mg, Qd		Apotex	
	Paroxetine			S				Apotex	
	Paroxetine			S				Apotex	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Escitalopram			S				Not Reported	
	Escitalopram			S				Not Reported	
	Zolpidem			C	Unknown			Not Reported	
	Zolpidem			C				Not Reported	
	Zolpidem			C				Not Reported	

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Supranuclear Palsy; Rapid	Clonazepam	C	Unknown	Not Reported
Eye Movement Sleep	Clonazepam	C		Not Reported
Behaviour Disorder;	Clonazepam	C		Not Reported
Urinary Incontinence				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13549836	EXPEDITED (15-DAY)		DE	FR-NORTHSTAR HEALTHCARE HOLDINGS-FR- 2017NSR000143		53 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed	Baclofen			S	Oral	Unk		Northstar	
Suicide; Overdose;	Colchicine			S		Unk		Not Reported	
Toxicity To Various Agents	Escitalopram			S		Unk		Not Reported	
	Metoprolol			S		Unk		Not Reported	
	Perindopril			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13549962	EXPEDITED (15-DAY)		DE	FR-NORTHSTAR HEALTHCARE HOLDINGS-FR- 2017NSR000147		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Baclofen			S	Oral	Unk		Northstar	
Intentional Overdose;	Acetaminophen			S		Unk		Not Reported	
Poisoning Deliberate;	Dextropropoxyphene			S		Unk		Not Reported	
Toxicity To Various Agents	Escitalopram			S		Unk		Not Reported	
	Valpromide			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13550199	EXPEDITED (15-DAY)		DS	CA-APOTEX- 2017AP011832		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Depression; Dizziness; Headache; Product Substitution Issue	Apo-Escitalopram	S	Unknown	Apotex

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16-May-2017	13551044	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-041487		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination	Abilify			S	Unknown	30 Mg, Qd		Bristol Myers Squibb	
	Olanzapine			S	Unknown	40 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	3 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13551187	EXPEDITED (15-DAY)		DE, HO, OT	CN-JNJFOC- 20170513795		62 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Overdose; Toxicity To Various Agents	Risperdal			S	Unknown			Not Reported	
	Risperdal			S	Unknown			Not Reported	
	Risperdal			S	Unknown			Not Reported	
	Risperdal			S	Unknown			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Artane			C	Unknown			Not Reported	
	Benzhexol			C	Unknown			Not Reported	
	Aripiprazole			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13551653	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1719621US		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Seizure	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Largactil			S	Oral	15 Gtt, Qd		Not Reported	
	Xanax			C	Unknown			Not Reported	
	Durogesic			C	Unknown			Not Reported	
	Pecfent			C	Unknown			Not Reported	
	Prazepam			C	Unknown			Not Reported	
	Zolpidem			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Carbosymag [Activated Charcoal\Magnesium Oxide\Simethicone]			C	Unknown			Not Reported	
	Olimel N7e			C	Unknown			Not Reported	
	Aminomix 800e			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13553220	DIRECT		OT			43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Burning Sensation; Condition Aggravated; Depersonalisation/Dereali sation Disorder; Erythema; Inflammation; Insomnia; Musculoskeletal Discomfort; Paraesthesia; Rheumatoid Arthritis; Stress; Vomiting	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13521041	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-139660		51 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg Total			Not Reported
	Xanax 0.25 Mg			S	Oral	0.25 Mg Total			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13552682	EXPEDITED (15-DAY)		OT	US-APOTEX- 2017AP012019		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Heart Rate Decreased; Hypotension; Myasthenia Gravis; Myocardial Infarction; Overdose; Presyncope	Clopidogrel Tablets Usp			S	Unknown	Unk			Apotex
	Amlodipine Besylate			S	Unknown	Unk			Apotex
	Carvedilol			S	Unknown	Unk			Apotex
	Losartan Potassium Film-Coated Tablets			S	Unknown	Unk			Apotex
	Escitalopram Oxalate			S	Unknown	Unk			Apotex
	Mirtazapine			S	Unknown	Unk			Apotex
	Pantoprazole Sodium Delayed-Release Tablets Usp			S	Unknown	Unk			Apotex
	Aspirin /00002701/			S	Unknown	Unk			Not Reported
	Hydralazine			S	Unknown	Unk			Not Reported
	Olmesartan			S	Unknown	Unk			Not Reported
	Finasteride			S	Unknown	Unk			Not Reported
	Niacin			S	Unknown	Unk			Not Reported
	Simvastatin			S	Unknown	Unk			Not Reported
	Nitroglycerin			S	Unknown	Unk, Prn			Not Reported
	Tylenol With Codeine			S	Unknown	Unk, Prn			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13553480	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011837			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Apo-Escitalopram Vyvanse			S S	Unknown Oral			Apotex Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13360700	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1710685US			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Electrocardiogram St Segment Depression; Micturition Urgency; Restlessness; Sucrose Intolerance; Thirst	Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Trittico			S S S C	Unknown	5 Mg, Qd 10 Mg, Qd 5 Mg, Qd 50 Mg In The Evening		Allergan Allergan Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13546755	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1028921			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Overdose; Nausea; Tremor	Escitalopram			S	Oral	200 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13559564	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-140518		21 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Overdose; Poisoning	Mirtazapine	S	Oral	870 Mg	Sun
Deliberate; Toxicity To	Escitalopram	S	Oral	100 Mg	Not Reported
Various Agents	Desvenlafaxine	S	Oral	500 Mg	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13559799	NON-EXPEDITED		OT	US-APOTEX-2017AP012030		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage	Escitalopram Oxalate			S	Unknown			Apotex
	Rivaroxaban			S	Oral	15 Mg, Bid		Not Reported
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13560422	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2017US08457			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Intentional Overdose; Localised Infection; Suicide Attempt; Vanishing Bile Duct Syndrome	Lamotrigine			S	Unknown	25 Mg, Bid		Cipla
	Escitalopram			S	Unknown	Unk		Invagen
	Meloxicam			S	Unknown	Unk		Cipla
	Cephalexin			S	Unknown	Unk		Cipla
	Moxifloxacin			S	Unknown	Unk		Cipla
	Aripiprazole			S	Unknown	Unk		Cipla
	Lorazepam			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Cipla
	Venlafaxine			S	Unknown	Unk		Cipla
	Levothyroxine			S	Unknown	Unk		Not Reported
	Dextropropoxyphene			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13560591	NON-EXPEDITED		OT	US-ROCHE-724719		55 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Ulcer	Naprosyn			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561085	NON-EXPEDITED			US-ROCHE-1442754			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity; Nausea	Naprosyn			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Hydrocodone Hcl			C	Unknown	As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561162	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1720132US		86 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Clonus; Renal Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Loramet			C	Oral	1 Mg, Qd		Not Reported
	Rocaltrol			C	Oral	0.25 Mg, Qd		Not Reported
	Calcium Carbonate			C	Oral	1 G, Qd		Not Reported
	Tamsulosine			C	Oral	0.4 Mg, Qd		Not Reported
	Glurenorm			C	Oral	30 Mg, Qd		Not Reported

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L-Thyroxine	C	Oral	125 Mg, Qd	Not Reported
Asaflow	C	Oral	80 Mg, Qd	Not Reported
Cordarone	C	Oral	200 Mg, Qd	Not Reported
Lasix	C	Oral	100 Mg, Qd	Not Reported
Zocor	C	Oral	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561163	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1719108US		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Emotional Disorder; Feeling Abnormal; Heart Rate Increased; Paranoia; Product Dose Omission; Self-Injurious Ideation; Violence-Related Symptom	Lexapro			S	Oral	Unk		Allergan
	Glipizide			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Claritin			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown			Not Reported
	Victoza			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561168	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1720140US		81 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported
	Zamudol Lp			C		Unk		Not Reported

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Diffu K	C	Unk	Not Reported
Ikorel	C	Unk	Not Reported
Lasilix	C	125 Mg, Qd	Not Reported
Lasilix	C	Unknown 40 Mg, Qam	Not Reported
Lasilix	C	Unknown 20 Mg, Qd	Not Reported
Metformine	C		Not Reported
Triatec (Codeine Phosphate/Paracetamol)	C		Not Reported
Esomeprazole	C		Not Reported
Gabapentin	C	Unk	Not Reported
Simvastatin	C	Unk	Not Reported
Tardyferon	C	Unk	Not Reported
Imovane	C	Unk	Not Reported
Uvedose	C	Unk	Not Reported
Lumigan	C	Unk	Not Reported
Tamsulosine Lp	C	Unk	Not Reported
Permixon	C	Unk	Not Reported
Bisoce	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561170	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1720193US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Dizziness; Dyspnoea; Dysstasia; Hot Flush; Lung Infection; Paraesthesia; Sputum Abnormal; Surgery	Escitalopram Oxalate - Bp			S		Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561193	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1720164US		152 DAY	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Foetal Growth Restriction	Escitalopram Oxalate - Bp	S	Transplacental	20 Mg, Unk	Allergan
	Subutex	S	Transplacental	8 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561576	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1720146US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aortic Disorder; Coagulopathy; Drug Interaction; Gastrointestinal Haemorrhage	Citalopram Hydrobromide - Bp			S				Allergan	
	Ass			S				Not Reported	
	Escitalopram Oxalate - Bp			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561824	EXPEDITED (15-DAY)		HO, OT	US-TEVA-768813USA		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Gastroesophageal Reflux Disease; Hyperhidrosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Phentermine			S	Unknown			Teva	
	Baclofen			S	Oral	30 Milligram Daily;		Ivax	
	Ampyra			S	Oral	20 Milligram Daily;		Not Reported	
	Ampyra			S				Not Reported	
	Lexapro			S	Oral	20 Milligram Daily;		Not Reported	
	Aspirin			C				Not Reported	
	Celebrex			C				Not Reported	
	Oxycontin			C				Not Reported	
	Oxycodone			C				Not Reported	
	Levemir			C				Not Reported	
	Spironolactone			C				Not Reported	
	Zyrtec			C				Not Reported	
	Movantik			C				Not Reported	
	Ambien			C				Not Reported	
	Clonidine			C				Not Reported	
	Vitamin D3			C				Not Reported	
	L-Methylfolate			C				Not Reported	

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Lisinopril	C	Not Reported
Maalox	C	Not Reported
Premarin	C	Not Reported
Pantoprazole	C	Not Reported
Multivitamin	C	Not Reported
Lipitor	C	Not Reported
Clonidine	C	Not Reported

Oral .2 Milligram Daily;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13562038	EXPEDITED (15-DAY)			JP-ALLERGAN-1720162US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hallucination; Seizure	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	12563591	EXPEDITED (15-DAY)		OT	US-JAZZ-2016-US-012843			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Depression; Vascular Graft	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Cymbalta			C		Unk		Not Reported
	Diovan			C				Not Reported
	Lantus			C		Unk		Not Reported
	Levemir			C				Not Reported
	Lopressor			C				Not Reported
	Lotensin			C				Not Reported
	Metformin Hcl			C				Not Reported
	Norvasc			C				Not Reported
	Novolog			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ritalin			C				Not Reported
Vicodin			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13485687	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2017175844		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Lyrica			S	Oral	Unk		Pfizer	
	Lyrica			S				Pfizer	
	Seroplex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13566253	DIRECT					70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaw Disorder; Migraine; Muscle Fatigue; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cvs Caremark	
	Dexilant			C				Not Reported	
	Synthroid			C				Not Reported	
	Glimpiride			C				Not Reported	
	Labetalol			C				Not Reported	
	Probiotics			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13566975	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Nausea; Palpitations	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13418427	EXPEDITED (15-DAY)		HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027128		< 1 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy;	Aripiprazole			S	Transplacental	2 Mg, Unk		Bristol Myers Squibb	

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Gastroesophageal Reflux Disease; Selective Eating Disorder	Aripiprazole	S	Transplacental	1 Mg, Unk	Bristol Myers Squibb
	Ambien	S	Transplacental		Not Reported
	Lamictal	S	Transplacental	Unk	Not Reported
	Lexapro	S	Transplacental	Unk	Not Reported
	Synthroid	S	Transplacental	Unk	Not Reported
	Simponi	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13568227	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20170513802		36 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Irritability; Memory Impairment; Toxicity To Various Agents	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown	Overdose		Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Lexapro			S	Unknown	Overdose		Not Reported
	Artane			C	Unknown			Not Reported
	Benzhexol			C	Unknown			Not Reported
	Aripiprazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13568326	EXPEDITED (15-DAY)		HO	SE-TEVA-767755ACC			Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Dyspnoea; Lip Swelling; Obesity; Peripheral Swelling		Escitalopram Teva		S		Ivax			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13568589	DIRECT		DE			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Eating Disorder; Fall; Insomnia; Intentional Self-Injury; Morbid Thoughts; Paranoia; Restlessness	Escitalopram			S	Oral	Quantity:.5 Tablet(S);		Lundbeck	
	Pravastatin Sodium			C				Not Reported	
	Irbesartan			C				Not Reported	
	Amlodipine Besylate			C				Not Reported	
	Zolpidem			C				Not Reported	
	Metoprolol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13568872	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00148			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypotonia; Respiratory Distress; Supraventricular Tachycardia	Escitalopram			S	Transplacental	10 Mg, 1x/Day		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13569154	EXPEDITED (15-DAY)		HO	CH-AKRIMAX-TIR-2017- 0489		85 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Overdose	Tirosint (Levothyroxine Sodium) Capsules, 150 Mcg; Akrimax Pharmaceuti			S	Oral	150mcg Daily		Not Reported	
	Tirosint (Levothyroxine Sodium) Capsules, 150 Mcg; Akrimax Pharmaceuti			S	Oral	150mcg Daily		Not Reported	

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	Escitalopram	S	Oral	Unknown	Not Reported
	Amlodipin-Mepha	C			Not Reported
	Atorvastatin	C			Not Reported
	Co Candesartan	C			Not Reported
	Dafalgan	C			Not Reported
	Vi-De 3	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13569231	EXPEDITED (15-DAY)	HO		CN-ALLERGAN-1720995US		36 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Risperdal			S	Unknown			Not Reported
	Risperdal			S	Unknown			Not Reported
	Risperdal			S				Not Reported
	Artane			C	Unknown			Not Reported
	Benzhexol			C	Unknown			Not Reported
	Aripiprazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13570040	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00214			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypotonia; Respiratory Distress; Supraventricular Tachycardia	Escitalopram			S	Transplacental	10 Mg, 1x/Day		Prinston Pharmaceutical

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13522525	EXPEDITED (15-DAY)		OT	ES-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00132		73 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Angle Closure Glaucoma;	Escitalopram	S	Unknown	Unk	Jubilant
Choroidal Effusion	Escitalopram	S	Unknown	"Duplicating The Drug Dose"; "Doubled"	Jubilant

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13570978	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-140928		49 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure; Therapy Partial Responder	Olanzapine			S	Unknown	Unk		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Lithium			S	Unknown	Unk		Sun	
	Nortriptyline			S	Unknown	Unk		Taro	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13571201	EXPEDITED (15-DAY)		HO	FR-ROCHE-1936624		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Valium			S	Oral			Not Reported	
	Seroplex			S	Oral	56 Tablets Of 20 Mg		Not Reported	
	Theralene (France)			S	Oral	3 Vials Of 30ml		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13571671	NON-EXPEDITED			US-PFIZER INC- 2017223057		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lorazepam			S		Unk		Pfizer	
	Diazepam			S		Unk		Pfizer	
	Paroxetine			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	

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Isosorbide			S			Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-May-2017	12629908	EXPEDITED (15-DAY)		HO		JP-FRI-1000086721			Male	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Mfr</u>		
Condition Aggravated; Drug Withdrawal Syndrome; Hallucination, Visual	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd			Allergan		
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd			Allergan		
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd			Allergan		
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd			Allergan		
	Escitalopram Oxalate - Bp			S	Oral	Unk			Allergan		
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd			Allergan		
	Solanax			C	Oral	Unk			Not Reported		
	Reflex			C	Oral	Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-May-2017	13418009	EXPEDITED (15-DAY)		OT		US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-027249		38 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Mfr</u>		
Caesarean Section; Hyperemesis Gravidarum; Maternal Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes; Product Use Issue	Aripiprazole			S	Unknown	5 Mg, Unk			Bristol Myers Squibb		
	Lexapro			S	Unknown	Unk			Not Reported		
	Wellbutrin			S	Unknown				Not Reported		
	Zofran /00955301/			S	Unknown				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-May-2017	13562042	EXPEDITED (15-DAY)		OT		US-ALLERGAN- 1719657US		50 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Mfr</u>		
Back Disorder;	Lexapro			S	Oral	20 Mg, Qd			Allergan		

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Hypotension; Off Label
Use; Parkinsonism;
Syncope

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13573781	EXPEDITED (15-DAY)		HO	US-JNJFOC- 20170520331		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Flat Affect; Hostility; Refusal Of Treatment By Patient	Invega Trinza			S	Intramuscular			Not Reported
	Lithium			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13575437	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US08880			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Resistance; Fall; Lafora'S Myoclonic Epilepsy	Lamotrigine			S	Unknown	Unk		Cipla
	Zonisamide			S	Unknown	Unk		Invagen
	Escitalopram			S	Oral	20 Mg, Daily		Invagen
	Levetiracetam			S	Unknown	Unk		Invagen
	Levetiracetam			S	Oral	1500 Mg, Bid		Invagen
	Sodium Valproate			S	Unknown	Unk		Cipla
	Sodium Valproate			S	Oral	300 Mg, Bid, Daily		Cipla
	Phenobarbital			S	Oral	40 Mg, Bid		Not Reported
	Piracetam			S	Oral	1200 Mg, Tid		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Clonazepam			S	Sublingual	Unk		Not Reported
	Clonazepam			S	Oral	4.5 Mg, Unk		Not Reported
	Lacosamide			S	Oral	150 Mg, Bid, Daily		Not Reported
	Calcium Carbonate-Vit D3			C	Unknown	Unk		Not Reported

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	Ferrous Fumarate		C	Unknown	Unk			Not Reported	
	Multivitamin		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13576182	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-30439			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram				S	Unknown			Aurobindo
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13576688	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Nervous System Disorder	Lexapro				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13577572	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1721267US		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction	Lexapro				S		Unk		Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13578189	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0087270		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Quetiapine Fumarate Tablets				S	Unknown			Not Reported
	Fluoxetine				S	Unknown			Not Reported
	Escitalopram				S	Unknown			Not Reported
	Mirtazapine				S	Unknown			Not Reported
	Lorazepam				S	Unknown			Not Reported

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Lisinopril	C	Unknown	Not Reported
Norvasc	C	Unknown	Not Reported
Proair	C	Unknown	Not Reported
Proair	C		Not Reported
Zantac	C	Unknown	Not Reported
Citalopram	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13578792	NON-EXPEDITED		OT	US-JAZZ-2017-US-004882			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Road Traffic Accident; Somnambulism; Sudden Onset Of Sleep; Wrong Technique In Product Usage Process	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xanax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Armodafinil			S		Unk		Not Reported
	Ropinirole Hcl			C				Not Reported
	Neupro			C		Unk		Not Reported
	Cialis			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported
	L-Methylfolate Calcium			C				Not Reported
	Pramipexole			C		Unk		Not Reported
	Adderall			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13578882	NON-EXPEDITED			US-JAZZ-2017-US-005054		56 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Pain In Extremity	Xyrem			S	Oral	2.25g, Bid		Jazz
	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	3.25 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Tramadol Hcl			C				Not Reported
	Vitamin D3			C				Not Reported
	Chia Seed			C				Not Reported
	Folic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Levothyroxine			C				Not Reported
	Nuvigil			C				Not Reported
	Fiber Choice Plus Calcium			C				Not Reported
	Vitamin E /00110501/			C				Not Reported
	Evening Primrose			C				Not Reported
	Flax Seed Oil			C				Not Reported
	Toviaz			C				Not Reported
	Midodrine Hcl			C				Not Reported
	Synthroid			C				Not Reported
	Inderal			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Olive Oil			C				Not Reported
	Protein			C				Not Reported
	Provigil /01265601/			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13579139	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1721520US		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Psychomotor Skills Impaired; Sedation; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Bromazepam			S	Oral	Unk, Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13501667	EXPEDITED (15-DAY)		HO	FR-ROCHE-1926254		77 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertension; Reversible Cerebral Vasoconstriction Syndrome	Avastin			S	Intravenous (not otherwise specified)	Last Dose Prior To Events On 07/Sep/2016		Not Reported	
	Seroplex			S	Oral			Not Reported	
	Carboplatin			C	Unknown			Not Reported	
	Carboplatin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13560117	EXPEDITED (15-DAY)		OT	CH-INDIVIOR LIMITED-INDV-101776-2017		34 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Foetal Growth Restriction; Foetal Placental Thrombosis; Induced Labour; Maternal Exposure During Pregnancy	Subutex 8mg Tablet			S	Unknown	8 Mg, Qd		Reckitt Benckiser	
	Ciprallex /01588502/			S	Unknown	20 Mg Per Day		Not Reported	
	Cannabis			S	Unknown	2-3 Joints Per Day		Not Reported	
	Nicotine			C	Unknown	5-10 Cigarettes Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13580794	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106915			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Amitriptyline			S	Unknown	Unk		Sun	
	Bupropion			S	Unknown	Unk		Sun	
	Citalopram			S	Unknown	Unk		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Fluoxetine			S	Unknown	Unk		Sun	
	Imipramine			S	Unknown	Unk		Mutual	
	Paroxetine			S	Unknown	Unk		Sun	
	Sertraline			S	Unknown	Unk		Sun	

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Venlafaxine	S	Unknown	Unk	Sun
Carbamazepine	S	Unknown	600-1400 Mg, Daily	Taro
Clonazepam	S	Unknown	1 Mg, Daily	Sun
Lamotrigine	S	Unknown	300-600 Mg, Daily	Taro
Methylphenidate	C	Unknown	5-20 Mg, Daily	Not Reported
Quetiapine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13582113	EXPEDITED (15-DAY)		HO, OT	CH-INDIVIOR LIMITED-INDV-101696-2017		3 DAY	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Low Birth Weight Baby	Subutex 8mg Tablet			S	Transplacental	8 Mg, Qd		Reckitt Benckiser
	Ciprallex			S	Transplacental	20 Mg, Qd		Not Reported
	Cannabis			S	Transplacental	2-3 Joints Per Day		Not Reported
	Nicotine			S	Transplacental	5-10 Cigarettes Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13406699	EXPEDITED (15-DAY)		HO, OT	US-ACORDA-ACO_135843_2017			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Confusional State; Hyperhidrosis; Insomnia; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
	Ampyra			S				Acorda
	Baclofen			S	Oral	10 Mg, Tid		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Phentermine			S	Unknown			Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported
	Celebrex			C	Oral	200 Mg, Qd As Needed		Not Reported
	Oxycontin			C	Unknown	30 Mg At Bedtime		Not Reported
	Oxycodone			C	Oral	15 Mg, 1 To 2 Tablets Tid		Not Reported
	Levemir			C	Unknown	20 Iu, Morning		Not Reported

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Levemir	C	Unknown	25 lu, At Bedtime	Not Reported
Spironolactone	C	Unknown	50 Mg, Bid	Not Reported
Zyrtec	C	Unknown	10 Mg, Qd As Needed	Not Reported
Movantik	C	Oral	25 Mg, Qd Prn	Not Reported
Ambien	C		10 Mg, Prn	Not Reported
Vitamin D3	C	Oral	5000 lu, Qd	Not Reported
Clonidine	C	Oral	0.1 Mg, Bid	Not Reported
L-Methylfolate	C	Unknown	Unk	Not Reported
Lisinopril	C	Oral	5 Mg, Qd	Not Reported
Maalox	C	Unknown	10 ML, 4 Times As Needed	Not Reported
Premarin	C	Unknown	0.3 Mg, Qd	Not Reported
Pantoprazole	C	Oral	40 Mg, Bid	Not Reported
Multivitamin	C	Unknown	1 Df, Bid	Not Reported
Lipitor	C	Oral	Unk	Not Reported
Other Therapeutic Products	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13585142	EXPEDITED (15-DAY)		DE	FR-LANNETT COMPANY, INC.-FR- 2017LAN000792		53 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Off Label Use; Toxicity To Various Agents	Baclofen (20mg)			S	Unknown	Unk		Lannett	
	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Colchicine			S	Unknown	Unk		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
	Perindopril			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13585571	EXPEDITED (15-DAY)		HO, OT	IT-JNJFOC- 20170519049			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction;	Itraconazole		S	Unknown	Not Reported
Electrocardiogram Qt	Fluconazole	Y	S	Unknown	Not Reported
Prolonged; Extrapyrimaldal	Ketorolac		S	Unknown	Not Reported
Disorder; Gastrointestinal	Acetylsalicylic Acid		S	Unknown	Not Reported
Disorder; Haemorrhage;	Simvastatin		S	Unknown	Not Reported
Hyperkalaemia;	Selegiline		S	Unknown	Not Reported
Hypokalaemia; Myopathy;	Ketoprofen		S	Unknown	Not Reported
Rhabdomyolysis;	Diclofenac		S	Unknown	Not Reported
Serotonin Syndrome	Alfuzosine		S	Unknown	Not Reported
	Venlafaxine		S	Unknown	Not Reported
	Metoclopramide		S	Unknown	Not Reported
	Alginic Acid		S	Unknown	Not Reported
	Trazodone		S	Unknown	Not Reported
	Biperiden		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Sertraline		S	Unknown	Not Reported
	Trifluoperazine		S	Unknown	Not Reported
	Ezetimibe/Simvastatin		S	Unknown	Not Reported
	Paroxetine		S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13586397	EXPEDITED (15-DAY)		DE	FR-LANNETT COMPANY, INC.-FR- 2017LAN000796		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Poisoning;	Baclofen (20mg)			S	Unknown	Unk		Lannett	
Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Silapap			S	Unknown	Unk		Lannett	
	Dextropropoxyphene			S	Unknown	Unk		Not Reported	
	Valpromide			S	Unknown	Unk		Not Reported	

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30-May-2017	13591620	DIRECT					72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Nightmare; Unevaluable Event	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo	
	Omeprazole			C				Not Reported	
	Lisinopril			C				Not Reported	
	Alprazolam			C				Not Reported	
	Quetiapine			C				Not Reported	
	Meloxicam			C				Not Reported	
	Vitamin C			C				Not Reported	
	Essential Oils (Brain Calm)			C				Not Reported	
	Calcium			C				Not Reported	
	Magnesium			C				Not Reported	
	Zinc			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Fish Oil			C				Not Reported	
	Acidophilus			C				Not Reported	
	Aspirin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13592543	EXPEDITED (15-DAY)		OT	CH-TEVA-771766ISR		18 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Dyspnoea; Gastrointestinal Disorder; Neck Pain	Azithromycin Mepha			S	Intravenous drip	1000 Milligram Daily;		Not Reported	
	Cipraxel			S	Unknown	160 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13430455	NON-EXPEDITED			US-PFIZER INC- 2017154322			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	

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	Methotrexate Sodium	S	Unk	Pfizer
	Ciprofloxacin	S	Unk	Unknown
	Morphine Sulfate	S	Unk	Pfizer
	Clindamycin Phosphate	S	Unk	Pfizer
	Lexapro	S	Unk	Not Reported
	Bentyl	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Levbid	S	Unk	Not Reported
	Dilaudid	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13595245	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2017US09634			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse	Escitalopram			S	Oral	Unk		Invagen
	Meloxicam			S	Oral	Unk		Cipla
	Loperamide			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13597729	DIRECT					37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Joint Swelling; Middle Insomnia; Night Sweats	Escitalopram			S	Oral			Teva
	Multivitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13600586	DIRECT		DS			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess Oral; Arthralgia	Lexapro			S				Not Reported

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31-May-2017	13631178	NON-EXPEDITED			US-ASTELLAS-1357761			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Decreased Appetite; Diarrhoea; Dizziness; Urinary Tract Infection	Tarceva			S	Oral			Not Reported	
	Tylenol With Codeine			S	Unknown			Not Reported	
	Ativan			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Trental			S	Unknown			Not Reported	
	Xanax			S	Unknown			Not Reported	
	Folic Acid			C				Not Reported	
	Mag 64			C				Not Reported	
	Zantac			C				Not Reported	
	Codeine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13479930	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1715830US		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Selincro			S	Oral	18 Mg, Qd		Not Reported	
	Brexin [Piroxicam]			S	Oral	20 Mg, Qd		Not Reported	
	Lamaline (Acetaminophen\Belladonna Leaf\Caffeine\Opium)			S	Oral	1 Df, Qid		Not Reported	
	Multicrom			S	Ophthalmic	1 Gtt, Unk		Not Reported	
	Rhinomaxil			S	Nasal	100 Mg, Bid		Not Reported	
	Duoresp Spiromax			C	Unknown			Not Reported	
	Singulair			C	Unknown			Not Reported	
	Bricanyl			C	Unknown			Not Reported	
	Tahor			C	Unknown			Not Reported	

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Coveram	C	Unknown	Not Reported
Kestinlyo	C	Unknown	Not Reported
Valium	C	Unknown	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13599959	EXPEDITED (15-DAY)		DE, LT	US-CIPLA LTD.- 2017US09640			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed Suicide; Lethargy	Escitalopram			S	Oral	Unk		Invagen	
	Meloxicam			S	Oral	Unk		Cipla	
	Loperamide			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13601184	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP012516		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Above Therapeutic; Somnolence; Toxicity To Various Agents	Aripiprazole Tablets			S	Unknown			Apotex	
	Divalproex Sodium Delayed- Release Tablets Usp			S	Unknown			Apotex	
	Escitalopram Oxalate			S	Unknown			Apotex	
	Clozapine			S	Unknown	400 Mg, Daily		Not Reported	
	Clozapine			S	Unknown	200 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13602585	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP012512		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Above Therapeutic; Hypotension; Mental Disorder; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown			Apotex	
	Clozapine			S	Unknown	450 Mg, Per Day		Not Reported	
	Clozapine			S	Unknown	200 Mg, Per Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13602832	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1722591US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrectomy	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13603274	EXPEDITED (15-DAY)		HO	PHHY2017US075732		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Somnolence	Clozapine			S	Unknown	400 Mg, Qd		Not Reported	
	Divalproex Sodium			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Aripiprazole			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13145573	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1702720US		42 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dystonia; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Dogmatyl			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13497466	EXPEDITED (15-DAY)		OT	ES-TEVA-762375ROM		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	10 Milligram Daily; 10mg/Day; Later Doubled The Dose		Ivax	
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax	

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20mg/Day

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02-Jun-2017	13607119	EXPEDITED (15-DAY)		OT	CH-ROCHE-1942216		41 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Avastin			S	Intravenous bolus			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Trittico			S	Oral			Not Reported	
	Campto			C	Unknown			Not Reported	
	Paraplatin			C	Unknown			Not Reported	
	Taxol			C	Unknown			Not Reported	
	Keppra			C	Unknown			Not Reported	
	Dexamethasone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13607243	EXPEDITED (15-DAY)		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2017-02810		16 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Galactorrhoea; Overdose; Suicide Attempt	Escitalopram			S	Oral	Unk, A Large Amount		Lupin	
	Escitalopram			S	Unknown	5 Mg, Per Day		Lupin	
	Pseudoephedrine Hydrochloride			S	Oral	Unk, A Large Amount		Not Reported	
	Metoclopramide			S	Oral	Unk, A Large Amount		Novel Labs	
	Fluoxetine			S	Unknown	20 Mg, Per Day		Not Reported	
	Fluoxetine			S	Unknown	10 Mg, Per Day		Not Reported	
	Risperidone			C	Unknown	0.5 Mg, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609367	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1722677US		77 YR	Female	FRA

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Blood Loss Anaemia; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Xarelto			S	Oral	15 Mg, Qd		Not Reported	
	Xarelto			S	Oral	15 Mg, Qd		Not Reported	
	Lasilix			C		Unk		Not Reported	
	Diffu K			C		Unk		Not Reported	
	Metformine			C		Unk		Not Reported	
	Tardyferon			C		Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Lansoyl			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609386	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1722675US		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609388	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1722683US		41 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Tritticot			S	Oral	50 Mg, Qd		Not Reported	
	Temodal			C	Unknown			Not Reported	
	Keytruda			C	Unknown			Not Reported	
	Campto			C	Unknown	Unk		Not Reported	

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Paraplatin	C	Unknown	Unk	Not Reported
Taxol	C	Unknown		Not Reported
Keppra	C	Unknown		Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609389	EXPEDITED (15-DAY)		OT	EE-ALLERGAN-1722684US			Female	EST
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cutaneous Lupus Erythematosus; Hyperhidrosis; Photosensitivity Reaction; Rosacea	Escitalopram Oxalate - Bp			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609644	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1722788US		42 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Q Week		Allergan	
	Citalopram			C	Unknown	Reduce By 20mg Every 3 Days, Then Stop- Advice B...		Not Reported	
	Promethazine Hydrochloride			C	Unknown	1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13610351	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Label Issue	Lexapro			S				Forest	

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03-Jun-2017	13611077	DIRECT		DE			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Poisoning; Asphyxia; Completed Suicide; Nightmare	Escitalopram Abilify	Y		S C	Oral	Quantity:1 Tablet(S);		Lupin Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2017	13610167	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2017M1032181			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram Citalopram Promethazine Hydrochloride			S C C		On Uptitration Reduce By 20mg Every 3 Days, Then Stop- Advice B... 1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Not Reported Mylan Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2017	13610188	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2017M1032414			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium	Quetiapine Quetiapine Quilonum Quetiapin Cipralext Tavor [Lorazepam] Tavor			S S S S S S S	Oral Oral Oral Oral Oral Oral Oral	400 Mg, Unk 7000 Mg, Unk 2 Mg, Unk 4 - 0.5 Mg/D		Not Reported Not Reported Mylan Mylan Mylan Mylan Mylan	

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Movicol	C	Oral	Mylan
Beloc Zok	C	Oral	Mylan
Candesartan	C	Oral	Mylan
L-Thyroxin	C	Oral	Mylan

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04-Jun-2017	13611224	DIRECT		LT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Crying; Depression; Histrionic Personality Disorder; Suicidal Ideation	Escitalopram			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13599335	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1722307US		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Grandiosity; Hallucination, Auditory; Insomnia; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Lithium			C	Oral			Not Reported
	Guanfacine			C	Oral			Not Reported
	Guanfacine			C	Oral			Not Reported
	Lamotrigine			C	Oral	25mg Po Qam		Not Reported
	Lamotrigine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13611889	DIRECT	Y	OT			24 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Therapy Cessation	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13612463	EXPEDITED (15-DAY)		DE, HO	FR-SYMPLMED PHARMACEUTICALS- 2017SYMPLMED00045 4			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Asthenia; Blood Sodium Increased; Haemorrhage; Pancytopenia	Coveram			S	Oral	1 (5mg/5mg) Tablet, Qd		Unknown	
	Previscan /00789001/			S	Oral	0.25 Mg, Qd		Not Reported	
	Seroplex			S	Unknown	40 Mg, Bid		Not Reported	
	Lorazepam			C				Not Reported	
	Bisoprolol Fumarate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13612976	EXPEDITED (15-DAY)		OT	US-SUNOVION- 2017SUN002341			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Sluggishness; Suicidal Ideation	Latuda			S	Oral			Sunovion	
	Lexapro			S		10 Mg, Qd		Not Reported	
	Trazodone			S		50 Mg, Hs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13615525	EXPEDITED (15-DAY)		DE	US-BION-006351		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse	Loperamide Hydrochloride			S				Bionpharma	
	Escitalopram			S				Not Reported	
	Meloxicam			S				Not Reported	

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06-Jun-2017	13615805	EXPEDITED (15-DAY)		DE, LT	US-BION-006368		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide Unknown Product			S				Bionpharma	
	Escitalopram			S				Not Reported	
	Meloxicam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13619199	DIRECT					34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depression; Dyspnoea; Fatigue; Feeling Abnormal; Headache; Immune System Disorder; Obsessive-Compulsive Disorder; Palpitations; Panic Reaction; Social Anxiety Disorder	Escitalopram			S	Oral	Quantity:90 Tablet(S);		Not Reported	
	Prenatal Vitamins			C				Not Reported	
	Fish Oil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	11078183	NON-EXPEDITED			US-JNJFOC-20150414688			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Weight Gain; Aggression;	Risperdal			S	Oral			Not Reported	
Gynaecomastia; Hyperprolactinaemia	Risperdal			S	Oral			Not Reported	
	Abilify			S	Unknown			Not Reported	
	Zoloft			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	12953902	EXPEDITED (15-DAY)		HO, OT	CA-ALEMBIC PHARMACUETICALS LIMITED- 2016SCAL000916			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Hydrochlorothiazide			S		Unk		Alembic
	Escitalopram			S		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Gliclazide			C		Modified-Release		Not Reported
	Insulin			C		Unk		Not Reported
	L-Thyroxine /00068001/			C		Unk		Not Reported
	Telmisartan			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Metformin			C		Increased To 1 Gram Twice A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13537423	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1718851US		47 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Central Nervous System Neoplasm; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Daily		Allergan
	Lamotrigine			C	Unknown	125 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13569880	EXPEDITED (15-DAY)		DE	US-PFIZER INC- 2017217474		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Xanax Xr			S	Oral	2 Mg, 1x/Day		Pfizer
	Xanax Xr			S				Pfizer
	Xanax			S	Oral	0.5 Mg, 2x/Day		Pfizer

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Xanax	S		Pfizer
Hydrocodone	S	Unk, As Needed	Not Reported
Hydrocodone	S		Not Reported
Lexapro	S	20 Mg, 1x/Day (Am)	Not Reported
Lexapro	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13585356	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2017JPN075867		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dropped Head Syndrome	Lamictal			S	Oral	25 Mg, Qod		Glaxosmithkline
	Lamictal			S	Oral	25 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	50 Mg, Qd		Glaxosmithkline
	Lamictal			S	Oral	100 Mg, Qd		Glaxosmithkline
	Reflex (Japan)			S	Oral	20 Mg, 1d		Not Reported
	Solanax			S	Oral	1.2 Mg, 1d		Not Reported
	Lexapro			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13620349	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723300US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chlamydial Infection	Escitalopram Oxalate Unk			S	Unknown			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13621375	NON-EXPEDITED			US-PFIZER INC-2017246431			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Sertraline Hcl			S		Unk		Pfizer
Drug Ineffective	Buspar			S		Unk		Not Reported

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Escitalopram			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13621691	NON-EXPEDITED			US-ROCHE-1774862			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Erythema; Periorbital Swelling	Klonopin			S	Unknown			Not Reported	
	Pristiq			S	Unknown	Only Took One Dose		Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13621812	NON-EXPEDITED			US-ROCHE-1885015		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Swelling; Weight Increased	Klonopin			S	Oral			Not Reported	
	Klonopin			S				Not Reported	
	Lyrica			S	Unknown	At Night		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Nortriptyline			C	Unknown	At Night		Not Reported	
	Flexeril (United States)			C				Not Reported	
	Treximet			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13625349	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/17/0091158		66 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium	Quetiapine			S	Oral			Not Reported	
	Quetiapine			S	Oral	Prolonged Release		Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Quilonum Retard			S	Oral			Not Reported	
	Cipralext			S	Oral			Not Reported	

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Tavor [Lorazepam]	S	Oral	Not Reported
Tavor	S	Oral	Not Reported
Movicol	C	Oral	Not Reported
Beloc Zok	C	Oral	Not Reported
Candesartan	C	Oral	Not Reported
Levothyroxine Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13626559	NON-EXPEDITED		OT	US-JNJFOC-20170424982		12 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use In Unapproved Indication; Weight Increased	Risperidone			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral	In The Morning		Not Reported
	Adderall			C	Oral	In The Morning		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13627113	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1033322			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram			S	Oral	Seit Wochen		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Risperidon			C	Oral			Mylan
	L-Thyroxin			C	Oral	Seit Jahren		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13627361	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1033324			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Anxiety Disorder;	Escitalopram	S	Oral	5 Mg, Unk	Not Reported
Dyskinesia; Dyskinesia;	Escitalopram	S	Oral	10 Mg, Unk	Not Reported
Loss Of Personal	Escitalopram	S	Oral	5 Mg, Unk	Not Reported
Independence In Daily Activities	Bisoprolol	C	Oral	Seit Monaten	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13627649	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-049536		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Aripiprazole			S	Unknown			Bristol Myers Squibb
Somnolence	Clozapine			S	Unknown	400 Mg, Qd		Not Reported
	Clozapine			S	Unknown	200 Mg, Qd		Not Reported
	Divalproex Sodium			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	11058795	EXPEDITED (15-DAY)		DE	CA-FRI-1000076049		17 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use Issue;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
Sudden Cardiac Death	Diphenhydramine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	11519212	EXPEDITED (15-DAY)		DE	CA-FRI-1000079540		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Clonazepam			C	Unknown	Daily Dose Not Reported		Not Reported
	Lansoprazole			C	Unknown	Daily Dose Not Reported		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lithium Carbonate	C	Unknown	Daily Dose Not Reported	Not Reported
Lorazepam	C	Unknown	Daily Dose Not Reported	Not Reported
Nadolol	C	Unknown	Daily Dose Not Reported	Not Reported
Quetiapine	C	Unknown	Daily Dose Not Reported	Not Reported
Synthroid	C	Unknown	Daily Dose Not Reported	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13574315	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1720790US		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Rash Maculo-Papular; Tubulointerstitial Nephritis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13625253	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015329		42 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram Citalopram Promethazine Hydrochloride			S C C				Unknown Unknown Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13628490	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017248703		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Lorazepam			S		0.5 Mg, Unk		Pfizer	
	Venclexta			S	Oral	600 Mg, Daily (Take Six Tablets By Mouth Daily)		Not Reported	
	Allopurinol			S		100 Mg, Unk		Not Reported	
	Zolpidem Tartate			S		10 Mg, Unk		Not Reported	
	Escitalopram Oxalate			S		10 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13629756	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723564US		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan	
	Bisoprolol			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13630243	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1723306US		36 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S		20 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S		15 Mg, Qd		Allergan	
	Risperidon			C	Oral	0.5 Mg, Qd		Not Reported	
	L-Thyroxin			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13631319	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1723099US		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hospitalisation; Menorrhagia; Pain; Postoperative Wound Complication; Stress	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13635303	DIRECT		OT			49 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Diarrhoea; Erectile Dysfunction; Flatulence; Gastric Disorder; Insomnia; Libido Decreased	Lexapro 20mg, Escitalopram			S	Oral	Quantity:1 Tablet(S);		Torrent
	20mg Prilosec			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	11102742	EXPEDITED (15-DAY)		OT	US-JNJFOC- 20150504386		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia; Hyperprolactinaemia; Obesity	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral	1-5mg		Not Reported
	Risperdal			S	Oral	Varying Doses Of 0.5 Mg To 5 Mg		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13637001	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2017-35063		42 YR	Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lip Swelling; Rash Generalised; Swelling Face; Swollen Tongue	Escitalopram			S	Unknown	5 Mg, Every Week		Aurobindo
	Citalopram			C	Unknown	Reduce By 20mg Every 3 Days, Then Stop- Advice B...		Not Reported
	Promethazine Hydrochloride			C	Unknown	1 Df, 1 At Night As Necessary, Maximum Of 1 Four Times A Day If Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13638793	EXPEDITED (15-DAY)		OT	CA-ALLERGAN- 1723539US			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Exposure During Pregnancy; Exposure Via Breast Milk; Facial Asymmetry; Hyperbilirubinaemia; Hypoglycaemia Neonatal; Jaundice Neonatal; Knee Deformity; Respiratory Distress; Selective Eating Disorder; Talipes; Weight Decrease Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	30 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Transmammary	30 Mg, Qd		Allergan
	Calcium			S	Transplacental	1000 Mg, Qd		Not Reported
	Calcium			S	Transmammary	1000 Mg, Qd		Not Reported
	Cholecalciferol			S	Transplacental	1000 Iu, Qd		Not Reported
	Cholecalciferol			S	Transmammary	1000 Iu, Qd		Not Reported
	Folic Acid			S	Transplacental	1000 Mg, Qd		Not Reported
	Folic Acid			S	Transmammary	1000 Mg, Qd		Not Reported
	Suboxone			S	Transplacental	12 Mg, Qd		Not Reported
	Suboxone			S	Transplacental	10 Mg, Qd		Not Reported
	Suboxone			S	Transmammary	12 Mg, Qd		Not Reported
	Subutex			S	Transplacental	12 Mg, Qd		Not Reported
	Subutex			S	Transplacental	10 Mg, Qd		Not Reported
	Nicotine			S	Transplacental	4 Cigarettes		Not Reported
	Nicotine			S	Transmammary	4 Cigarettes		Not Reported
	Prenatal Multiple Vitamin			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639154	NON-EXPEDITED			US-ROCHE-682583		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Depressed Mood; Malaise; Poor Quality Sleep; Product Quality Issue; Sleep Disorder; Tremor	Klonopin			S	Oral	Other Indication: Postpartum Depression		Not Reported	
	Lexapro			S	Oral	Other Indication: Depression		Not Reported	
	Tekturna			C	Unknown			Not Reported	
	Hydrochlorothiazide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639184	NON-EXPEDITED		OT	US-ROCHE-798674			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Tremor	Klonopin			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Fioricet			S	Unknown			Not Reported	
	Cymbalta			S	Unknown	4 Tablets Taken In Morning		Not Reported	
	Reglan			S	Unknown			Not Reported	
	Pristiq			S	Unknown	Prolonged Release Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639225	NON-EXPEDITED			US-ROCHE-683344		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nystagmus	Klonopin			S	Unknown			Not Reported	
	Lexapro			S	Oral	Other Indication: Anxiety		Not Reported	
	Wellbutrin			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639280	NON-EXPEDITED			US-ROCHE-1233151			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased	Klonopin			S	Unknown			Not Reported	
	Lexapro			S	Oral	Initially 5 Mg In The Morning Later Shifted To 5 Mg At The Bed Time		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639622	NON-EXPEDITED		HO	US-ROCHE-679942		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Abnormal; Intentional Overdose; Suicide Attempt	Klonopin			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Ambien			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639641	NON-EXPEDITED			US-ROCHE-1224057		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue	Klonopin			S	Unknown	Daily		Not Reported	
	Escitalopram			S	Oral	Daily		Not Reported	
	Valsartan Hct			C	Unknown	81 Mg/12.5 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639769	NON-EXPEDITED			US-ROCHE-1510226			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Psychotic	Klonopin			S	Unknown			Not Reported	

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Disorder	Lexapro	S	Unknown	Not Reported
	Abilify	S	Unknown	Not Reported
	Ambien	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639895	NON-EXPEDITED			US-ROCHE-703211		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Increased Appetite; Weight Increased	Klonopin			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13640016	NON-EXPEDITED			US-ROCHE-742882		40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Pruritus	Klonopin			S	Oral	Co-Indication: Panic Disorder		Not Reported
	Klonopin			S	Oral			Not Reported
	Lexapro			S	Oral	Co-Indication: Generalized Anxiety Disorder And Panic Disorder		Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2017	13641407	DIRECT	Y					Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Night Sweats	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13642026	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2017-02893		66 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Aspartate Aminotransferase Increased; Delirium; Disorientation; Distractibility	Quilonum			S	Oral	225 Mg, Qd		Not Reported	
	Quetiapine Fumarate Extended- Release Tablets			S	Oral	300 Mg, Qd		Lupin	
	Quetiapine			S	Oral	400 Mg, Qd		Lupin	
	Quetiapine			S	Oral	7000 Mg, Qd		Lupin	
	Cipralext			S	Oral	15 Mg, Qd		Not Reported	
	Tavor [Lorazepam]			S	Oral	2 Mg, Qd		Not Reported	
	Tavor [Lorazepam]			S	Oral	4 - 0.5 Mg/D		Not Reported	
	Movicol			C	Oral	3 Df, Qd		Not Reported	
	Beloc Zok			C	Oral	47.5 Mg, Qd		Not Reported	
	Candesartan			C	Oral	8 Mg, Qd		Not Reported	
	L-Thyroxin			C	Oral	25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13642107	EXPEDITED (15-DAY)		HO	FR-009507513- 1706FRA002435		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Toxicity To Various Agents	Zepatier			S	Oral	100 Mg, Qd		Merck	
	Elbasvir			S		50 Mg, Qd		Merck	
	Ribavirin			S	Oral	800 Mg, Qd		Merck	
	Seresta			S	Oral	25 Mg, Bid		Not Reported	
	Seresta			S	Oral	150 Mg (15 Tablet), Once		Not Reported	
	Seresta			S	Oral	25 Mg, Bid		Not Reported	

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Seroplex			S		1 Df, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13642952	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723794US		1 DAY	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643008	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723784US		1 DAY	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643009	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723790US		1 DAY	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress;	Lexapro			S	Transplacental			Allergan	

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Detailed Report

Exposure During
Pregnancy; Injury;
Nervous System Disorder;
Pain

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643082	EXPEDITED (15-DAY)		OT	DE-TEVA-774754GER		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder;	Escitalopram			S	Oral			Ivax	
Dyskinesia; Dyskinesia;	Escitalopram			S	Oral			Ivax	
Loss Of Personal	Escitalopram			S	Oral			Ivax	
Independence In Daily	Bisoprolol			C	Oral	For Months		Not Reported	
Activities									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643106	EXPEDITED (15-DAY)		OT	DE-TEVA-774763GER		36 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety;	Escitalopram			S	Oral	For Weeks		Ivax	
Haematoma;	Escitalopram			S	Oral			Ivax	
Haemorrhagic Disorder;	Escitalopram			S	Oral			Ivax	
Loss Of Personal	Risperidon			C	Oral			Not Reported	
Independence In Daily	L-Thyroxin			C	Oral	For Years		Not Reported	
Activities; Menstrual									
Disorder; Tension									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643278	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1034366			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Dizziness; Eye	Escitalopram Mylan Generiques			S		10 Mg, Unk		Mylan	
Paraesthesia; Nausea;	5 Mg, Comprimé Pelliculé								
Ophthalmoplegia;	Escitalopram Mylan Generiques			S		5 Mg, Unk		Mylan	
Vomiting	5 Mg, Comprimé Pelliculé								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643845	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723788US		1 DAY	Unknown	USA
<u>Preferred Term</u> Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain <u>Product</u> Lexapro <u>Comp.</u> <u>OTC</u> <u>Role</u> S <u>Route</u> Transplacental <u>Dosage Text</u> <u>Duration</u> <u>Mfr</u> Allergan									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643846	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723786US		1 DAY	Unknown	USA
<u>Preferred Term</u> Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain <u>Product</u> Lexapro <u>Comp.</u> <u>OTC</u> <u>Role</u> S <u>Route</u> Transplacental <u>Dosage Text</u> <u>Duration</u> <u>Mfr</u> Allergan									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643847	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723782US		1 DAY	Unknown	USA
<u>Preferred Term</u> Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; <u>Product</u> Lexapro <u>Comp.</u> <u>OTC</u> <u>Role</u> S <u>Route</u> Transplacental <u>Dosage Text</u> <u>Duration</u> <u>Mfr</u> Allergan									

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Nervous System Disorder;
Pain

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13643880	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1723318US		29 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Lethargy; Sedation	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Magnesium Citrate			C	Unknown			Not Reported	
	Riboflavin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13644368	NON-EXPEDITED			US-ROCHE-680036		37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Somnolence	Klonopin			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13645438	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1724330US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13089878	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP016176			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hospitalisation; Thinking Abnormal	Apo-Topiramate			S	Unknown	Unk		Apotex	
	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13526012	EXPEDITED (15-DAY)		OT	FR-AMGEN- FRASP2017069297		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Musculoskeletal Pain; Nausea; Underdose	Procoralan			S	Oral	1 Df, Bid		Amgen	
	Trivastal			S	Oral	1 Df, Qd		Not Reported	
	Epitomax			S	Oral	100 Mg, Bid		Not Reported	
	Levocarnil			S	Unknown	30 MI, Qd		Not Reported	
	Seroplex			S	Oral	20 Mg, Qd		Not Reported	
	Tecfidera			S	Oral	240 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13553503	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX- 2017AP011836		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Product Substitution Issue	Apo-Escitalopram			S	Unknown	10 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13561220	EXPEDITED (15-DAY)			JP-ALLERGAN- 1720157US		23 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Convulsions Local; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Myslee			C	Oral			Not Reported	
	Rohypnol			C	Oral			Not Reported	
	Depas (Etizolam)			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13569940	EXPEDITED (15-DAY)		DE, HO, OT	CN-ALLERGAN- 1721036US		62 YR	Female	CHN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Mg, Unk		Allergan
	Risperdal			S	Unknown	Unk		Not Reported
	Risperdal			S				Not Reported
	Aripiprazole			C	Unknown	Unk		Not Reported
	Artane			C	Unknown	Unk		Not Reported
	Benzhexol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13579141	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1721227US		59 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Daydreaming; Death; Dysarthria; Fear Of Eating; Gait Disturbance; Insomnia; Mydriasis; Obsessive Thoughts; Off Label Use; Paranoia; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Xanax			S	Oral	0.25 Mg, Bid		Not Reported
	Ambien			C		10 Mg, Unk		Not Reported
	Pravastatin			C	Oral	40 Mg, Qd		Not Reported
	Metoprolol			C	Oral	25 Mg, Unk		Not Reported
	Amlodipine			C	Oral	2.5 Mg, Unk		Not Reported
	Irbesartan			C		300 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13646886	EXPEDITED (15-DAY)		DE	US-TORRENT-00002816		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Pantoprazole			S				Unknown
	Escitalopram			S				Unknown
	Amlodipine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13648069	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1723792US			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Decreased Interest; Emotional Disorder; Emotional Distress; Exposure During Pregnancy; Injury; Nervous System Disorder; Pain	Lexapro			S	Transplacental			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13649072	EXPEDITED (15-DAY)		DS, HO	GB-ALLERGAN- 1724292US		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
Involuntary; Mydriasis; Nausea; Speech Disorder	Omega-3 Acids			C	Unknown			Not Reported	
	Multivitamin			C	Endocervical			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13403486	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1711402US		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Haemorrhage; Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Seresta			C	Oral	30 Mg, Qd		Not Reported	
	Seresta			C	Oral	10 Mg, Qd		Not Reported	
	Simvastatin			C	Oral			Not Reported	
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported	
	Amlor			C	Oral	5 Mg, Qd		Not Reported	
	Imovane			C	Oral	3.75 Mg, Qd		Not Reported	
	Tardyferon			C	Oral	20 Mg, Qd		Not Reported	

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Uvedose	C	Unknown	Not Reported
Doliprane	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13649470	EXPEDITED (15-DAY)	HO		FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2017- BI-03		84 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Fall; Hyponatraemia	Micardis			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported
	Sotalol (Hydrochlorid Od)			C	Oral	Unknown		Not Reported
	Levemir Flexpen 100 Iu/MI			C	Subcutaneous	Strength: 100 Iu/MI		Not Reported
	Kardegic 75mg			C	Oral			Not Reported
	Risperdal 1mg/MI			C	Oral	Strength: 1mg/MI		Not Reported
	Seresta 10mg			C	Oral			Not Reported
	Tahor 10mg			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13650908	EXPEDITED (15-DAY)	OT		DE-AUROBINDO-AUR- APL-2017-35453		36 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Escitalopram			S	Oral	15 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	20 Mg, Daily		Aurobindo
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo
	Risperidon			C	Oral	0.5 Mg, Daily		Not Reported
	L-Thyroxin			C	Oral	175 Mcg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13651067	EXPEDITED (15-DAY)	OT		DE-AUROBINDO-AUR- APL-2017-35454		28 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram			S	Oral	5 Mg, Daily		Aurobindo	
	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo	
	Escitalopram			S	Oral	5 Mg, Daily		Aurobindo	
	Bisoprolol			C	Oral	2.5 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13651716	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US07434			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Heart Rate Increased; Hyperhidrosis	Bupropion Hcl XI			S	Oral	150 Mg, Unk		Invagen	
	Bupropion Hcl XI			S	Oral	300 Mg, Unk		Invagen	
	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	
	Gabapentin			S	Unknown	400 Mg, Per Day		Invagen	
	Adderall			S	Unknown	Unk		Not Reported	
	Clonazepam			C	Unknown	0.5 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13653746	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1724560US		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Facial Bones Fracture; Fall; Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Tramadol			S	Oral	1 Df, Bid		Not Reported	
	Seresta			S	Oral	10 Mg, Tid		Not Reported	
	Amlodipine			S	Oral	5 Mg, Qd		Not Reported	
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported	
	Simvastatin			S	Oral	10 Mg, Qd		Not Reported	
	Tardyferon			S	Oral	80 Mg, Bid		Not Reported	
	Omeprazole			S		20 Mg, Qd		Not Reported	

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	Kardegic	C	Oral	1 Df, Qd	Not Reported
	Uvedose	C		Unk	Not Reported
	Doliprane	C		Unk	Not Reported
	Movicol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13468609	NON-EXPEDITED			US-PFIZER INC-2017171487			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Zithromax			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13524233	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1717994US		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Osteoporosis	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Quilonum Retarded			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13577813	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1721293US		18 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Dyspnoea;	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan	
Gastrointestinal Disorder;	Azithromycin Mepha			S	Intravenous drip	500 Mg, Q12h		Not Reported	
Neck Pain; Overdose	Azithromycin Mepha			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13654328	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1724538US		90 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Epistaxis; Face Injury; Fall; Haematoma	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
	Kardegic	S	Oral	75 Mg, Qd	Not Reported
	Kardegic	S	Oral	75 Mg, Qd	Not Reported
	Donepezil	C	Unknown		Not Reported
	Candesartan	C	Unknown		Not Reported
	Diffu K	C	Unknown		Not Reported
	Seresta	C	Unknown		Not Reported
	Atarax	C	Unknown		Not Reported
	Lactulose	C	Unknown		Not Reported
	Cacit D3	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13654798	EXPEDITED (15-DAY)		DE	US-TORRENT-00002882		25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride			S				Unknown
	Escitalopram			S				Unknown
	Lamotrigine			S				Unknown
	Clonazepam			S				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13654874	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002953		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S				Unknown
	Escitalopram			S				Unknown
	Atenolol			S				Unknown
	Clonazepam			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13655048	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-003119		36 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Body Mass Index	Orkambi			S	Oral	400/250 Mg, Bid		Vertex	
Decreased; Depression;	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported	
Drug Interaction; Forced	Escitalopram			S				Not Reported	
Expiratory Volume	Oxycodone			C				Not Reported	
Decreased; Infective	Marijuana			C				Not Reported	
Pulmonary Exacerbation	Hydroxyzine			C		25 Mg, Bid		Not Reported	
Of Cystic Fibrosis;								Not Reported	
Substance Abuse									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13655193	EXPEDITED (15-DAY)		DE	US-TORRENT-00003045		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Trazodone			S				Unknown	
Toxicity To Various Agents	Citalopram			S				Unknown	
	Buspirone			S				Unknown	
	Atenolol			S				Unknown	
	Eszopiclone			S				Unknown	
	Levothyroxine			S				Unknown	
	Clonazepam			S				Unknown	
	Ethanol			S				Unknown	
	Escitalopram Oxalate			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13655379	EXPEDITED (15-DAY)		OT	SE-ACCORD-052679		61 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue;	Escitalopram Accord			S		Strength: 10 Mg		Accord	
Urticaria									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13656090	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002987		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest;	Escitalopram			S				Unknown	

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Completed Suicide; Toxicity To Various Agents	Propranolol Venlafaxine Hydrochloride	S S	Unknown Not Reported						
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13657782	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003000		34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Toxicity To Various Agents	Trazodone			S				Unknown	
	Escitalopram			S				Unknown	
	Oxycodone			S				Unknown	
	Alprazolam			S				Unknown	
	Oxymorphone Hydrochloride			S				Unknown	
	Gabapentin			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	10485261	EXPEDITED (15-DAY)		HO	CA-FRI-1000071085		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Dose Omission	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Tylenol			S	Oral	2 Tablets, Tid		Not Reported	
	Wellbutrin XI			S	Oral	150 Mg, Bid		Not Reported	
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported	
	Domperidone			S	Oral	10 Mg, Bid		Not Reported	
	Gabapentin			S	Oral	300 Mg, Qam		Not Reported	
	Gabapentin			S	Oral	600 Mg, At Noon And Bedtime		Not Reported	
	Ferrous Sulfate			S	Oral	300 Mg, Tid		Not Reported	
	Vitalux			S	Oral	Unk, Bid		Not Reported	
	Temazepam			S	Oral	30 Mg, At Bedtime		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13657857	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003025		53 YR	Female	USA

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Completed Suicide; Toxicity To Various Agents	Duloxetine			S				Unknown	
	Escitalopram			S				Unknown	
	Clonazepam			S				Unknown	
	Baclofen			S				Unknown	
	Metformin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13657877	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002966		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S				Unknown	
	Citalopram			S				Unknown	
	Amlodipine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13657883	EXPEDITED (15-DAY)		DE	US-TORRENT-00003062		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Metoprolol			S				Unknown	
	Bupropion			S				Unknown	
	Escitalopram			S				Unknown	
	Amlodipine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13657908	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002887		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S				Unknown	
	Trazodone Hydrochloride			S				Unknown	
	Olanzapine			S				Unknown	
	Topiramate			S				Unknown	
	Dextromethorphan Hydrobromide			S				Unknown	
	Cyclobenzaprine Hydrochloride			S				Unknown	
	Meloxicam			S				Unknown	

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		Sumatriptan		S					Unknown
		Benzonatate		S					Unknown
		Chlorphenamine Maleate		S					Unknown
		Buspirone Hydrochloride		S					Unknown
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13657910	EXPEDITED (15-DAY)		DE	US-TORRENT-00002993		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents	Escitalopram Oxalate			S				Unknown	
	Trazodone			S				Unknown	
	Lisinopril			S				Unknown	
	Clonazepam			S				Unknown	
	Zolpidem			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13658460	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00002996		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Zolpidem			S				Unknown	
	Escitalopram			S				Unknown	
	Metoprolol			S				Unknown	
	Oxycodone			S				Unknown	
	Diazepam			S				Unknown	
	Venlafaxine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13659010	EXPEDITED (15-DAY)		DE	US-TORRENT-00003085		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Sertraline			S				Unknown	
	Quetiapine			S				Unknown	
	Acetaminophen			S				Unknown	
	Escitalopram Oxalate			S				Unknown	
	Buspirone			S				Unknown	

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16-Jun-2017	13660169	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/17/0091490		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Hip Arthroplasty; Somnolence	Divalproex Sodium			S	Unknown			Not Reported	
	Clozapine			S	Unknown			Not Reported	
	Aripiprazole			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13661697	EXPEDITED (15-DAY)		DS, HO	GB-MYLANLABS-2017M1034975			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder	Escitalopram			S	Oral			Not Reported	
	Omega-3 Fatty Acids			C				Mylan	
	Multivitamin			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13662054	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1724907US		56 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Doxepin			C	Oral	50 Mg, Unk		Not Reported	
	Galvus			C	Oral	50 Mg, Unk		Not Reported	
	Amlodipin			C	Oral	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13662058	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1724800US		35 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Essential Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13662074	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1725070US		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Haematoma; Loss Of Consciousness; Muscle Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Brilique			S	Oral	180 Mg, Qd		Not Reported	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Tahor			C	Unknown	40 Mg, Unk		Not Reported	
	Bisoce			C	Unknown	5 Mg, Unk		Not Reported	
	Aerius (Ebastine)			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13662712	DIRECT					65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Reaction To Excipient; Hot Flush; Insomnia; Product Substitution Issue; Pruritus; Rash; Restlessness	Eccitalopram 10mg			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Lexapro			C				Not Reported	
	Crestor			C				Not Reported	
	Evista			C				Not Reported	
	Biotin			C				Not Reported	
	Pericolace			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13662802	DIRECT	Y				45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety	Escitalopram			S	Oral			Not Reported	

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16-Jun-2017	13663288	DIRECT	Y				52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Product Substitution Issue	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2017	13662302	EXPEDITED (15-DAY)		DE	US-TORRENT-00003003		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Exposure Via Ingestion; Intentional Overdose; Toxicity To Various Agents	Trazodone			S				Unknown	
	Clonazepam			S				Unknown	
	Ethanol			S				Unknown	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	12397266	NON-EXPEDITED			US-PFIZER INC-2016254576		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zoloft			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Bactrim Ds			S	Oral	800/160 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	13515228	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1717408US		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertension; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	13531325	NON-EXPEDITED			US-PFIZER INC-2017203320		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Effexor Xr			S		150 Mg, 1x/Day		Pfizer	
	Pristiq			S		100 Mg, 1x/Day		Pfizer	
	Lexapro			S		10 Mg, 1x/Day		Not Reported	
	Klonopin			S		1 Mg, 2x/Day		Not Reported	
	Remeron			S		7.5 Mg, 1x/Day (Take Half At Night)		Not Reported	
	Celexa			S		Unk Unk, 1x/Day		Not Reported	
	Buspar			S		15 Mg, 1x/Day		Not Reported	
	Cymbalta			S		120 Mg, 1x/Day		Not Reported	
	Abilify			S		Unk, 1x/Day (One Half To One Tablet Once A Day)		Not Reported	
	Rexulti			S		2 Mg, 1x/Day		Not Reported	
	Ativan			S		1 Mg, 3x/Day		Not Reported	
	Lithium			S		Unk		Not Reported	
	Lithium			S				Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Wellbutrin			S				Not Reported	
	Mirapex			S		Unk		Not Reported	
	Mirapex			S				Not Reported	
	Trintellix			S		Unk		Not Reported	
	Trintellix			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	13663433	NON-EXPEDITED			US-PFIZER INC-2017263320		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Xanax			S		Unk		Pfizer	

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Effexor	S	Unk	Pfizer
Lexapro	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Prozac	S	Unk	Not Reported

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19-Jun-2017	13663674	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-051352			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Weight Increased	Abilify			S	Unknown			Bristol Myers Squibb
	Rexulti			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13668515	EXPEDITED (15-DAY)		OT	DE-ACCORD-052388		66 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium	Quetiapine			S	Oral			Accord
	Quilonum			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Movicol			C	Oral			Not Reported
	Beloc Zok			C	Oral			Not Reported
	Candesartan			C	Oral			Not Reported
	L-Thyroxin			C	Oral			Not Reported
	Tavor			S	Oral	4 - 0.5 Mg/D		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13669511	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS- 2017-003182		17 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Mood Altered; Suicide Attempt	Orkambi			S	Oral			Vertex	
	Orkambi			S	Oral	Unk		Vertex	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13672057	EXPEDITED (15-DAY)		DS, HO	GB-TEVA-777232ACC		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coordination Abnormal; Dizziness; Energy Increased; Gait Disturbance; Hunger; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder; Tremor	Escitalopram			S	Oral			Ivax	
	Omega-3 Acids			C				Not Reported	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13672311	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006625		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Dyskinesia; Dyskinesia; Loss Of Personal Independence In Daily Activities	Escitalopram			S				Unknown	
	Bisoprolol Fumarate			C				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13672721	EXPEDITED (15-DAY)		OT	DE-TORRENT-00006621		36 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety;	Escitalopram			S				Unknown	

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Haematoma; Haemorrhagic Disorder; Loss Of Personal Independence In Daily Activities; Menstrual Disorder; Tension	Risperidone Levothyroxine Sodium	C C	Unknown Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13673398	EXPEDITED (15-DAY)		DS, HO	GB-CIPLA LTD.- 2017GB10530			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Inappropriate Affect; Malaise; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Speech Disorder	Escitalopram Omega-3 Acids Multivitamin			S C C	Oral Unknown Unknown	10 Mg, Unk Unk Unk, Vegan		Invagen Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13675369	EXPEDITED (15-DAY)		LT, OT	DE-ALLERGAN- 1725717US		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram Oxalate - Bp Folio			S C	Transplacental Transplacental	20 Mg, Qd 0.4 Mg, Qd		Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13675370	EXPEDITED (15-DAY)		OT	DE-ALLERGAN- 1725727US		33 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Escitalopram Oxalate - Bp Folio			S C	Transplacental Transplacental	20 Mg, Qd 0.4 Mg, Qd		Allergan Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13677352	DIRECT		DS, HO, LT, OT			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Depersonalisation/Dereali sation Disorder; Depression; Economic Problem; Feeling Abnormal; Hyperacusis; Insomnia; Photophobia; Suicidal Ideation; Withdrawal Syndrome	Ativan			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Klonopin			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Lexapro			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13676820	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2017VAL000931		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Subileus	Furosemide			S	Oral	60 Mg, Qd		Validus	
	Fumafer			S	Oral	1 Df, Tid		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	20 Mg, Qd		Not Reported	
	Rivastigmine			C		Unk		Not Reported	
	Amlor			C		Unk		Not Reported	
	Atorvastatin			C		Unk		Not Reported	
	Bisoprolol			C		Unk		Not Reported	
	Eliquis			C		Unk		Not Reported	
	Keppra			C		Unk		Not Reported	
	Perindopril			C		Unk		Not Reported	
	Vimpat			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13681096	DIRECT	Y	DE			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Inlyta 5mg			S	Oral			Pfizer	
	Amiodarone			C				Not Reported	
	Aspirin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	B-Complex			C				Not Reported	
	Benicar			C				Not Reported	
	Clonazepam			C				Not Reported	
	Eliquis			S				Not Reported	
	Escitalopram			S				Not Reported	
	Fluticasone			C				Not Reported	
	Hydralazine			C				Not Reported	
	Levocetirizi			C				Not Reported	
	Metoprol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Mirtazapine			C				Not Reported	
	Renvela			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13681461	DIRECT		DS			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Impaired Work Ability; Paraesthesia; Seizure	Escitalopram			S	Oral			Forest	
	Motrin			C				Not Reported	
	Tramadol			C				Not Reported	
	Cpap			C				Not Reported	
	Multi-Vitamin (No Iron)			C				Not Reported	
	Vitamin D Supplement			C				Not Reported	
	Calcium Supplement			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13681754	DIRECT		HO			57 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Depression; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Tablet(S);		Allergan
	Viibryd			C				Not Reported
	Amlodipine			C				Not Reported
	Modafinil			C				Not Reported
	Amitriptyline			C				Not Reported
	Tramadol			C				Not Reported
	Amantadine			C				Not Reported
	Metoprolol			C				Not Reported
	Effexor			C				Not Reported
	Adult Multivitamin			C				Not Reported
	Vitamin C			C				Not Reported
	Calcium With Vitamin D			C				Not Reported
	Fish Oil			C				Not Reported
	Excedrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13681931	DIRECT	Y	DS			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Brain Injury	Simvastatin 20mg Tablet			S				Not Reported
	Alprazolam 0.25mg			S				Not Reported
	Olanzapine 15mg			S				Not Reported
	Aripiprazole 10 Mg			S				Not Reported
	Escitalopram 20mg			S				Not Reported
	Lantus			S				Not Reported
	Metformin			S				Not Reported
	Meloxicam 15mg			S				Not Reported
	Omeprazole 20mg			S				Not Reported
	Toviaz Er			S				Not Reported
	Divalproex Sod			S				Not Reported
	Propranolol 40mg Tab Her			S				Not Reported
	Ibuprofen			S				Not Reported
	Ventolin Hfa			S				Not Reported
	Epipen			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	12604755	NON-EXPEDITED			US-PFIZER INC- 2016351217		73 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Benzylopicillin Potassium			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Oxycodone			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Remeron			S		Unk		Not Reported
	Sucralfate			S		Unk		Not Reported
	Valium			S		Unk		Not Reported
	Zantac			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13680803	EXPEDITED (15-DAY)		LT, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017005241			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Lactic Acidosis; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S	Transplacental	20 Mg, Qd (0-40.4 Gestational Week)		Macleods
	Folio			C	Transplacental	0.4 Mg, Qd (0-20. Gestational Week)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13681377	NON-EXPEDITED			US-PFIZER INC- 2017273172		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer

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Potassium Chloride	S	Unk	Unknown
Levofloxacin	S	Unk	Pfizer
Clonidine	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13682547	EXPEDITED (15-DAY)	HO		CH-JNJFOC-20170620138		71 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Subdural Haematoma	Xarelto			S	Oral			Not Reported
	Cipralext			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Ventolin			C	Unknown			Not Reported
	Pravastatin Sodium			C	Unknown			Not Reported
	Janumet			C	Unknown			Not Reported
	Targin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Pulmicort			C	Unknown			Not Reported
	Atrovent			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Cordarone			C	Unknown			Not Reported
	Cardura			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13684763	EXPEDITED (15-DAY)		LT, OT	DE-TEVA-778461GER		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neonatal Asphyxia;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax

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Neonatal Hypoxia; Small Folio C Transplacental .4 Milligram Daily; Not Reported
For Dates Baby

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13686748	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1725985US		71 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Zolpidem Streuli			S	Unknown	Unk, Unknown		Not Reported
	Xarelto			S	Unknown	Unk, Unknown		Not Reported
	Cordarone			C	Unknown	Unk, Unknown		Not Reported
	Atacand			C	Unknown	Unk, Unknown		Not Reported
	Torem			C	Unknown	Unk, Unknown		Not Reported
	Cardura			C	Unknown	Unk, Unknown		Not Reported
	Pravalotin			C	Unknown	Unk, Unknown		Not Reported
	Janumet			C	Unknown	Unk, Unknown		Not Reported
	Targin			C	Unknown	Unk, Unknown		Not Reported
	Lyrica			C	Unknown	Unk, Unknown		Not Reported
	Pulmicort			C	Unknown	Unk, Unknown		Not Reported
	Atrovent			C	Unknown	Unk, Unknown		Not Reported
	Ventolin			C	Unknown	Unk, Unknown		Not Reported
	Rivaroxaban			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13687813	DIRECT		OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Spasms; Muscle Twitching; Serum Serotonin Decreased; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Jubilant
	Ibuprofen			C				Not Reported
	Montelukast			C				Not Reported
	Oxycodone			C				Not Reported

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Prolia	C	Not Reported
Tylenol	C	Not Reported
Citracal	C	Not Reported
Vitamin D Nos	C	Not Reported
Cetirizine Hydrochloride	C	Not Reported
Nexium	C	Not Reported
Sudafed	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2017	13687718	EXPEDITED (15-DAY)		HO	PHHY2017FR091938		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disorientation; Hyponatraemia	Cotareg			S	Oral	Unk		Novartis
	Seroplex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2017	13687753	EXPEDITED (15-DAY)		LT, OT	DE-MYLANLABS-2017M1036832			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Folio			C	Transplacental	0.4 [Mg/D]		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2017	13689323	DIRECT		OT			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sexual Dysfunction; Therapy Cessation	Escitalopram			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);		Unknown
	Bupropion			C				Not Reported
	Levothyroxine			C				Not Reported
	Albuterol			C				Not Reported

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Vitamin D Nos	C	Not Reported
Vitamin B	C	Not Reported
Iron	C	Not Reported
Fish Oil	C	Not Reported
Zyrtec	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13688203	EXPEDITED (15-DAY)		HO	FR-009507513-1706FRA009634			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Encephalopathy; Hepatitis	Januvia			S	Oral	100mg At Lunch Qd		Merck
	Loxapac (Loxapine Succinate)			S	Oral	25 Mg/ML, 5 Drops If Needed		Not Reported
	Mianserine Distireti			S	Oral	10 Mg, Qd		Not Reported
	Lysanxia			S	Oral	15 Mg/ML: 10-10-10 Drops		Not Reported
	Contramal			S	Oral	37.5mg, Qd		Not Reported
	Galvus			S	Oral	50 Mg, Qd		Not Reported
	Metformin			S	Oral	1.5 G, Qd		Not Reported
	Memantine			S	Oral	20 Mg, Qd		Not Reported
	Inexium (Esomeprazole Sodium)			S	Oral	20 Mg, Qd		Not Reported
	Doliprane			S	Oral	3 G, Qd		Not Reported
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Lantus			S	Subcutaneous	14 Iu, Qd		Not Reported
	Novorapid			S	Subcutaneous	Depending On Glycemia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13688966	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2017-35795		35 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Essential Tremor	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13691799	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00114			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Taste Disorder	Escitalopram			S		Unk		Prinston Pharmaceutical Not Reported	
	Synthroid			S		Unk			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13691800	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00066		90 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Penile Pain	Escitalopram			S	Oral	1 Tablets, Once		Prinston Pharmaceutical Not Reported	
	Metoprolol			C		12.5 Mg, 1x/Day			
	Aspirin			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2017	13692487	EXPEDITED (15-DAY)		OT	TW-CIPLA LTD.- 2017TW10854			Unknown	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Major Depression	Atorvastatin			S	Unknown	40 Mg, Daily		Cipla Invagen Invagen Cipla Not Reported Not Reported Not Reported Not Reported	
	Escitalopram			S	Unknown	10 Mg, Daily			
	Escitalopram			S	Unknown	10 Mg, Daily			
	Zaleplon			S	Unknown	10 Mg, Nightly			
	Sevikar			S	Unknown	5mg/20mg, Daily			
	Glucomet Plus			S	Unknown	5mg/500mg, Bid			
	Clonazepam			S	Unknown	0.75 Mg, Daily			
	Clonazepam			S	Unknown	2 Mg, Nightly			

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2017	13694105	EXPEDITED (15-DAY)		DE	AT-ASTRAZENECA-2017SE65115		74 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Drug Interaction	Esomeprazole			S	Oral			Astrazeneca	
	Escitalopram			S	Unknown			Not Reported	
	Dominal (Prothipendyl Hydrochloride)			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2017	13695292	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1726818US		23 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Bupropion			S	Unknown	150 Mg, Unk		Not Reported	
	Alprazolam			C	Unknown			Not Reported	
	Propranolol			C	Unknown			Not Reported	
	Sertraline			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13558253	NON-EXPEDITED			US-PFIZER INC-2017213121		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Erythromycin			S	Oral	Unk		Pfizer	
	Lexapro			S	Oral	Unk		Not Reported	
	Motrin			S	Oral	Unk		Not Reported	
	Motrin			S				Not Reported	
	Vioxx			S	Oral	Unk		Not Reported	
	Vioxx			S				Not Reported	
	Ultram			S	Oral	Unk		Not Reported	
	Ultram			S				Not Reported	

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28-Jun-2017	13609798	EXPEDITED (15-DAY)		HO, OT	TR-ALLERGAN-1722760US		16 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Discomfort; Galactorrhoea; Intentional Overdose; Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Pseudoephedrine			S	Unknown			Not Reported	
	Metoclopramide			S	Unknown			Not Reported	
	Fluoxetine			C	Unknown	20 Mg, Qd		Not Reported	
	Fluoxetine			C	Unknown	10 Mg, Qd		Not Reported	
	Risperidone			C	Unknown	0.5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13696325	EXPEDITED (15-DAY)		DE, HO, OT	SE-CIPLA LTD.-2017SE11080			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Blood Pressure Increased; Bradycardia; Confusional State; Dehydration; Dizziness; Nausea; Product Administration Error; Renal Tubular Necrosis; Urinary Tract Infection; Vomiting; Wound	Escitalopram			S	Unknown	20 Mg, Qd		Invagen	
	Rivastigmine			S	Transdermal	9.5 Mg, Per 24 H, Patch		Not Reported	
	Aspirin			S	Unknown	75 Mg, Qd		Not Reported	
	Alprazolam			S	Unknown	0.5 Mg, Qd		Cipla	
	Mirtazapine			S	Unknown	15 Mg, Qd		Cipla	
	Dimethicone			S	Unknown	200 Mg, Tid		Not Reported	
	Etilefrine			S	Unknown	5 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13696597	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE65407		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Encephalopathy; Hepatitis	Inexium			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

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Metformin	S	Oral	One Dosage Form In The Morning And Two Dosage Forms At Night (Non Az Product)	Not Reported
Loxapac	S	Oral	5.0mg As Required	Not Reported
Mianserin	S	Oral	10 Mg In The Evening	Not Reported
Lysanxia	S	Oral		Not Reported
Contramal	S	Oral		Not Reported
Januvia	S	Oral	100 Mg At Lunch Time	Not Reported
Galvus	S	Oral	50 Mg In The Evening	Not Reported
Memantine	S	Oral		Not Reported
Doliprane	S	Oral		Not Reported
Lantus	S	Subcutaneous		Not Reported
Novorapid	S	Subcutaneous	As Per Glycemia	Not Reported
Movicol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13697678	EXPEDITED (15-DAY)		LT, OT	DE-AUROBINDO-AUR-APL-2017-35850		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram 20 Mg			S	Transplacental	20 Mg, Daily		Aurobindo
	Folio /00349401/			C	Transplacental	0.4 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13698604	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1726829US		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Flatulence; Hypokalaemia; Subileus; Vomiting	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Fumafer			S	Oral			Not Reported

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Tramadol	S	Oral	Not Reported
Lasix	S	Oral	Not Reported
Amlor	C	Unknown	Not Reported
Atorvastatin	C	Unknown	Not Reported
Bisoprolol	C	Unknown	Not Reported
Eliquis	C	Unknown	Not Reported
Keppra	C	Unknown	Not Reported
Perindopril	C	Unknown	Not Reported
Vimpat	C	Unknown	Not Reported
Rivastigmine	C	Transdermal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13698657	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1727044US		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Plavix			S	Oral			Not Reported	
	Coaprovel			C	Unknown			Not Reported	
	Pravastatine			C	Unknown			Not Reported	
	Nicorandil			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13698902	EXPEDITED (15-DAY)		OT	MX-ALLERGAN-1726812US		35 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cold Sweat; Confusional State; Depression; Dysstasia; Hypotension; Malaise; Nausea; Obsessive-Compulsive Disorder; Paraesthesia; Somnolence; Syncope;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Brintellix			C	Oral			Not Reported	
	Brintellix			C				Not Reported	
	Brintellix			C				Not Reported	

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Tachycardia	Valdoxan	C	Unknown			Not Reported
	Valdoxan	C				Not Reported
	Arcalion	C	Oral	100 Mg, Unk		Not Reported
	Macrochantin	C	Oral	100 Mg, Q6hr		Not Reported
	Lamotrigine	C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13699236	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC- 2017-IPXL-01903		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion Of Replacement	Carbidopa-Levodopa Er			S	Unknown	Unk		Impax	
	Alprazolam Er			S	Unknown	Unk		Impax	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13654855	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-142935		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 MI Total		Not Reported	
	Alprazolam			S	Oral	10 MI Total		Sun	
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13656323	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2017-35424		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 MI, Unk		Aurobindo	
	Alprazolam			S	Oral	10 MI, Total		Not Reported	
	Esomeprazol /01479301/			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13656942	EXPEDITED (15-DAY)		OT	IT-TEVA-776905ACC		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax	
	Alprazolam			S	Oral			Actavis	
	Esomeprazole Sodium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13689560	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ACTELION-A-CH2013-93009		76 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Condition Aggravated; Myocardial Infarction; Pneumonia; Pulmonary Arterial Hypertension; Pulmonary Embolism; Pulseless Electrical Activity; Sleep Apnoea Syndrome; Sleep Study; Sudden Death	Selexipag			S	Oral	1400 Mg, Bid		Actelion	
	Selexipag			S	Oral	1400 Mg, Bid		Actelion	
	Upravi			S	Oral	1400 Mg, Qd		Actelion	
	Tracleer			S	Oral	Unk		Actelion	
	Revatio			S	Unknown	Unk		Not Reported	
	Inexium			S	Unknown			Not Reported	
	Lasix			S	Unknown			Not Reported	
	Aldactone			S	Unknown	Unk		Not Reported	
	Seroplex			S	Unknown			Not Reported	
	Previscan (Fluindione)			S	Unknown			Not Reported	
	Acenocoumarol			C		Unk		Not Reported	
	Alendronate			C		Unk		Not Reported	
	Calcium D3			C		Unk		Not Reported	
	Dipotassium Chlorazepate			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13703019	EXPEDITED (15-DAY)		DE	FR-VALIDUS PHARMACEUTICALS		79 YR	Female	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

LLC-FR-
2017VAL000971

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Furosemide			S	Unknown	Unk		Validus
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported
	Upravi			S	Oral	1400 Mg, Qd		Not Reported
	Tracleer /01587701/			S	Unknown	Unk		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Aldactone /00006201/			S	Unknown	Unk		Not Reported
	Previscan /00789001/			S	Unknown	Unk		Not Reported
	Inexium /01479303/			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13703447	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017278306		32 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Pneumonia Aspiration; Toxicity To Various Agents	Xanax			S	Oral	Unk		Pfizer
	Xanax			S	Oral	Unk		Pfizer
	Seroplex			S	Oral	Unk		Not Reported
	Abilify			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13705183	DIRECT					27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Amphetamine Salts 15mg Tablet			S	Oral	Other		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Headache; Product
Substitution Issue

Strength:Mg;Quantity:60
Tablet(S);

Wellbutrin	C	Not Reported
Klonopin	C	Not Reported
Lexapro	S	Not Reported
Adderall	C	Not Reported
Soylent	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13640342	EXPEDITED (15-DAY)		HO	DE-TORRENT-00006589		48 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine	Sertraline			S				Unknown
Phosphokinase Increased	Lorazepam			C				Unknown
	Escitalopram			S				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13673765	NON-EXPEDITED			US-VERTEX PHARMACEUTICALS- 2017-003245			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Food Interaction; Palpitations	Orkambi			S	Oral	2 Df (200-125mg) Each, Bid		Vertex
	Escitalopram			S	Unknown			Not Reported
	Albuterol			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Cholecalciferol			C				Not Reported
	Dornase Alfa			C				Not Reported
	Flonase			C				Not Reported
	Advair			C				Not Reported
	Zenpep			C				Not Reported
	Loratadine			C				Not Reported
	Adek			C				Not Reported
	Ranitidine			C				Not Reported

FDA Adverse Event Reporting System

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	Omeprazole	C	Not Reported
	Miralax	C	Not Reported
	Hypersal	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13682791	EXPEDITED (15-DAY)		DE	JP-JNJFOC-20170619742		30 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Circulatory Collapse; Completed Suicide; Inappropriate Schedule Of Product Administration; Off Label Use; Overdose; Product Use In Unapproved Indication	Concerta			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported
	Brotizolam			S	Oral			Not Reported
	Chlorpromazine			S	Unknown			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Flunitrazepam			S	Unknown			Not Reported
	Invega			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13707865	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1727456US		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disorientation; Hyperleukocytosis; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Cotareg			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13707934	EXPEDITED (15-DAY)		DE	AT-ALLERGAN-1727359US		74 YR	Female	AUT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Drug Interaction	Escitalopram Oxalate - Bp			S		1 Df, Qd		Allergan	
	Esomeprazole			S		1 Df, Qd		Not Reported	
	Dominal (Prothipendyl Hydrochloride)			S		1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13707935	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1727362US		90 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Hyponatraemia; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan	
	Lorazepam			C		Unk		Not Reported	
	Atorvastatin Calcium			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13708094	NON-EXPEDITED		HO, LT	ES-EISAI MEDICAL RESEARCH-EC-2017-028937		53 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Fycompa			S	Oral			Not Reported	
	Fycompa			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Pregabalina			S	Oral	75 Mg, 25 Mg, 75 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13708514	NON-EXPEDITED			US-SUNOVION-2017SUN002681			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Somnolence	Latuda			S	Oral	40 Mg, Unk		Sunovion	
	Latuda			S	Oral	80 Mg, Unk		Sunovion	

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	Lamotrigine	S	200 Mg, Unk	Not Reported
	Lamotrigine	S	300 Mg, Unk	Not Reported
	Lexapro	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13710584	DIRECT		DS			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disturbance In Attention; Malaise; Product Substitution Issue; Tremor	Escitalopram			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S); Daily Oral		Aurobindo
	Bupropion			C				Not Reported
	Ibuprofen			C				Not Reported
	Acetomenophen			C				Not Reported
	Zinc			C				Not Reported
	Vitamin B12			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13710538	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-551438		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Encephalopathy; Hepatitis	Novorapid			S	Subcutaneous	According To The Glycaemia		Novo Nordisk
	Loxapac /00401801/			S	Oral	25 Mg/MI (5 Drops As Needed)		Not Reported
	Mianserine Arrow			S	Oral	10 Mg Evening		Not Reported
	Lysanxia			S	Oral	15 Mg, Qd ((10 Droops In Morning, 10 At Noon And 10 Droops In Evening)		Not Reported
	Contramal			S	Oral	37.5 Mg, Qd		Not Reported
	Galvus			S	Oral	50 Mg, Qd (1df In Evening, In Replacement Of Januvia)		Not Reported
	Januvia			S	Oral	100 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metformine Arrow	S	Oral	1.5 G, Qd (1 Df In Morning And 2 Df In Evening)	Not Reported
Memantine	S	Oral	20 Mg, Qd	Not Reported
Inexium /01479302/	S	Oral	20 Mg, Qd (1 Df In Evening)	Not Reported
Doliprane	S	Oral	3 G, Qd	Not Reported
Escitalopram Arrow	S	Oral	5 Mg, Qd	Not Reported
Lantus	S	Subcutaneous	14 Iu, Qd	Not Reported
Monoprost	C		50 Microgram/ML, 1df Evening	Not Reported
Movicol Plain	C		2 Df, Qd	Not Reported
Seresta Expidet	C		10 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13711040	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2017AP013743		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Overdose; Suicide Attempt	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Apotex	
	Escitalopram Oxalate			S	Unknown	Unk		Apotex	
	Ivacaftor W/Lumacaftor			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13711270	EXPEDITED (15-DAY)		DE, HO	FR-SA-2017SA113845		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Encephalopathy; Hepatitis	Doliprane			S	Oral			Not Reported	
	Lantus			S	Subcutaneous			Not Reported	
	Mianserine			S	Oral			Not Reported	
	Lysanxia			S	Oral			Not Reported	
	Contramal			S	Oral			Not Reported	

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Galvus	S	Oral		Not Reported
Januvia	S	Oral	100 Mg At Noon	Not Reported
Metformin	S	Oral		Not Reported
Memantine	S	Oral		Not Reported
Inexium	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Novorapid	S	Subcutaneous	According To Glycaemia	Not Reported
Loxapac	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13711420	EXPEDITED (15-DAY)		DE, OT	AT-MYLANLABS-2017M1039406			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asphyxia	Escitalopram			S		1 Df, Qd		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S		1 Df, Qd		Mylan
	Esomeprazole			S		1 Df, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	10185571	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2014SE33140		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Crestor			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Metformin			S	Oral	Non-Astrazeneca Product, 150 Mg Twice Daily		Not Reported
	Alfuzosin			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported

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Levothyrox	S	Oral	Not Reported
Aprovel	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13713533	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707- 003926		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Alfuzosin Tablet			S	Oral	Daily		Concordia
	Imovane			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Amarel			C				Not Reported
	Bromazepam			C				Not Reported
	Meteospasmyl [Alverine Citrate;DI-Methionine			C				Not Reported
	Montelukast			C				Not Reported
	Symbicort			C				Not Reported
	Valerian			C				Not Reported
	Lepticur			C				Not Reported
	Theralene			C				Not Reported
	Movicol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13713732	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US11382			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coeliac Disease	Escitalopram			S	Oral	Unk		Invagen

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13713815	EXPEDITED (15-DAY)		HO, OT	DE-HETERO LABS LTD-2022868		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram Cyanocobalamin, Folic Acid			S C	Transplacental Transplacental			Hetero Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13714018	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2017-36302		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Encephalopathy; Hepatitis	Escitalopram Arrow			S	Oral	5 Mg, Once A Day		Aurobindo	
	Mianserin Arrow			S	Oral	10 Mg, Daily		Not Reported	
	Metformin Arrow			S	Oral	1.5 G, Once A Day		Aurobindo	
	Memantine Arrow			S	Oral	20 Mg, Once A Day		Aurobindo	
	Loxapac /00401801/			S	Oral	5 Mg If Necessary		Not Reported	
	Lysanxia			S	Oral	15 Mg, Once A Day		Not Reported	
	Contramal			S	Oral	37.5 Mg, Once A Day		Not Reported	
	Galvus			S	Oral	50 Mg, Once A Day		Not Reported	
	Januvia			S	Oral	100 Mg, Once A Day		Not Reported	
	Inexium /01479302/			S	Oral	20 Mg, Daily		Not Reported	
	Doliprane			S	Oral	3 G, Daily		Not Reported	
	Lantus			S	Subcutaneous	14 Iu, Daily		Not Reported	
	Novorapid			S	Subcutaneous	According To Glycemia		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13714121	NON-EXPEDITED			US-TAKEDA- 2017TUS014128		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

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Drug Ineffective; Nausea	Trintellix	S	Oral	10 Mg, Qd	Takeda
	Trintellix	S	Oral	20 Mg, Qd	Takeda
	Lexapro	S	Oral	Unk	Not Reported
	Alprazolam	C	Oral	2 Mg, Qid	Not Reported
	Neurolink	C	Oral	Unk Unk, Qid	Not Reported
	Neurolink	C	Oral	Unk Unk, Bid	Not Reported
	Sam-E	C	Oral	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13714527	EXPEDITED (15-DAY)		OT	ES- ELI_LILLY_AND_COMP ANY-ES201706012480			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Olanzapine			S	Unknown	5 Mg, Daily		Eli Lilly And Co	
	Olanzapine			S	Unknown	10 Mg, Daily		Eli Lilly And Co	
	Olanzapine			S	Unknown	15 Mg, Daily		Eli Lilly And Co	
	Mirtazapine			S	Unknown	60 Mg, Daily		Not Reported	
	Fluvoxamine			S	Unknown	Unk, Unknown		Not Reported	
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported	
	Risperidone			S	Unknown	3 Mg, Daily		Not Reported	
	Quetiapine			S	Unknown	50 Mg, Daily		Not Reported	
	Carbamazepine			C	Unknown	1200 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13715294	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-058957		32 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Lung Disorder; Toxicity To Various Agents	Abilify			S	Oral	Unk		Bristol Myers Squibb	
	Xanax			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	

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Risperdal			S		Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13715340	EXPEDITED (15-DAY)	DE		AT-TEVA-781214ISR		74 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia	Escitalopram			S		1 Dosage Forms Daily;		Ivax	
	Esomeprazol			S		1 Dosage Forms Daily;		Teva	
	Dominal 80mg			S		1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13658775	EXPEDITED (15-DAY)	OT		ES-AUROBINDO-AUR-APL-2017-35571		42 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown			Aurobindo	
	Mirtazapine			S	Unknown	60 Mg, Daily		Aurobindo	
	Mirtazapine			S				Aurobindo	
	Olanzapine 10mg			S	Unknown	10 Mg, Daily		Aurobindo	
	Olanzapine 10mg			S	Unknown	20 Mg, Daily		Aurobindo	
	Olanzapine 10mg			S	Unknown	5 Mg, Daily		Aurobindo	
	Olanzapine 10mg			S	Unknown	15 Mg, Daily		Aurobindo	
	Quetiapine			S	Unknown	50 Mg, Daily		Aurobindo	
	Quetiapine			S				Aurobindo	
	Risperidone			S	Unknown	3 Mg, Daily		Aurobindo	
	Risperidone			S				Aurobindo	
	Fluvoxamine			S	Unknown			Not Reported	
	Carbamazepine			C	Unknown			Not Reported	
	Carbamazepine			C	Unknown	1200 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13718075	EXPEDITED (15-DAY)	HO, LT		FR-JNJFOC-20170624009		32 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Intentional Overdose; Pneumonia Aspiration; Toxicity To Various Agents	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral	4 Boxes		Not Reported	
	Xanax			S	Oral	6 Boxes		Not Reported	
	Seroplex			S	Oral	3 Boxes		Not Reported	
	Abilify			S	Oral	6 Boxes		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13718297	EXPEDITED (15-DAY)		HO	FR-DSJP-DSE-2017-120981			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Orthostatic Hypotension	Sevikar 20 Mg/ 5 Mg			S	Oral	20/5 Mg, Qd		Daiichi	
	Imovane			S	Oral	7.5 Mg, Qd		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Theralene			S		40 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13718622	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1727462US		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Previscan (Fluindione)			S	Unknown	Unk		Not Reported	
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported	
	Tracleer			S	Unknown	Unk		Not Reported	
	Uptravi			S	Oral	1400 Mg, Qd		Not Reported	
	Revatio			S	Unknown	Unk		Not Reported	
	Lasilix			S	Unknown	Unk		Not Reported	
	Aldactone			S	Unknown	Unk		Not Reported	
	Inexium			S	Unknown	Unk		Not Reported	

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05-Jul-2017	13719284	EXPEDITED (15-DAY)		DE	US-BAYER-2017-122659		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Vanishing Bile Duct Syndrome	Moxifloxacin			S		Unk		Bayer	
	Cefalexin			S		Unk		Not Reported	
	Lamotrigine			S		25 Mg, Bid		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Aripiprazole			C		Unk		Not Reported	
	Prednisone			C		Unk		Not Reported	
	Meloxicam			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	10196725	EXPEDITED (15-DAY)		OT	FR-FRI-1000067560		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Alfuzosine Hydrochloride			S	Oral	10 Mg, Qd		Not Reported	
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported	
	Atarax			S	Oral	25 Mg, Bid		Not Reported	
	Metformin Hcl			S	Oral	150 Mg, Bid		Not Reported	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Levothyrox			S	Oral	125 Mg, Qd		Not Reported	
	Crestor			S	Oral	5 Mg, Qd		Not Reported	
	Aprovel			S	Oral	150 Mg, Qd		Not Reported	
	Eupantol			C		20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	10282393	EXPEDITED (15-DAY)		DS	FI-FRI-1000068674		20 YR	Male	FIN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depressed Mood; Disturbance In Sexual Arousal; Genital Paraesthesia; Libido Decreased; Male Orgasmic Disorder; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
	Sertralin			S	Oral	50 Mg, Unk		Not Reported	
	Moclobemid			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13667838	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00006554		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Burning Sensation; Diarrhoea; Fatigue; Feeling Abnormal; Hot Flush; Listless; Nausea; Panic Attack; Skin Burning Sensation; Suicidal Ideation; Vision Blurred	Escitalopram Heumann 10 Mg Filmtabletten			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13700542	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1726821US		20 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tonic Convulsion	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13720146	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1728109US		51 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dry Mouth; Migraine; Nausea; Photophobia; Suicide	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Neurontin			S	Unknown	100 Mg, Qd		Not Reported	

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Attempt; Trismus; Vomiting		Kliovance		C	Unknown		Unk, Unknown		Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720182	EXPEDITED (15-DAY)		LT, OT	DE-TORRENT-00006665		1 DAY	Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lactic Acidosis; Neonatal Asphyxia; Neonatal Hypoxia; Small For Dates Baby	Escitalopram Folio			S				Unknown	
				C				Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720560	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2028195-00			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Humira 40mg/0.8ml Ciprallex			S	Subcutaneous			Not Reported	
				S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13721526	EXPEDITED (15-DAY)		OT	US-TORRENT-00003159		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Off Label Use	Sertraline Quetiapine Escitalopram Oxalate Aripiprazole Valproic Acid			S				Unknown	
				S				Unknown	
				S				Unknown	
				S				Unknown	
				S				Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13724554	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017288743		69 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Arthritis; Insomnia; Pre-Existing Condition	Pristiq	S	50 Mg, Unk	Pfizer
Improved; Psoriasis;	Lexapro	S	Unk	Not Reported
Therapeutic Response Unexpected	Wellbutrin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13724659	EXPEDITED (15-DAY)		HO	KR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2017- BI-03		66 YR	Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection	Giotrif			S	Oral			Boehringer Ingelheim
	Trisonekit			S	Unknown			Not Reported
	Trisonekit			S				Not Reported
	Targin			S	Unknown	Strength: 5mg/Naloxone 2.5mg, Unit Dose And Daily Dose:10/5 Mg		Not Reported
	Targin			S	Unknown	Strength: 10mg/Naloxone 5mg,Unit Dose And Daily Dose: 20/10mg		Not Reported
	Matrifen			S	Unknown			Not Reported
	Resipilene (Zipeprol Dihydrochloride)			S	Unknown	Strength: 5mg/MI, Unit Dose And Daily Dose: 15mg/MI		Not Reported
	Ircodon			S	Unknown			Not Reported
	Harnal D			S	Unknown			Boehringer Ingelheim
	Folic Acid			S	Unknown			Not Reported
	Bromazepam			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Lithium Carbonate			S	Unknown			Not Reported
	Hilase			S	Unknown			Not Reported
	Saropram			S	Unknown			Not Reported
	Zolmin			S	Unknown			Not Reported

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Hinecol			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13725321	DIRECT		DS			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Anger; Depressed Mood; Flatulence; Hallucination, Visual; Heart Rate Irregular; Hypoaesthesia; Incontinence; Insomnia; Irritability; Neuralgia; Overdose; Pain; Paraesthesia; Pruritus; Scratch; Serotonin Syndrome; Somnolence; Suicidal Ideation; Tachyphrenia; Tremor	Escitalopram Vitamin C Vitamin D Nos Vitamin B Complex Nattokinase Krill Oil			S C C C C C	Oral	Quantity:1 Tablet(S); Oral		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13725397	DIRECT	Y				53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Escitalopram			S	Oral	Other Dose:Mg;		Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13725905	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1728114US		36 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dengue Fever; Intentional Dose Omission; Therapy Cessation	Escitalopram Oxalate - Bp Mirtazapine			S C	Unknown Unknown	10 Mg, Qd 45 Mg, Qd		Allergan Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13725971	EXPEDITED (15-DAY)		OT	FR-SA-2014SA061839		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Alfuzosin Hydrochloride			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Amarel			C	Unknown			Not Reported
	Bromazepam			C	Unknown			Not Reported
	Meteospasmyl [Alverine Citrate;DI-Methionine			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported
	Valerian			C	Unknown			Not Reported
	Lepticur			C	Oral			Not Reported
	Theralene			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13726499	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1039833			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Headache; Status	Escitalopram			S		20 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

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Epilepticus	Quetiapine		S			400 Mg, Qd		Not Reported	
	Quetiapine		S			600 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13726689	DIRECT	Y	OT			42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13386349	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1712392US		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Glycosylated Haemoglobin Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13726842	EXPEDITED (15-DAY)		HO	IN-TORRENT-00001249		50 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate			S				Unknown	
	Bupropion			S				Unknown	
	Paroxetine			S				Unknown	
	Vilazodone Hydrochloride			S				Unknown	
	Mirtazapine			S				Unknown	
	Sertraline Hydrochloride			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13732557	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1728380US		32 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coma; Pneumonia	Escitalopram Oxalate - Bp	S	Oral	Allergan
Aspiration; Toxicity To	Xanax	S	Oral	Not Reported
Various Agents	Abilify	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13732558	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1728545US		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2017	13734122	EXPEDITED (15-DAY)		OT	FR-ZYDUS-015738		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State;	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
Headache; Status	Quetiapine/Quetiapine Fumarate			S	Unknown	400 Mg, Qd		Not Reported	
Epilepticus	Quetiapine/Quetiapine Fumarate			S	Unknown	600 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2017	13734327	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001307			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Suicidal	Metformin			S		500 Mg, Unk		Ipca	
Ideation	Escitalopram			S		20 Mg, Unk		Not Reported	
	Paracetamol			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2017	13735548	DIRECT					30 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Of Body Temperature Change; Formication; Incorrect Dose Administered; Neck Pain; Nervousness; Panic Attack; Paraesthesia	Lexapro (Escitalopram)			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Cipla	
	Mirtazapine (Remeron)			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	10195739	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-20797627		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Metformin Hydrochloride			S	Oral	150 Mg, Bid		Bristol Myers Squibb	
	Metformin Hydrochloride			S	Oral	850 Mg, Bid		Bristol Myers Squibb	
	Metformin Hydrochloride			S	Oral	850 Mg, Tid		Bristol Myers Squibb	
	Aprovel			S	Oral	150 Mg, Qd		Not Reported	
	Levothyrox			S	Oral	125 Mg, Qd		Not Reported	
	Imovane			S	Oral	3.75 Mg, Qd		Not Reported	
	Atarax			S	Oral	25 Mg, Bid		Not Reported	
	Atarax			S	Oral	12.5 Mg, Qd		Not Reported	
	Seroplex			S	Oral	5 Mg, Qd		Not Reported	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Crestor			S	Oral	5 Mg, Qd		Not Reported	
	Crestor			S	Oral	10 Mg, Unk		Not Reported	
	Alfuzosine			S	Oral	10 Mg, Qd		Not Reported	
	Eupantol			C	Unknown			Not Reported	
	Amarel			C	Unknown	1 Df, Unk		Not Reported	
	Meteospasmyl /01017401/			C	Unknown	1 Tab, Tid		Not Reported	
	Montelukast			C	Unknown	10 Mg, Qd		Not Reported	
	Symbicort			C	Unknown	Unk, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bromazepam	C	Unknown	Unk, Prn	Not Reported
Valerian	C	Unknown	Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	10211428	EXPEDITED (15-DAY)		OT	7291845		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia; Fatigue; Nasal Congestion; Nausea	Novothyrox			S	Oral			Merck Kgaa
	Metformin Hydrochloride			S	Oral			Not Reported
	Metformin Hydrochloride			S	Oral			Not Reported
	Imovane			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Atarax			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Alfuzosine Hydrochloride			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Aprovel			S	Oral			Not Reported
	Eupantol			C				Not Reported
	Amarel			C				Not Reported
	Meteospasmyl [Alverine Citrate;DI-Methionine			C				Not Reported
	Montelukast			C				Not Reported
	Symbicort			C				Not Reported
	Bromazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	11926821	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-109945		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bipolar Disorder; Blood Prolactin Increased; Blunted Affect;	Fluoxetine	S	Unknown	10 Mg	Sun
Gastrointestinal Disorder; Homicidal Ideation; Overdose; Panic Attack; Suicidal Ideation;	Acetaminophen	S	Unknown	Over Dosed	Ohm Lab
Therapeutic Response Decreased	Escitalopram	S	Unknown	Unk	Not Reported
	Risperidone	S	Unknown	0.5 Mg, Bid	Ranbaxy
	Aripiprazole	S	Unknown	2mg	Not Reported
	Aripiprazole	S	Unknown	5mg	Not Reported
	Lamotrigine	C	Unknown	25 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	13734793	EXPEDITED (15-DAY)		OT	US-TORRENT-00003147		51 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Psychotic Disorder	Bupropion Hydrochloride			S				Unknown
	Escitalopram			S				Unknown
	Sertraline			C				Unknown
	Trazodone			C				Unknown
	Zolpidem			C				Unknown
	Hydroxyzine			C				Unknown
	Aripiprazole			C				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	13734884	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017005308			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased	Escitalopram Oxalate			S	Unknown	Unk (Anidepressant)		Macleods
	Olanzapine			S	Unknown	10 Mg, Qd (Low Dose Neuroleptics)		Macleods
	Olanzapine			S	Unknown	15 Mg, Qd		Macleods
	Olanzapine			S	Unknown	5 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd (Low Dose Neuroleptics)		Macleods

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fluvoxamine	S	Unknown	Unk(Antidepressant)	Not Reported
Mirtazapine	S	Unknown	60 Mg, Qd (Antidepressant)	Not Reported
Risperidone	S	Unknown	3 Mg, Qd (Low Dose Neuroleptic)	Not Reported
Carbamazepine	C	Unknown	Unk	Not Reported
Carbamazepine	C	Unknown	1200 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	13736624	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1710885US		18 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use	Vraylar			S	Oral	1.5 Mg, Unk		Allergan	
	Vraylar			S	Oral	6 Mg, Qd		Allergan	
	Lexapro			S	Oral	Unk, Qd		Allergan	
	Lamictal			C	Oral	Unk		Not Reported	
	Abilify			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	10270143	EXPEDITED (15-DAY)		DS	FI-TEVA-490332ISR		19 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depressed Mood; Disturbance In Sexual Arousal; Genital Paraesthesia; Libido Decreased; Male Orgasmic Disorder	Sertraline Ratiopharm 50 Mg			S	Oral	50 Milligram Daily;		Not Reported	
	Cipralext 10 Mg			S	Oral	10 Milligram Daily;		Not Reported	
	Cipralext 10 Mg			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	12492839	NON-EXPEDITED			US-PFIZER INC-2016285898			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity	Amoxicillin	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Celebrex	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer
	Fentanyl Citrate	S	Unk	Unknown
	Norvasc	S	Unk	Pfizer
	Buspar	S	Unk	Not Reported
	Catapres	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Dilaudid	S	Unk	Not Reported
	Kenalog	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Lisinopril	S	Unk	Not Reported
	Macrobid	S	Unk	Not Reported
	Macrochantin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13707660	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017280847		52 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Transaminases Increased	Duavive			S		Unk		Pfizer
	Lorazepam			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13708954	EXPEDITED (15-DAY)		HO, OT	DE-HETERO LABS LTD-2022817		62 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anxiety; Burning Sensation; Diarrhoea; Fatigue; Fatigue; Feeling Abnormal; Hot Flush; Listless; Nausea; Panic Attack; Skin Burning Sensation; Suicidal Ideation; Vision Blurred	Escitalopram	S	Oral					Hetero

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13743076	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1728790US		30 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epistaxis; Platelet Count Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13743404	EXPEDITED (15-DAY)		OT	PHHY2017FR100453		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia	Stalevo			S	Oral	1 Df, Tid		Novartis	
	Seroplex			S	Oral	10 Mg, Qd		Not Reported	
	Pradaxa			C	Unknown	Unk		Not Reported	
	Corenitec			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13334121	EXPEDITED (15-DAY)		OT	US-JAZZ-2016-US-024512		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Disturbance In Attention; Sleep Apnoea Syndrome; Sleep-Related Eating Disorder; Weight Increased	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustment		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Seroquel			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro	S	Not Reported
Remeron	S	Not Reported
Cyclobenzaprine	C	Not Reported
Naproxen	C	Not Reported
Vitamin D3	C	Not Reported
Cymbalta	C	Not Reported
Adderall	C	Not Reported
Alprazolam	C	Not Reported
Nexium /01479302/	C	Not Reported
Propranolol	C	Not Reported
Viibryd	C	Not Reported
Nortriptyline Hcl	C	Not Reported
Lortab /00607101/	C	Not Reported
Latuda	C	Not Reported
Lithium Carbonate	C	Not Reported
Effexor Sr	C	Not Reported
Inderal	C	Not Reported
Lisinopril Hctz	C	Not Reported
Trileptal	C	Not Reported
Imipramine Hcl	C	Not Reported
Topamax	C	Not Reported
Lipitor	C	Not Reported
Testosterone Cypionate	C	Not Reported
Klonopin	C	Not Reported
Lamictal	C	Not Reported
Lortab /00607101/	C	Not Reported
Advil /00044201/	C	Not Reported
Amoxicillin	C	Not Reported
Rexulti	C	Not Reported
Vraylar	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13746882	EXPEDITED (15-DAY)		HO, OT	PT-ALLERGAN-1728845US		41 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anterograde Amnesia;	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan
Conversion Disorder;	Olanzapine			C	Unknown			Not Reported
Decreased Appetite;	Mexazolam			C	Unknown			Not Reported
Derealisation; Eating Disorder; Irritability;	Bupropion			C	Unknown			Not Reported

FDA Adverse Event Reporting System

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Somnolence; Urinary Retention	Carbamazepine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13747968	EXPEDITED (15-DAY)		OT	FR-ORION CORPORATION ORION PHARMA-ENTC2017-0307		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia	Stalevo			S	Oral	Strength: 200/50/200 Mg		Not Reported	
	Seroplex			S	Oral			Not Reported	
	Pradaxa			C	Unknown			Not Reported	
	Corenitech			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13752700	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1729211US		35 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Hyperactivity	Escitalopram Oxalate Unk			S	Oral	Overdose: 14 Dosage Forms		Allergan	
	Tavor [Lorazepam]			S	Oral	Overdose: 5 Dosage Forms		Not Reported	
	Gabapentin			C	Unknown			Not Reported	
	Haldol			C	Unknown			Not Reported	
	En			C	Unknown	0.5 Mg, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13752703	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1729191US		52 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Headache; Incorrect Dose Administered; Insomnia;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan	
	Benzatropine			S	Unknown	2 Mg, Unknown		Not Reported	

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Parosmia; Schizophrenia	Clonazepam	S	Unknown	0.5 Mg, Unknown	Not Reported
	Quetiapine	S	Unknown	25 Mg, Unknown	Not Reported
	Risperidone	S	Unknown	2 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	12845652	EXPEDITED (15-DAY)		HO, OT	BR-ABBVIE-16P-020-1752969-00		67 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arrhythmia; Arrhythmia; Blood Potassium Decreased; Depression; Diarrhoea; Fatigue; Gastric Cancer; Gastrointestinal Carcinoma; Generalised Anxiety Disorder; Iron Deficiency; Pain In Extremity; Swelling; Thirst; Weight Decreased	Synthroid			S	Oral			Not Reported
	Esc			S	Unknown	Daily Dose: 20 Mg;At Night		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13681463	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-143434		71 YR	Male	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Hypertriglyceridaemia; Somnolence	Venlafaxine			S	Unknown	75 Mg, Daily		Sun
	Venlafaxine			S				Sun
	Fenofibrate			C	Unknown	200 Mg, Daily		Not Reported
	Fenofibrate			C	Unknown	200 Mg, Daily		Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Famotidine			C				Not Reported
	Sennosides			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levocetirizine	C	Unknown	Not Reported
Mirtazapine	S	Unknown	Sun
Escitalopram	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13753080	EXPEDITED (15-DAY)		DE, LT, OT	JP-GLAXOSMITHKLINE-JP2017JPN106709		55 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Malaise; Somnolence	Lamictal			S	Oral	400 Mg, 1d		Glaxosmithkline
	Effexor			S	Oral	Unk		Not Reported
	Effexor			S	Oral	37.5 Mg, 1d		Not Reported
	Lexapro			S	Oral	20 Mg, 1d		Not Reported
	Abilify			S	Oral	3 Mg, 1d		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2017	13757223	DIRECT		HO, OT			44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Diverticulitis; Influenza; Insomnia; Migraine; Myalgia; Nausea	Lexapro Esclopiam			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Not Reported
	Abilify			S	Oral	Other Strength:Mg;Quantity:30 Tablet(S);		Not Reported
	Migraine Meds			C				Not Reported
	Nausea Meds			C				Not Reported
	Bactrim Ds			C				Not Reported
	Flagyl			C				Not Reported
	Klonopin			C				Not Reported
	Benadryl			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2017	13758591	DIRECT		DS, LT			29 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Disorder; Amnesia; Blood Glucose Decreased; Chronic Fatigue Syndrome; Cognitive Disorder; Decreased Appetite; Fatigue; Hypotension; Influenza Like Illness; Loss Of Libido; Menstruation Irregular; Muscular Weakness; Neurotoxicity; Sexual Dysfunction; Weight Decreased; Withdrawal Syndrome	Scippa (Escitalopram)			S	Oral	Other Strength:Mg;Quantity:0.5 Tablet(S);		Gedeon Richter

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13759410	NON-EXPEDITED			US-ALLERGAN- 1719282US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Macular Hole; Wrong Technique In Product Usage Process	Namenda Xr			S	Oral	28 Mg, Qd		Allergan
	Namzaric			S	Oral	1 Df, Qd		Allergan
	Lexapro			S	Oral			Allergan
	Aleve			C	Oral	220 Mg, Q12h		Not Reported
	Vitamin D2			C	Oral	3000 Units, Unk		Not Reported
	Aspirin			C	Oral	81 Mg, Unk		Not Reported
	Stool Softener			C	Oral	100 Mg, Unk		Not Reported
	Flomax			C	Oral	0.4 Mg, Unk		Not Reported
	Voltaren			C	Transdermal	Unk Unk, Qid		Not Reported
	Oxybutynin Chloride			C	Oral	5 Mg, Bid		Not Reported
	Oxybutynin Chloride			C	Oral	5 Mg, Bid		Not Reported
	Ativan			C	Oral	1 Mg, Tid		Not Reported
	Finasteride			C	Oral	10 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coumadine	C	Oral	5 Mg, Unk	Not Reported
Coumadine	C	Oral	5 Mg, Unk	Not Reported
Murine Ear Wax Removal System	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13760756	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1729643US		22 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13760783	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1729608US		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Qd		Allergan	
Erythematous; Toxic Skin Eruption	Alprazolam			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13760824	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1729626US		56 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar I Disorder; Condition Aggravated; Drug Ineffective; Generalised Anxiety Disorder; Major Depression; Overdose; Psychotic Disorder; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	60 Mg		Allergan	
	Brintellix			S	Unknown			Not Reported	
	Avanza			S	Unknown	15 Mg, Qd		Not Reported	
	Efexor			S	Unknown	75 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13761476	EXPEDITED (15-DAY)		OT	PHHY2017US102759		36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction	Hydroxyzine			S	Unknown	25 Mg, Bid		Novartis
	Hydroxyzine			S				Novartis
	Methadone			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Ivacaftor			S	Unknown	400 Mg, Q12h		Not Reported
	Ivacaftor			S	Unknown	250 Mg, Q12h		Not Reported
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13761479	EXPEDITED (15-DAY)		OT	PHHY2017US102758		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction	Lorazepam			S	Unknown			Novartis
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Ivacaftor			S	Unknown	400 Mg, Q12h		Not Reported
	Ivacaftor			S	Unknown	250 Mg, Q12h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13698617	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1726615US		45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cervical Vertebral Fracture; Hand Fracture; Lower Limb Fracture; Off Label Use; Road Traffic Accident; Surgery	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited Zoloft	S	Oral	10 Mg, Qd	Allergan
		C	Oral	50 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13734298	EXPEDITED (15-DAY)		HO	BE-TEVA-783368ROM		82 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Dyspnoea; Hyperthermia; Psychomotor Hyperactivity; Serotonin Syndrome	Azilect 1 Mg Tabletten Sipralexa			S				Teva
				S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13761810	EXPEDITED (15-DAY)		DS, OT	AU-TAKEDA-2017TUS015030			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bipolar I Disorder; Condition Aggravated; Drug Ineffective; Generalised Anxiety Disorder; Major Depression; Overdose; Psychotic Disorder; Suicidal Ideation	Brintellix			S	Unknown	Unk		Takeda
	Lexapro			S	Intracardiac	20 Mg, Qd		Not Reported
	Lexapro			S	Intracardiac	40 Mg, Qd		Not Reported
	Lexapro			S	Intracardiac	60 Mg, Qd		Not Reported
	Avanza			S	Unknown	15 Mg, Unk		Not Reported
	Efexor			S	Unknown	75 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13762848	EXPEDITED (15-DAY)		DE, HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2017-03769		20 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Overdose	Methylphenidate			S	Unknown	Unk		Novel Labs

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Escitalopram	S	Unknown	Unk	Lupin
Brotizolam	S	Unknown	Unk	Not Reported
Aripiprazole	C	Unknown	1 Df, Unk	Not Reported
Trazodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Risperidone	C	Unknown	0.5 MI, Single	Not Reported
Flunitrazepam	C	Unknown	Unk	Not Reported
Chlorpromazine	C	Unknown	Unk	Not Reported
Paliperidone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13762902	EXPEDITED (15-DAY)		DE	US-BION-006476			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Death	Loperamide Unknown Product			S				Bionpharma
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13764438	EXPEDITED (15-DAY)		HO	CH-ARALEZ PHARMACEUTICALS R&D INC.-ARA-TP-CH- 2017-		79 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Orthostatic Hypotension	Metoprolol Succinate			S	Oral			Aralez
	Cipralext			S	Oral			Pharmaceuticals
	Aprovel			S	Oral			Not Reported
	Aspirin Cardio			C				Not Reported
	Dafalgan			C				Not Reported
	Calcimagon-D3			C				Not Reported
	Tramal			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13765215	EXPEDITED (15-DAY)		OT	HR-TEVA-786288ACC		65 YR	Female	HRV

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Hallucination, Auditory; Myalgia; Pruritus; Tinnitus; Vision Blurred	Serpentil [Escitalopram Oxalate]			S	Oral	15 Milligram Daily;		Ivax	
	Rosix			C	Oral	10 Milligram Daily;		Not Reported	
	Normabel			C	Oral	15 Milligram Daily;		Not Reported	
	Brufen Powders, Effervescent Powders/Granules			C	Oral	600 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13765272	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017306649		29 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Somnolence; Suicide Attempt	Alprazolam			S	Oral	One Blister		Pfizer	
	Fluzepam (Flurazepam Hydrochloride)			S	Oral	Two Blisters		Not Reported	
	Escitalopram			S	Oral	Two Blisters		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13766128	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1042452			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Drug Interaction; Infective Pulmonary Exacerbation Of Cystic Fibrosis	Escitalopram			S	Unknown	30 Mg Daily		Not Reported	
	Escitalopram			S	Unknown	30 Mg Daily		Not Reported	
	Hydroxyzine			S	Unknown			Not Reported	
	Hydroxyzine			S	Unknown			Not Reported	
	Ivacaftor W/Lumacaftor			S	Unknown	250/400 Mg At Every 12 Hours		Mylan	
	Methadone			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13766780	EXPEDITED (15-DAY)		CA, OT	IL-CIPLA LTD.-2017IL12338			Unknown	ISR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Talipes	Lamotrigine			S	Transplacental	Unk		Cipla	
	Folic Acid			S	Transplacental	Unk		Invagen	
	Escitalopram			S	Transplacental	Unk		Invagen	
	Desipramine			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13768193	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC- 2017SUN00256		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Anxiety; Depression; Drug Interaction; Drug Use Disorder; Therapeutic Product Effect Decreased	Escitalopram			S	Unknown	30 Mg, Daily		Taro	
	Escitalopram			S				Taro	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Alprazolam			S				Not Reported	
	Hydroxyzine			S	Unknown	25 Mg, Bid		Not Reported	
	Hydroxyzine			S				Not Reported	
	Lumacaftor-Ivacaftor			S	Unknown	400/250 Mg Every 12 Hours		Not Reported	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Quetiapine			S				Not Reported	
	Methadone			C				Not Reported	
Oxycodone			C				Not Reported		
Marijuana			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13768202	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC- 2017SUN00255		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Interaction; Therapeutic Product Effect Decreased	Escitalopram			S	Unknown			Taro	
	Bupropion			S	Unknown			Not Reported	

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Olanzapine	S	Unknown	Not Reported
Trazodone	S	Unknown	Not Reported
Lorazepam	S	Unknown	Not Reported
Lumacaftor-Ivacaftor	S	Unknown	400/250 Mg, Every 12 Hours Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13768388	DIRECT		OT			30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Dizziness; Eating Disorder; Fear; Unevaluable Event; Withdrawal Syndrome	Lexapro 20mg			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);		Lundbeck
	Protein Powder			C				Not Reported
	Creatine			C				Not Reported
	Aminoacids			C				Not Reported
	Omega3			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13768456	DIRECT	Y	OT			35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Headache	Escitalopram			S	Oral	Other Dose:Mg;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13770025	EXPEDITED (15-DAY)		DE, OT	JP-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-063555		55 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Cardio- Respiratory Arrest; Chest Pain; Somnolence	Abilify			S	Oral	3 Mg, Daily		Bristol Myers Squibb
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported

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Lamictal			S		Oral	400 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13648068	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1724323US		72 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Interaction; Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Amiodarone Hydrochloride			S	Unknown	Unk		Not Reported	
	Mexitil			C	Unknown	Unk		Not Reported	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Bayaspirin			C	Oral	Unk		Not Reported	
	Enalapril			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13720140	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1727943US		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Gait Disturbance; Speech Disorder; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Rivastigmine			C	Transdermal			Not Reported	
	Nicardipine			C	Oral			Not Reported	
	Acide Alendronique			C	Unknown			Not Reported	
	Paracetamol			C	Unknown	Once Every 6 Hours If Pain Or Fever		Not Reported	
	Paracetamol Leponex			C C	Unknown			Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13740100	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2017-36718		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Toxicity To Various Agents	Alprazolam	S	Unknown	Aurobindo
	Citalopram	S	Unknown	Aurobindo
	Escitalopram	S	Unknown	Aurobindo
	Amphetamine	S	Unknown	Not Reported
	Hydrocodone	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13774754	EXPEDITED (15-DAY)		OT	FR-TEVA-787837ROM			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention;	Modiodal			S	Oral	4 Dosage Forms Daily;		Cephalon	
Disturbance In Attention;	Xyrem			S	Oral	8 Gram Daily;		Not Reported	
Sedation; Somnolence;	Escitalopram Mylan Generiques			S	Oral	15 Milligram Daily;		Not Reported	
Somnolence; Vertigo	5 Mg, Comprimé Pelliculé								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13360464	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1710674US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Urso			C		Unk		Not Reported	
	Halcion			C		Unk		Not Reported	
	Travelmin (Diphenhydramine Salicylate/Diprophylline)			C		Unk		Not Reported	
	Bezato			C				Not Reported	
	Furosemide			C		Unk		Not Reported	
	Luvox			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13777002	DIRECT	Y	HO			46 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hot Flush	Lexapro			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777016	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US- 2017LAN000939		61 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Sleep Apnoea Syndrome	Baclofen (20mg)			S	Unknown	20 Mg, Tid		Lannett	
	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Gabapentin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777589	EXPEDITED (15-DAY)		HO, OT	CN-BAUSCH-BL-2017- 022064		61 YR	Female	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Clonazepam			S	Intravenous (not otherwise specified)			Not Reported	
	Clonazepam			S	Unknown	Per Night		Not Reported	
	Clonazepam			S	Unknown	Every Night		Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Paroxetine			S	Unknown			Not Reported	
	Haloperidol			S	Unknown	At Night		Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Zyprexa			S		1.25-3.75 Mg Per Night		Not Reported	
	Nitrazepam			S	Unknown			Not Reported	
	Flupentixol			S	Unknown			Not Reported	
Melitracen			S	Unknown			Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13779285	EXPEDITED (15-DAY)		HO, OT	CN-APOTEX- 2017AP015981			Unknown	CHN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Seroxat			S	Unknown	30 Mg, Unk		Apotex
	Clonazepam Solution For Infusion			S	Intravenous (not otherwise specified)	0.5 Mg, Unk		Not Reported
	Haloperidol Tablet			S	Unknown	At Night		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa Tablet			S	Unknown	1.25-3.75 Mg Per Night		Not Reported
	Nitrazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Clonazepam Tablet			S	Unknown	Per Night		Not Reported
	Clonazepam			S	Unknown	Every Night		Not Reported
	Flupentixol			S	Unknown	Unk		Not Reported
	Melitracen Tablet			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	11552621	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Torticollis	Escitalopram			S	Unknown			Hikma
	Escitalopram			S	Unknown			Hikma
	Escitalopram			S	Unknown			Hikma
	Clonazepam			C	Unknown	At Bedtime		Not Reported
	Clonazepam			C	Unknown	At Bedtime		Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Celecoxib			C	Unknown			Not Reported
	Tamsulosin			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

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24-Jul-2017	13171868	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017GB009661		52 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrima Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome	Citalopram			S	Oral	10 Mg, Unk		Novartis
	Citalopram			S	Oral	10 Mg, Unk		Novartis
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13690502	EXPEDITED (15-DAY)		HO	PHHY2017IT090219		41 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech;	Lorazepam			S	Oral	10 MI, Unk		Novartis
	Escitalopram			S	Oral	6 Df, Unk		Not Reported

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Sopor	Carbolithium	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13780472	NON-EXPEDITED			US-CELGENEUS-USA-20170703930			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Increased Tendency To Bruise	Revlimid			S	Oral	10 Milligram		Celgene	
	Revlimid			S	Oral	5 Milligram		Celgene	
	Revlimid			S	Oral	15 Milligram		Celgene	
	Revlimid			S	Oral	25 Milligram		Celgene	
	Lexapro			S	Unknown			Not Reported	
	Baby Aspirin			S	Unknown			Not Reported	
	Xanax			C	Unknown			Not Reported	
	Vitamin B-12			C	Unknown			Not Reported	
	Dexamethasone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13781605	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2017-03884		61 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Escitalopram Tablets			S	Unknown	10 Mg, Qd		Lupin	
	Paroxetine			S	Unknown	30 Mg, Qd		Lupin	
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, Qd (At Night)		Not Reported	
	Clonazepam			S	Unknown	10 Mg, Qd (At Night)		Not Reported	
	Zyprexa			S	Unknown	1.25-3.75 Mg Per Night		Not Reported	
	Haloperidol			C	Unknown	2 Mg, Qd (Per Night)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13782527	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-064444			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bruxism; Cogwheel Rigidity; Depression; Weight Decreased	Aripiprazole			S	Unknown			Bristol Myers Squibb	
	Buspar			C	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Cymbalta			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Vitamin B12 /00056201/			S	Unknown			Not Reported	
	Pristiq			S	Unknown	200 Mg, Unk		Not Reported	
	Latuda			S	Unknown	40 Mg, Unk		Not Reported	
	Latuda			S	Unknown	60 Mg, Unk		Not Reported	
	Latuda			S	Unknown	80 Mg, Unk		Not Reported	
	Adderall			S	Unknown	1 Df, Bid		Not Reported	
	Adderall			S	Unknown	20 Mg, Bid		Not Reported	
	Rexulti			S	Unknown	0.5 Mg, Qd		Not Reported	
	Rexulti			S	Unknown	1 Mg, Qd		Not Reported	
	Rexulti			S	Unknown	2 Mg, Qd		Not Reported	
	Rexulti			S	Unknown	3 Mg, Qd		Not Reported	
	Rexulti			S	Unknown	2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13784111	EXPEDITED (15-DAY)		HO	US-TEVA-789764USA		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Cystic Fibrosis; Depression; Drug Interaction	Escitalopram			S	Unknown	30 Milligram Daily;		Ivax	
	Escitalopram			S	Unknown	30 Mg Daily		Ivax	

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	Hydroxyzine	S	Unknown		Barr
	Hydroxyzine	S	Unknown		Barr
	Ivacaftor, Lumacaftor	S	Unknown	250/400 Mg At Every 12 Hours	Not Reported
	Methadone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13784285	EXPEDITED (15-DAY)		OT	PHHY2017ES105950		81 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rectal Haemorrhage	Sintrom			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Omeprazole			S	Oral	20 Mg, Qd		Novartis
	Sinemet Plus			C	Oral	1 Df, Tid		Not Reported
	Seguril			C	Oral	40 Mg, Bid		Not Reported
	Aldactone			C	Oral	25 Mg, Qd		Not Reported
	Masdil			C	Oral	60 Mg, Bid		Not Reported
	Singulair			C	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13698603	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1726828US		20 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Overdose: Dose		Allergan
	Trazodone Hydrochloride			S	Oral			Not Reported
	Concerta			S	Oral	Overdose: Dose		Not Reported
	Lendormin			S	Oral			Not Reported
	Risperdal			C		Unk		Not Reported
	Rohypnol			C	Unknown			Not Reported

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Abilify	C	Unknown	Not Reported
Contomin	C	Unknown	Not Reported
Invega	C	Unknown	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13786698	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Label Confusion	Escitalopram Oxalate			S	Oral	Type - Bottle 10 Mg		Not Reported	
	Escitalopram			S	Oral	Type - Bottle 10 Mg		Not Reported	
	Montelukast Sodium								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13790185	NON-EXPEDITED			PHEH2017US021842			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion	Cosentyx			S	Subcutaneous	300 Mg, Unk		Novartis	
	Cosentyx			S	Subcutaneous	300 Mg, Unk		Novartis	
	Lasix			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Meloxicam			S	Unknown	Unk		Not Reported	
	Tribenzor			S	Unknown	Unk		Not Reported	
	Xyzal			S	Unknown	Unk		Not Reported	
	Meclizine			S	Unknown	Unk		Not Reported	
	Biotin			S	Unknown	Unk		Not Reported	
	B6			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13790931	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-065668			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Affective Disorder; Memory Impairment; Sleep Disorder	Abilify	S	Unknown	Bristol Myers Squibb
	Lexapro	S	Unknown	Not Reported

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25-Jul-2017	13791147	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2017M1043041			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Disturbance In Attention; Sedation; Somnolence; Somnolence; Vertigo	Escitalopram Mylan			S	Oral	1 Df, Qd		Mylan	
	Modiodal			S	Oral	2 Df, Bid		Mylan	
	Modiodal			S		1 Df, Bid		Mylan	
	Xyrem			S	Oral	4 G, Bid		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13791492	EXPEDITED (15-DAY)		HO	PHHY2017PL105086		23 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Apathy; Apathy; Asthenia; Bipolar Disorder; Cognitive Disorder; Decreased Activity; Depressed Mood; Drug Resistance; Fear; Increased Appetite; Somnolence; Tearfulness	Aripiprazole			S	Unknown			Not Reported	
	Quetiapine			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Lithium Carbonate			S	Unknown	1000 Mg, Qd		Not Reported	
	Lithium Carbonate			S	Unknown	1500 Mg, Qd		Not Reported	
	Ziprasidone			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Lamotrigine			S	Unknown	50 Mg, Qd		Not Reported	
	Lamotrigine			S	Unknown	100 Mg, Qd		Not Reported	
	Vortioxetine			S	Unknown	20 Mg, Qd		Not Reported	
	Vortioxetine			S	Unknown	10 Mg, Qd		Not Reported	
	Reboxetine			S	Unknown			Not Reported	
	Atenolol			C	Unknown	25 Mg, Unk		Not Reported	
	Atenolol			C				Not Reported	

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25-Jul-2017	13791728	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1730518US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13792654	EXPEDITED (15-DAY)		HO, OT	CN-ELI_LILLY_AND_COMP ANY-CN201707008200		61 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Gastrointestinal Disorder; Meige'S Syndrome	Olanzapine			S	Unknown	Unk Unk, Daily		Eli Lilly And Co	
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Each Evening		Not Reported	
	Clonazepam			S	Unknown	10 Mg, Each Evening		Not Reported	
	Paroxetine			S	Unknown	30 Mg, Daily		Not Reported	
	Haloperidol			S	Unknown	2 Mg, Each Evening		Not Reported	
	Lexapro			S	Unknown	10 Mg, Daily		Not Reported	
	Nitrazepam			S	Unknown	Unk, Unknown		Not Reported	
	Lorazepam			S	Unknown	Unk, Unknown		Not Reported	
	Flupentixol			S	Unknown	Unk, Unknown		Not Reported	
	Melitracen			S	Unknown	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2017	13777829	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1728639US		20 YR	Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

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26-Jul-2017	13795467	EXPEDITED (15-DAY)		OT	US-HETERO LABS LTD-2023789		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cystic Fibrosis; Depression	Escitalopram			S	Unknown			Hetero	
	Bupropion Hydrochloride			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Ivacaftor W/Lumacaftor			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2017	13795959	EXPEDITED (15-DAY)		HO	CZ-ALLERGAN- 1731283US		13 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Intentional Overdose; Intentional Product Misuse; Pupillary Reflex Impaired; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	100 Mg, Unk		Allergan	
	Paralen (Acetaminophen)			S	Unknown	6000 Mg, Qd		Not Reported	
	Stopex			S	Unknown	Unk		Not Reported	
	Tetrahydrocannabinol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2017	13798283	DIRECT	Y	OT			38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Lexapro			S	Oral			Not Reported	
	Zoloft			C				Not Reported	
	Motrin			C				Not Reported	
	Colace			C				Not Reported	
	Ferrous Sulfate			S				Not Reported	
	Xanax			C				Not Reported	

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27-Jul-2017	13181325	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1703919US		52 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Trittico/Trazodon-Hydrochloride			C	Unknown			Not Reported	
	Trittico/Trazodon-Hydrochloride			C	Unknown	100 Mg, Qd		Not Reported	
	Trittico/Trazodon-Hydrochloride			C	Unknown	150 Mg, Qd		Not Reported	
	Pantoprazol/Pantoprazol			C	Unknown			Not Reported	
	Sertralín/Sertralín			C	Unknown			Not Reported	
	Sertralín/Sertralín			C	Unknown			Not Reported	
	Sertralín/Sertralín			C	Unknown			Not Reported	
	Mefenabene/Mefenamic Acid			C	Unknown			Not Reported	
	Mefenabene/Mefenamic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13769181	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-063375		93 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis;	Eliquis			S	Oral	5 Mg, Qd		Bristol Myers Squibb	
Hepatocellular Injury;	Tahor			S	Oral	40 Mg, Qd		Not Reported	
Ischaemic Stroke;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
Lymphadenopathy; Off Label Use; Pelvic Mass									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13791630	EXPEDITED (15-DAY)		HO, OT	CN-ALLERGAN-1730788US		61 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Gastrointestinal Disorder;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	

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Meige'S Syndrome; Product Use In Unapproved Indication	Flupentixol-Form-Unknown	S	Unknown	Unknown	Not Reported
	Clonazepam	S	Intravenous (not otherwise specified)	0.5 Mg, Qd	Not Reported
	Clonazepam	S	Intravenous (not otherwise specified)	0.5 Mg, Qd, At Night	Not Reported
	Clonazepam	S		10 Mg, Qd	Not Reported
	Paroxetine	S	Unknown	30 Mg, Qd	Not Reported
	Haloperidol	S	Unknown		Not Reported
	Zyprexa	S	Unknown		Not Reported
	Nitrazepam	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Melitracen	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13797064	EXPEDITED (15-DAY)		HO	FR-AMGEN- FRASP2017109982		83 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Diarrhoea	Xgeva			S	Subcutaneous	Unk		Amgen
	Xgeva			S				Amgen
	Aranesp			S	Unknown	300 Mug, Q2wk		Amgen
	Firmagon			S	Unknown	80 Mg, Unk		Not Reported
	Zytiga			S	Oral	1000 Mg, Qd		Not Reported
	Seroplex			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13797660	EXPEDITED (15-DAY)		OT	US-ZYDUS-015838		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Interaction; Forced Expiratory Volume Decreased; Infective	Bupropion/Bupropion Hydrochloride			S	Unknown			ZyduS Pharm
	Escitalopram			S	Unknown			ZyduS Pharm

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmonary Exacerbation Of Cystic Fibrosis	Olanzapine	S	Unknown		Not Reported
	Trazodone	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Lumacaftor/Ivacaftor	S	Unknown	400/250 Mg Every 12 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13797676	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015839		36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anhedonia; Anxiety; Depressed Mood; Depression; Drug Interaction; Feeling Abnormal; Forced Expiratory Volume Decreased; Infective Pulmonary Exacerbation Of Cystic Fibrosis	Escitalopram			S	Unknown			Zydus Pharm
	Oxycodone			S	Unknown			Nesher
	Hydroxyzine			S	Unknown			Not Reported
	Lumacaftor/Ivacaftor			S	Unknown	400/250 Mg Every 12 Hours		Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Methadone			C	Unknown			Not Reported
	Quetiapine/Quetiapine Fumarate			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Escitalopram			S	Unknown			Zydus Pharm
	Hydroxyzine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13801561	EXPEDITED (15-DAY)		HO	FR-FERRINGPH- 2017FE03532			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Diarrhoea	Firmagon			S	Subcutaneous	1 Df, Long Term Treatment With Unknown Frequency		Ferring
	Zytiga			S	Oral	1000 Mg, Daily		Not Reported
	Xgeva			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Seroplex	S	Oral	Unk				Not Reported	
	Aranesp	C	Unknown	300 Mg, Every 2nd Week				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13801903	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1731567US		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Flagyl			S	Oral	1500 Mg, Qd		Not Reported	
	Flagyl			S	Oral	1500 Mg, Qd		Not Reported	
	Doxycycline			S	Oral	300 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	11089516	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-96658		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catatonia; Drug Withdrawal Syndrome	Clozapine			S	Unknown	Unk		Sun	
	Clozapine			S				Sun	
	Quetiapine			S	Unknown	Unk		Sun	
	Quetiapine			S				Sun	
	Escilatopram			S	Unknown	Unk		Not Reported	
	Escilatopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	12992755	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2016003618			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Acute Kidney Injury; Bezoar; Cardiogenic	Escitalopram 10mg Tablet			S	Oral	28 Df, Unk (Seroplex 10mg)		Macleods	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Shock; Coma; Gastrointestinal Ischaemia; Haemodynamic Instability; Hyperlactacidaemia; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Sevikar	S	Oral	129 Tablets (1.29 G Of Amlodipine And 5.16 G Of Olmesartan)	Not Reported
	Atarax	S	Oral	28 Df, (700 Mg Of Hydroxyzine)	Not Reported
	Citalopram	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown	Unk	Not Reported
	Lysanxia 10 Mg	S	Oral	42 Df, (420 Mg Of Prazepam)	Not Reported
	Nordazepam	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13471326	EXPEDITED (15-DAY)		OT	PHHY2017CA053223		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Inflammation; Rash Macular; Skin Lesion	Atorvastatin Sandoz			S	Oral	20 Mg, Qd		Novartis
	Escitalopram Sandoz			S	Oral	10 Mg, Qd		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	Unk Unk, Qd		Not Reported
	Singulair			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13741078	EXPEDITED (15-DAY)		HO, OT	CN-ACCORD-053183		61 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Intolerance; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Meige'S Syndrome; Social Problem	Clonazepam			S	Intravenous (not otherwise specified)	Later 10 Mg/Day, Every Night Given For Anxiety		Accord
	Paroxetine			S				Not Reported
	Haloperidol			S		Haloperidol Tablets 2mg At Night		Not Reported
	Lexapro			S				Not Reported
	Zyprexa			S		1.25-3.75 Mg Per Night		Not Reported
	Nitrazepam			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lorazepam	S	Not Reported
Flupentixol/Flupentixol	S	Not Reported
Decanoate/Flupentixol		
Dihydrochloride		
Melitracen/Melitracen	S	Not Reported
Hydrochloride		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13804165	NON-EXPEDITED			US-ABBVIE-17P-163-1923103-00		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Taste Disorder	Synthroid			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Calcium			C				Not Reported
	Probiotic			C				Not Reported
	Cranberry Extract			C				Not Reported
	Preservision			C				Not Reported
	Fish Oil			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13805919	EXPEDITED (15-DAY)		OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-144767		69 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Gemcitabine			S	Unknown	Unk		Sun
Back Pain; Constipation;	Paracetamol			S	Unknown	Unk		Ohm Lab
Disease Progression;	Ibuprofen			S	Unknown	In Maximum Dose		Ranbaxy
Pain; Somnolence;	Nimesulide			S	Unknown	In Maximum Dose		Not Reported
Therapeutic Product Effect	Aceclofenac			S	Unknown	In Maximum Dose		Not Reported
Incomplete	Diclofenac			S	Unknown	In Maximum Dose		Sun
	Tramal			S	Unknown	400 Mg, Daily		Not Reported
	Fentanyl			S	Unknown	Increase To 100 Ug/H		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregabalin S Unknown In A Maximum Dose Of 300mg Per Day Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13806079	NON-EXPEDITED			US-ASTRAZENECA-2017SE75619			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Post Procedural Haematoma	Brilinta			S	Oral			Astrazeneca
	Lexapro			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13807876	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1731407US		35 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Hypothermia; Intentional Overdose; Respiratory Rate Decreased	Escitalopram Oxalate - Bp			S	Oral	28 Df, Single		Allergan
	Selincro			S	Oral	504 Mg, Single		Not Reported
	Baclofen			S	Oral	600 Mg, Single		Not Reported
	Alprazolam			S	Oral	60 Df, Single		Not Reported
	Paracetamol			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13807896	EXPEDITED (15-DAY)		DS, OT	FR-ALLERGAN-1731568US		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Head Injury; Mydriasis; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported
	Janumet			C	Unknown	50/1000		Not Reported
	Repaglinide			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Irbesartan Hct			C	Unknown	150/12.5		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tercian	C	Unknown	Not Reported
Seresta	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13814412	DIRECT	Y	OT			30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Product Physical Issue; Product Substitution Issue	Lexapro			S	Oral			Actavis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2017	13164697	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-MYLANLABS-2017M1004244			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrima Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision	Escitalopram Citalopram			S S	Oral Oral	10 Mg, Unk 10 Mg, Unk		Not Reported Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blurred; Visual
Impairment; Vitreous
Floaters; Withdrawal
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13149788	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ALLERGAN-1702719US		52 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams;	Citalopram Hydrobromide - Bp			S	Oral			Allergan	
Anaemia; Anger; Anxiety;	Escitalopram Oxalate - Bp			S	Oral			Allergan	
Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrima l Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13738148	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1728642US		77 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Interstitial Lung Disease	Escitalopram Oxalate - Bp	S	Oral	Unk	Allergan
	Quetiapine	S	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13759489	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017304017		93 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis;	Tahor			S	Oral	40 Mg, 1x/Day		Pfizer
Hepatocellular Injury;	Eliquis			S	Oral	5 Mg, 1x/Day		Not Reported
Ischaemic Stroke;	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
Lymphadenopathy; Off Label Use; Pelvic Mass								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13812963	EXPEDITED (15-DAY)		HO	US-HETERO LABS LTD-2023935		36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Condition	Escitalopram			S	Unknown			Hetero
Aggravated; Condition	Hydroxyzine			S	Unknown			Not Reported
Aggravated; Depression; Lung Disorder; Substance Abuse	Ivacaftor W/Lumacaftor			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13813116	EXPEDITED (15-DAY)		OT	HR-ROCHE-1970930		48 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose;	Rivotril			S	Oral			Not Reported
Somnolence; Suicide Attempt; Vomiting	Trittico			S	Oral			Not Reported
	Prazine (Promazine Hydrochloride)			S	Oral			Not Reported
	Flurazepam Hydrochloride			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Escitalopram			S		Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13814911	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-MEDA-2017070058		63 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hepatic Failure; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Zolpidem			S				Meda	
	Sevikar 10 Mg			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported	
	Atarax 25 Mg			S	Oral			Not Reported	
	Lysanxia 10 Mg			S	Oral			Not Reported	
	Seroplex 10 Mg			S	Oral			Not Reported	
	Citalopram			S				Not Reported	
	Nordazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13817481	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1731226US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder	Viibryd			S	Unknown	Unk, Unknown		Allergan	
	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13818562	EXPEDITED (15-DAY)		DE, OT	US-ALLERGAN-1731671US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Homicide	Lexapro			S		Unk		Allergan	
	Xanax			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13819903	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-GLENMARK PHARMACEUTICALS- 2017GMK028308		63 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hepatic Failure; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Citalopram Hydrobromide			S	Unknown	Unk		Glenmark	
	Sevikar			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported	
	Atarax /00058401/			S	Oral	28 Tabets Of 25 Mg In Total		Not Reported	
	Lysanxia			S	Oral	42 Tablets Of 10mg In Total		Not Reported	
	Seroplex			S	Oral	28 Tablets 10 Mg		Not Reported	
	Zolpidem			S	Unknown	Unk		Not Reported	
	Nordazepam			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13693008	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-143443		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral	10 MI Total		Sun	
	Escitalopram			S	Oral	6 Df Total		Not Reported	
	Carbolithium 150 Mg			C	Unknown			Not Reported	
	Quetiapine Fumarate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13819978	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017005418			Unknown	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Somnolence	Escitalopram			S	Oral	300 Mg, Unk		Macleods	
	Melatonine			S	Oral	60 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13821173	EXPEDITED (15-DAY)		HO	LT-ORION CORPORATION ORION PHARMA-ENT2016-0253			Male	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Gait Disturbance; Nausea; Product Dispensing Error; Wrong Product Administered	Escitalopram Orion			S	Oral	Not Used		Not Reported	
	Entacapone (Trade Name Unknown)			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13822667	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2017329424		54 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Suicide Attempt	Ziprasidone Hcl			S	Oral	40 Mg		Pfizer	
	Mirzaten			S	Oral	30 Mg		Not Reported	
	Serpentil /01588502/			S	Oral	10 Mg		Not Reported	
	Loquen			S	Oral	200 Mg		Not Reported	
	Diazepam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13822729	EXPEDITED (15-DAY)		HO	PHHY2017PT112464		79 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antipsychotic Drug Level Above Therapeutic; Coma;	Clozapine			S	Unknown	Unk		Not Reported	

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Hallucination, Visual; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Mutism; Neuroleptic Malignant Syndrome; Pyrexia; Renal Impairment; Rhabdomyolysis; Urinary Tract Infection	Carbidopa, Levodopa Escitalopram Memantine Pregabalin Amantadine Sandoz Lithium Zotepine	S S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk Unk Unk	Not Reported Not Reported Not Reported Not Reported Novartis Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13020376	NON-EXPEDITED		OT	FR-EISAI MEDICAL RESEARCH-EC-2016- 023171			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Aricept			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Seroplex			S	Oral	Dose Reduced (Unspecified)		Not Reported	
	Neurontin			S	Oral	1800 Mg		Not Reported	
	Neurontin			S	Oral	Dose Reduced (Unspecified)		Not Reported	
	Inegy			C		Unknown		Not Reported	
	Bisoprolol			C		Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13170106	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-CIPLA LTD.- 2017GB01382			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal;	Citalopram			S	Oral	10 Mg		Invagen	
	Escitalopram			S	Oral	10 Mg		Invagen	

Dizziness; Dyskinesia;
Fatigue; Food Intolerance;
Functional Gastrointestinal
Disorder; Hypervigilance;
Lacrimonal Disorder; Mood
Swings; Muscle Disorder;
Muscle Tightness;
Musculoskeletal Stiffness;
Nausea; Panic Reaction;
Paraesthesia; Restless
Legs Syndrome; Saliva
Altered; Sinus Node
Dysfunction; Sleep
Disorder; Syncope;
Tearfulness; Vision
Blurred; Visual
Impairment; Vitreous
Floaters; Withdrawal
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13183374	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-132335		52 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Anaemia; Anger; Anxiety; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimonal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction;	Citalopram Escitalopram			S S	Oral Oral	10 Mg 10 Mg		Sun Not Reported

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Paraesthesia; Restless
Legs Syndrome; Saliva
Altered; Sinus Node
Dysfunction; Sleep
Disorder; Syncope;
Tearfulness; Vision
Blurred; Visual
Impairment; Vitreous
Floaters; Withdrawal
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13824725	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-TEVA-790033ACC		52 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Anaemia; Anger; Anxiety; Atrial Tachycardia; Body Temperature Abnormal; Bradycardia; Bruxism; Coordination Abnormal; Dizziness; Dyskinesia; Fatigue; Food Intolerance; Functional Gastrointestinal Disorder; Hypervigilance; Lacrimonal Disorder; Mood Swings; Muscle Disorder; Muscle Tightness; Musculoskeletal Stiffness; Nausea; Panic Reaction; Paraesthesia; Restless Legs Syndrome; Saliva Altered; Sinus Node Dysfunction; Sleep Disorder; Syncope; Tearfulness; Vision Blurred; Visual Impairment; Vitreous Floaters; Withdrawal Syndrome	Escitalopram Citalopram			S S	Oral Oral			Ivax Actavis

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13825580	NON-EXPEDITED			US-GLENMARK PHARMACEUTICALS- 2017GMK027367			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Diarrhoea; Dizziness; Gait Disturbance; Nausea; Product Substitution Issue	Omeprazole			S	Oral	1 Df, Am		Glenmark	
	Lexapro			S	Unknown	Unk		Not Reported	
	Hydrochloroth			S	Unknown	Unk		Not Reported	
	Metoprolol			C	Oral	25 Mg, Qd		Not Reported	
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported	
	Vitamin D3			C	Oral	2000 Iu, Qd		Not Reported	
	Hydrochlorothiazide			C	Oral	12.5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13825896	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-067348			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Prolactin-Producing Pituitary Tumour	Abilify			S	Unknown	Unk		Bristol Myers Squibb	
	Rexulti			S	Unknown	1 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13828786	DIRECT					47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Crying; Drug Ineffective; Mood Altered; Product Colour Issue; Product Substitution Issue	Escitalopram Oxalate Oral Solution 5 Mg5ml Batch No. E162342	Y		S	Oral	Quantity:10 MI;		Camber	
	Zyrtec			C				Not Reported	
	Sumatriptan			C				Not Reported	
	Valium			C				Not Reported	

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Calcium	C	Not Reported
Vitamin C	C	Not Reported
Probiotics	C	Not Reported
Metamucil	C	Not Reported
Miralax	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13828974	DIRECT		DS			26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne Cystic; Drug Ineffective; Pain; Product Substitution Issue	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13577406	NON-EXPEDITED			US-PFIZER INC-2017228100		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Calan			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Augmentin			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Benicar			S		Unk		Not Reported
	Ceftin			S		Unk		Not Reported
	Compazine			S		Unk		Not Reported
	Entex La /00922801/			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

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Macrobid	S	Unk	Not Reported
Motrin	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Tamiflu	S	Unk	Not Reported
Tetanus Vaccines & Toxoid	S	Unk	Not Reported
Valium	S	Unk	Not Reported
Xylocaine /00033402/	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13828377	NON-EXPEDITED			US-PFIZER INC-2017333238		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Paxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Vivactil			S		Unk		Not Reported
	Parnate			S		Unk		Not Reported
	Emsam			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13829575	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ELI_LILLY_AND_COMP ANY-CZ201707012131		63 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Intentional Product Misuse; Overdose; Suicide Attempt	Humalog Lispro	S	Unknown	200 Ug, Bid	Eli Lilly And Co
	Cipralext /01588501/	S	Unknown	20 Mg, Daily	Not Reported
	Spiropent	S	Unknown	Unk Unk, Unknown	Not Reported
	Spiropent	S	Unknown	20 Mg, Daily	Not Reported
	Robitussin /00048102/	S	Unknown	100 MI, Single	Not Reported
	Metfirex	S	Unknown	20 Df, Single	Not Reported
	Siofor	S	Unknown	500 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13831329	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1732446US		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual; Malaise; Nervousness; Psychotic Disorder; Tachycardia; Vision Blurred	Lexapro			S	Unknown	5 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13143797	EXPEDITED (15-DAY)		HO, LT	FR-ABBVIE-17P-056-1845878-00		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Bronchitis; Coma; Fear; Intentional Product Misuse; Nightmare; Oral Viral Infection; Sleep Disorder; Suicidal Ideation; Suicide Attempt	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Seresta			S	Unknown			Not Reported	
	Zopiclone			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13727755	EXPEDITED (15-DAY)		OT	PHEH2017US019860		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Faeces Soft; Haematochezia; Hyperhidrosis; Muscle Spasms; Pain; Tremor	Cosentyx	S	Subcutaneous	150 Mg, Qw	Novartis
	Cosentyx	S			Novartis
	Escitalopram Oxalate	S	Unknown	10 Mg, Qd	Not Reported
	Calcium Vitamin D3	C	Unknown	1200 Mg, Unk	Not Reported
	Folic Acid	C	Unknown	Unk Unk, Bid	Not Reported
	Atorvastatin	C	Unknown	40 Mg, Qhs	Not Reported
	Hydrochlorothiazide	C	Unknown	25 Mg, Qhs (Bed Time)	Not Reported
	Methotrexate	C	Unknown	10 Df, Unk (On Monday)	Not Reported
	Oxycodone And Acetaminophen	C	Unknown	Unk Unk, Prn	Not Reported
	Aspirin	C	Unknown	325 Mg, Unk	Not Reported
	Prednisone	C	Unknown	3 Df, Qw	Not Reported
	Eye Drops	C	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Vitamin D2	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Hydroxyzine	C	Unknown		Not Reported
	Xanax	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13780657	NON-EXPEDITED			US-PFIZER INC- 2017318206		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Desvenlafaxine Succinate			S		Unk		Pfizer
	Monohydrate							
	Lexapro			S		Unk		Not Reported
	Celexa /00582602/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13836244	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-068507		61 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use In Unapproved Indication; Therapeutic Response Decreased	Abilify			S	Endocervical	5 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Endocervical	15 Mg, Qd		Bristol Myers Squibb
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Haloperidol			C	Oral	1 Mg, Q12h		Not Reported
	Haloperidol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13836396	EXPEDITED (15-DAY)		DE	JP-ELI_LILLY_AND_COMP ANY-JP201708000775		30 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Completed Suicide; Decreased Appetite; Insomnia	Zyprexa			S	Oral	20 Mg, Daily		Eli Lilly And Co
	Zyprexa			S	Oral	15 Mg, Daily		Eli Lilly And Co
	Abilify			S	Oral	24 Mg, Daily		Not Reported
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Reflex /01293201/			S	Oral	15 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2017	13839105	DIRECT		OT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Product Substitution Issue; Pruritus; Vision Blurred	Escitalopram Teva	Y		S	Oral	Quantity:1 Tablet(S);		Teva
	Lexapro			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Apple And Ginger Tea			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2017	13839151	DIRECT		LT, OT				Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Self-Injurious Ideation; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Capsule(S);		Cipla	
	Lisinopril			C				Not Reported	
	Prilosec			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Miralax			C				Not Reported	
	Fish Oil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13018272	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016569456		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Cyanosis; Jaw Disorder; Malaise; Musculoskeletal Disorder; Pallor	Aricept			S	Oral	10 Mg, 1x/Day		Pfizer	
	Neurontin			S	Oral	3 Df, Daily (1800 Mg)		Pfizer	
	Neurontin			S	Oral	(Dose Reduced (Unspecified) (Unknown)		Pfizer	
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported	
	Seroplex			S	Oral	Dose Reduced (Unspecified) (Unknown)		Not Reported	
	Inegy			C		Unk		Not Reported	
	Bisoprolol Hemifumarate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13506827	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163- 1960253-00		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Allopurinol			C				Not Reported	
	Allopurinol			C				Not Reported	
	Imuran			C				Not Reported	
	Tramadol			C				Not Reported	

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	Omeprazole	C	Not Reported
	Calcium	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Risaquad	C	Not Reported
	Combivent	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13778791	NON-EXPEDITED			US-PFIZER INC-2017314617			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depressive Symptom; Disease Recurrence; Drug Intolerance; Gastrointestinal Disorder	Sertraline Hcl			S	Oral	100 Mg, 1x/Day		Pfizer	
	Sertraline Hcl			S				Pfizer	
	Escitalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13838483	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2014-06285		74 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Haemorrhage; Tachycardia	Mirtazapine 30mg			S	Oral	30 Mg, Daily		Aurobindo	
	Mirtazapine 30mg			S	Oral	15 Mg, Daily		Aurobindo	
	Cipralext /01588501/			S	Oral	5 Mg, Daily		Not Reported	
	Cipralext /01588501/			S	Oral	10 Mg, Daily		Not Reported	
	Clexane			S	Subcutaneous	0.6 MI, Unk		Not Reported	
	Clexane			S	Subcutaneous	1.2 MI, Daily		Not Reported	
	Clexane			S	Subcutaneous	0.6 MI, Daily		Not Reported	
	Ebixa			C	Oral	10 Mg, Daily		Not Reported	
	Ebixa			C	Oral	15 Mg, Daily		Not Reported	
	Ebixa			C	Oral	20 Mg, Daily		Not Reported	
	Ebixa			C	Oral	15 Mg, Daily		Not Reported	
	Ebixa			C	Oral	10 Unk, Unk		Not Reported	
	Risperdal			C	Oral	1 Mg, Daily		Not Reported	

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	Risperdal		C	Oral		0.5 Mg, Daily			Not Reported
	Bisoprolol		C	Oral		5 Mg, Daily			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13839254	EXPEDITED (15-DAY)		OT	JP-009507513-1707JPN000521J		33 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Suicide Attempt	Belsomra Tab 20mg			S	Oral	160 Mg, Unk		Merck	
	Tetramide Tablets 10mg			S	Oral	220 Mg, Unk		Not Reported	
	Lexapro			S	Oral	10 Mg, Unk		Not Reported	
	Loxoprofen			S	Oral	180 Mg, Unk		Not Reported	
	Flunitrazepam			S	Oral	4 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13839716	NON-EXPEDITED			US-SUNOVION-2017SUN003249		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Hypomania; Sleep Disorder	Latuda			S	Oral	20 Mg, Unk		Sunovion	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	11054240	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2015-03378		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Missed; Exposure During Pregnancy	Mirtazapine			S	Oral	7.5 Mg, Unk		Aurobindo	
	Cipralext /01588502/			S	Oral	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13463271	EXPEDITED (15-DAY)		DS, OT	IE-ALLERGAN-1715101US		32 YR	Female	IRL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Escitalopram Oxalate - Bp			S	Oral	Between 2.5 Mg And 5 Mg, Every 3/4 Days		Allergan
Affect Liability; Anxiety;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
Back Pain; Constipation;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
Decreased Appetite;	Valium			C	Oral	2.5 Mg - 5 Mg Daily, Prn		Not Reported
Depressed Mood;	Valium			C	Oral	Between 2.5 Mg And 5 Mg Daily Every 3/4 Days		Not Reported
Diarrhoea; Disturbance In	Valium			C				Not Reported
Attention; Dizziness; Drug	Lexapro Film-Coated Tablets			S	Oral			Not Reported
Dependence; Dyspepsia;	Lexapro Film-Coated Tablets			S	Oral			Not Reported
Electrocardiogram Qt	Lexapro Film-Coated Tablets			S	Oral			Not Reported
Prolonged; Fatigue;	Lexapro Film-Coated Tablets			S	Oral			Not Reported
Feeling Abnormal;	Lexapro Film-Coated Tablets			S	Unknown			Not Reported
Flatulence; Flushing;								
Headache; Heart Rate								
Irregular; Hot Flush;								
Hyperhidrosis;								
Inappropriate Schedule Of								
Product Administration;								
Insomnia; Irritability;								
Irritable Bowel Syndrome;								
Malaise; Nausea;								
Nervousness; Pain;								
Palpitations; Panic Attack;								
Photophobia; Sleep								
Paralysis; Somnolence;								
Tension Headache;								
Withdrawal Syndrome								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13743647	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1728858US		82 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression;	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan
Disorientation; Drug	Azilect			S	Unknown	Unknown		Not Reported
Interaction; Dyspnoea;	Fenoterol Hydrobromide			C	Unknown			Not Reported
Hyperthermia; Malaise;	W/Ipratropium Bromide			C	Unknown			Not Reported
Nervousness;	Fluticasone Propionate							
Psychomotor	W/Formoterol Fumarate							
Hyperactivity; Serotonin								

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Syndrome	Methylprednisolone	C	Unknown		Not Reported
	Pramipexole	C	Unknown		Not Reported
	Levodopa Benserazide	C	Unknown		Not Reported
	Bumetanide	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Molsidomine	C	Unknown		Not Reported
	Omeprazol	C	Unknown		Not Reported
	Azitromycine	C	Unknown	3 Times A Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13842445	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1733422US		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Single		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Duloxetine Base			S	Oral	840 Mg, Single		Not Reported	
	Duloxetine Base			S	Oral	60 Mg, Qd		Not Reported	
	Quetiapine			C	Unknown			Not Reported	
	Perindopril/Indapamide			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13842447	EXPEDITED (15-DAY)		HO, LT	CZ-ALLERGAN-1733418US		63 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 20x28 Tablet		Allergan	
	Robitussin			S	Unknown	Overdose: 100 MI = 150 Mg		Not Reported	
	Spiropent			S	Unknown	Overdose:500 X 10 Tablet		Not Reported	
	Siofor			S	Unknown	500mg X 10times		Not Reported	
	Metformin			S	Unknown	Overdose: 500x20		Not Reported	

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Humalog			S		Unknown		Overdose: 2 X 200 Ug		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Aug-2017	13843430	DIRECT	Y					Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Wrong Product Administered	Citalopram Hydrobromide			S				Not Reported		
	Escitalopram Oxalate			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Aug-2017	13847306	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1733483US		< 1 DAY	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Exposure During Pregnancy; Hypotonia Neonatal; Respiratory Distress	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg		Allergan		
	Paroxetine Arrow			S	Transplacental	20 Mg, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Aug-2017	13847754	DIRECT	Y	OT			53 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Withdrawal Syndrome	Escitalopram 10mg			S				Aurobindo		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Aug-2017	13848425	NON-EXPEDITED			US-PURDUE-USA-2017-0139906			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Nausea	Butrans			S	Transdermal	10 Mcg/Hr, Weekly		Purdue		
	Lexapro			S	Oral			Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13848942	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Therapy Non-Responder	Escitalopram 20 Mg Mylan			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13849292	DIRECT		OT				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Lupin	
	Lisinopril			C				Not Reported	
	Low Dose Aspirin			C				Not Reported	
	Ibuprofen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13850234	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1733769US		19 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Sopor	Escitalopram Oxalate Unk			S	Oral	Overdose: 120 Mg		Allergan	
	Lamictal			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13850574	EXPEDITED (15-DAY)		OT	FR-SA-2017SA143166		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Stilnox			S	Oral			Not Reported	
	Valsartan			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13820282	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-38399		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depressed Mood; Expiratory Reserve Volume Decreased	Olanzapine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Trazodone			S				Aurobindo	
	Bupropion			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13821081	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2017-38401		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Interaction; Expiratory Reserve Volume Decreased; Failure To Thrive; Lung Disorder	Escitalopram			S	Unknown	30 Mg, Daily		Aurobindo	
	Hydroxyzine			S	Unknown	25 Mg, Two Times A Day		Aurobindo	
	Hydroxyzine			S				Aurobindo	
	Ivacaftor W/Lumacaftor			S	Unknown	250/400mg At Every 12 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13853628	EXPEDITED (15-DAY)		HO	CH-BAYER-2017-150291		36 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epistaxis; Haematoma; Mouth Injury; Periorbital Haematoma	Aspirin Cardio 100 Mg			S	Oral	100 Mg, Qd		Bayer	
	Cipraxel			S		10 Mg, Qd		Not Reported	
	Plavix			C	Oral	75 Mg, Qd		Not Reported	
	Atorvastatin Calcium			C		40 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13854216	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product	Escitalopram Oxalate			S				Not Reported	
Dispensing Error	Citalopram Hydrobromide			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13857141	NON-EXPEDITED			US-ROCHE-766923		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nausea	Tamiflu			S	Oral			Not Reported	
	Lexapro			S	Oral	Other Indication: Depression		Not Reported	
	Lexapro			S	Oral			Not Reported	
	Zocor			C	Oral			Not Reported	
	Diovan			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13857215	NON-EXPEDITED			US-ROCHE-763066			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Tamiflu			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13752118	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1728792US		69 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Polyuria; Seizure; Thirst	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

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Bufferin	C	Oral	Unk	Not Reported
Lansoprazole	C	Oral	Unk	Not Reported
Lansoprazole	C		15 Mg	Not Reported
Pravastatin Na	C	Oral	Unk	Not Reported
Pravastatin Na	C		5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13859048	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201708- 004611			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Use Disorder; Product Prescribing Error	Paracetamol			S				Not Reported
	Prednisolone			S				Concordia
	Clonidine			S				Concordia
	Alprazolam			S				Not Reported
	Buprenorphine Hydrochloride			S				Not Reported
	Cocaine			S				Not Reported
	Dexamfetamine Sulphate			S				Not Reported
	Escitalopram			S				Not Reported
	Fentanyl			S				Not Reported
	Folic Acid			S				Not Reported
	Lorazepam			S				Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S				Not Reported
	Oxazepam			S				Not Reported
	Oxycodone			S				Not Reported
	Pantoprazole			S				Not Reported
	Pregabalin			S				Not Reported
	Temazepam			S				Not Reported
	Ritalin			S				Not Reported
	Tramadol			S				Not Reported
	Zolpidem			S				Not Reported
	Cannabis Preparation			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13859810	EXPEDITED (15-DAY)		HO	FR-ASTELLAS- 2017US030402		76 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Hepatic Function Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use	Vesicare			S	Oral			Astellas
	Seroplex			S	Oral			Not Reported
	Furosemide			C	Oral	20 Mg, Thrice Daily (Long Term Treatment)		Not Reported
	Metformine			C	Oral			Not Reported
	Bisoprolol			C	Oral			Not Reported
	Simvastatine			C	Oral	20 Mg, Once Daily (Long Term Treatment)		Not Reported
	Aspegic /00002703/			C	Oral			Not Reported
	Permixon			C	Oral	1 Df, Twice Daily (Long Term Treatment)		Not Reported
	Procoralan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Procoralan			C	Unknown	Unk, Unknown Freq.		Not Reported
	Lexomil			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Diffu K			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Temesta /00273201/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Timoferol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13861281	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1734120US			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Feeling Abnormal	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Cymbalta			S	Unknown			Not Reported
	Pristiq			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13795948	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1731418US		38 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Aphasia; Drug Abuse; Dysarthria; Self-Injurious Ideation; Sopor		Escitalopram Oxalate Unk Delorazepam		S	Unk		Allergan		
				S	Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13819264	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2017-37896		38 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	1 Df, Total		Not Reported	
	Escitalopram			S	Oral	1 Df Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13863454	EXPEDITED (15-DAY)		OT	US-APOTEX- 2017AP016384			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carcinoid Syndrome; Condition Aggravated; Drug-Disease Interaction; Insomnia	Escitalopram Oxalate			S	Unknown	20 Mg, Every Day		Apotex	
	Escitalopram Oxalate			S				Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13865685	EXPEDITED (15-DAY)		HO, OT	PHFR2017GB006484		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram			S	Unknown			Novartis	
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13865881	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1734634US		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Bid		Allergan	

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Hormone Secretion; Incorrect Dose Administered	Cisplatin	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
	Navelbine	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Levothyrox	C	Oral	75 Mg, Qd	Not Reported
	Seresta	C	Oral	10 Mg, Bid	Not Reported
	Oxycontin Lp	C	Oral	10 Mg, Bid	Not Reported
	Oxynorm	C	Oral	Unk, Prn	Not Reported
	Emend	C	Unknown	125 Mg, Single	Not Reported
	Emend	C	Unknown	80 Mg, Single	Not Reported
	Emend	C	Unknown	80 Mg, Single	Not Reported
	Primperan	C	Unknown	10 Mg, Qd	Not Reported
	Zophren	C	Unknown		Not Reported
	Acupan	C	Unknown		Not Reported
	Cortancyl	C	Unknown	40 Mg, Qd	Not Reported
	Paracetamol	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Buspirone	C	Unknown		Not Reported
	Hydroxyzine	C	Unknown		Not Reported
	Eupantol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13866853	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1734649US		94 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cordarone			S	Oral	200 Mg, Qd		Not Reported
	Eliquis			S	Oral	2.5 Mg, Qd		Not Reported

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Tahor	S	Oral	10 Mg, Qd	Not Reported
Lasilix	C	Oral		Not Reported
Coversyl	C	Unknown		Not Reported
Inipomp	C	Unknown		Not Reported
Forlax	C	Unknown		Not Reported
Gaviscon	C	Unknown		Not Reported
Doliprane	C	Unknown		Not Reported
Xanax	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13869720	EXPEDITED (15-DAY)		CA, HO	FR-ASTRAZENECA-2017SE81799		< 1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section; Maternal Drugs Affecting Foetus; Spina Bifida	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Inexium			S	Transplacental			Astrazeneca
	Seroplex			S	Transplacental	10 Mg/MI		Not Reported
	Seroplex			S	Transplacental	10 Mg/MI		Not Reported
	Colchicine			S	Transplacental			Not Reported
	Colchicine			S	Transplacental			Not Reported
	Coumadine			S	Transplacental			Not Reported
	Coumadine			S	Transplacental			Not Reported
	Dafalgan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Dalfagan Codeine			S	Transplacental			Not Reported
	Specialfoldine			S	Transplacental	5mg/J		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13869851	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017345909		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Rhabdomyolysis; Serotonin Syndrome	Zyvoxid			S	Oral	600 Mg, 2x/Day		Pfizer	
	Modopar			S	Oral	1 Df, Daily		Not Reported	
	Seroplex			S	Oral	1 Df, Daily		Not Reported	
	Coveram			C		Unk		Not Reported	
	Lasilix /00032601/			C		Unk		Not Reported	
	Dermoval /00337102/			C		Unk		Not Reported	
	Neo Mercazole			C		Unk		Not Reported	
	Doliprane			C		Unk		Not Reported	
	Exelon /01383201/			C		Unk		Not Reported	
	Kardegic			C		Unk		Not Reported	
	Levothyrox			C		Unk		Not Reported	
	Atenolol			C		50 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13870100	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1734651US		94 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypochloraemia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Lasilix			S	Oral	40 Mg, Qd		Not Reported	
	Coversyl			S	Oral	2 Mg, Qd		Not Reported	
	Inipomp			S	Oral	20 Mg, Qd		Not Reported	
	Forlax			S	Oral	4 G, Qd		Not Reported	
	Tahor			C	Unknown			Not Reported	
	Eliquis			C	Unknown			Not Reported	

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Gaviscon	C	Unknown	Not Reported
Doliprane	C	Unknown	Not Reported
Xanax	C	Unknown	Not Reported
Cordarone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871290	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2017005698			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Escitalopram			S	Oral	10 Mg, Unk		Macleods	
	Citalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871362	NON-EXPEDITED			US-FRI-1000087220			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S		Unk		Allergan	
	Celexa			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871371	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1000084086		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Suicide Attempt	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Celexa			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871463	NON-EXPEDITED			US-ALLERGAN- 1679093US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective	Citalopram Hydrobromide - Bp Lexapro		S S					Allergan Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871595	NON-EXPEDITED			US-ALLERGAN-1711380US			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Palpitations	Lexapro Celexa			S S					Allergan Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871653	NON-EXPEDITED			US-ALLERGAN-1722214US			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia	Celexa			S		Unknown			Allergan
	Lexapro			S		Unknown			Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13873164	NON-EXPEDITED		HO	FR-EISAI MEDICAL RESEARCH-EC-2017-030159		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Disorder	Aricept			S		Oral			Not Reported
	Seroplex			S		Oral			Not Reported
	Kardegic			C		Oral			Not Reported
	Movicol			C		Oral			Not Reported
	Uvedose			C		Oral			Not Reported
	Seresta			C		Oral			Not Reported
	Kayexalate			C		Oral			Not Reported
	Zopiclone			C		Oral			Not Reported
	Paracetamol			C		Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13873690	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1734898US		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Disturbance In Attention; Drug Ineffective; Encephalitis; Hallucination; Memory Impairment; Myoclonus; Paranoia; Respiratory Distress; Small Cell Lung Cancer	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13873932	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1734929US		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13875208	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1051028			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome	Amisulpride			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Oxazepam			S		Unk		Not Reported	
	Clozapine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	12100319	NON-EXPEDITED			US-CELGENEUS-USA-2016024167		62 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Pressure Increased; Decreased Appetite; Diarrhoea; Heart Rate Increased; Nausea; Weight Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	40 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Singulair			C	Unknown			Not Reported
	Buspar			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	12111319	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2016105438		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Self-Injury; Suicidal Ideation; Suicide Attempt	Sertraline Hcl			S	Oral	25 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	50 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	75 Mg, 1x/Day		Pfizer
	Sertraline Hcl			S	Oral	100 Mg, 1x/Day		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13858372	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-147337		29 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Erectile Dysfunction; Libido Decreased; Sexual Dysfunction; Therapy Cessation	Paroxetine			S	Unknown	10 Mg Every 24h		Sun
	Escitalopram			S	Unknown	15 Mg, Daily		Not Reported
	Lorazepam			S	Unknown	20 Mg, Daily		Sun
	Lorazepam			S				Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13875871	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-			Unknown	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13876461	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00015497		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram			S				Unknown	
	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13876467	EXPEDITED (15-DAY)		HO, OT	BR-TORRENT-00004111		68 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Headache; Off Label Use; Platelet Count Decreased	Espran			S				Torrent	
	Losartan Potassium			C				Unknown	
	Glifage			C				Unknown	
	Puran T4			C				Unknown	
	Azukon Mr			S				Torrent	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13876774	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2017FR13909			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Escitalopram			S	Unknown	Unk, Titrated From 5 To 20 Mg/Day		Invagen	
	Escitalopram			S	Unknown	30 Mg, Unk		Invagen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13878176	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1734887US		36 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epistaxis; Haematoma; Wound	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Aspirin Cardio			S	Oral	100 Mg, Qd		Not Reported	
	Plavix			C	Oral	75 Mg, Qd		Not Reported	
	Atorvastatin Pfizer			C	Oral	40 Mg, Qd		Not Reported	
	Tamesta			C	Unknown	Unk		Not Reported	
	Tamesta			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13879366	EXPEDITED (15-DAY)		OT	CA-TEVA-796262ACC		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram			S	Oral	20 Milligram Daily;		Ivax	
	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13879575	EXPEDITED (15-DAY)		DS, HO	CA--2017-CA-000007		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Optic Nerve Injury; Shock	Amlodipine Besylate Brand			S	Unknown			Vivimed Labs	
	Unspecified (Vivimed)								
	Escitalopram			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	12525811	EXPEDITED (15-DAY)		DE, OT	JP-009507513-1607JPN000690			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Mirtazapine	S	Oral	Unknown	Merck
	Levomepromazine	S	Unknown	Unk	Not Reported
	Duloxetine Hydrochloride	S	Oral	Unk	Not Reported
	Alprazolam	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13820787	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1045646			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	1 Df Total		Not Reported
	Escitalopram			S	Oral	1 Df Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13821971	EXPEDITED (15-DAY)		HO	IT-TEVA-791523ACC		38 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphasia; Drug Abuse; Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13879898	EXPEDITED (15-DAY)		CA, HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-071694		< 1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Spina Bifida	Coumadine			S	Transplacental	6 Mg, Qd		Bristol Myers Squibb
	Dafalgan Codeine			S	Transplacental	2 Tab, Unk		Bristol Myers Squibb
	Dafalgan Codeine			S	Transplacental	2 Tab, Unk		Bristol Myers Squibb
	Dafalgan			S	Transplacental	3 G, Qd		Bristol Myers Squibb
	Dafalgan			S	Transplacental	3 G, Qd		Bristol Myers Squibb

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	Colchicine Opocalcium	S	Transplacental	1 Mg, Qd	Not Reported
	Lovenox	S	Transplacental	40000 Iu, Qd	Not Reported
	Lovenox	S	Transplacental	60000 Iu, Qd	Not Reported
	Inexium /01479302/	S	Transplacental	40 Mg, Qd	Not Reported
	Inexium /01479302/	S	Transplacental	20 Mg, Qd	Not Reported
	Speciafoldine	S	Transplacental	5 Mg, Qd	Not Reported
	Seroplex	S	Transplacental	10 Mg, Qd	Not Reported
	Cortancyl	S	Transplacental	10 Mg, Qd	Not Reported
	Cortancyl	S	Transplacental	7.5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13880278	EXPEDITED (15-DAY)	HO		US-ABBVIE-17K-163-2052012-00		29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dermatitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Allergic; Drug Hypersensitivity;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Dyspnoea; Perirectal Abscess; Supraventricular Tachycardia	Lexapro			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Zyrtec			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13880705	EXPEDITED (15-DAY)	OT		FR-PFIZER INC-2017347072		94 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypochloraemia; Hyponatraemia	Inipomp			S	Oral	20 Mg, Qd		Pfizer
	Seroplex			S	Oral	10 Mg, Daily		Not Reported
	Lasilix			S	Oral	40 Mg, Qd		Not Reported
	Coversyl			S	Oral	2 Mg, Qd		Not Reported
	Forlax			S	Oral	4 G, Qd		Not Reported
	Cordarone			C		Unk		Not Reported

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	Eliquis	C	Unk	Not Reported
	Tahor	C	Unk	Not Reported
	Doliprane	C	Unk	Not Reported
	Xanax	C	Unk	Not Reported
	Gaviscon	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881533	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1735288US		1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Spina Bifida	Escitalopram Oxalate - Bp			S	Transplacental			Allergan
	Colchicine			S	Transplacental	1 Mg, Qd		Not Reported
	Coumadin			S	Transplacental			Not Reported
	Dafalgan Codeine			S	Transplacental	6 Df, Unk		Not Reported
	Dafalgan Codeine			S	Transplacental	2 Df, Bid		Not Reported
	Inexium			S	Transplacental	40 Mg, Qd		Not Reported
	Inexium			S	Transplacental	20 Mg, Qd		Not Reported
	Speciafoldine			S	Transplacental	5 Mg, Qd		Not Reported
	Cortancyl			C	Unknown			Not Reported
	Cortancyl			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Dafalgan			C	Unknown	3 Mg, Unk		Not Reported
	Lovenox			C	Unknown			Not Reported
	Lovenox			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881545	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1735296US		40 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy	Colchicine	S	Unknown	1 Mg, Qd	Not Reported
	Coumadin	S	Unknown		Not Reported
	Dafalgan Codeine	S	Unknown		Not Reported
	Dafalgan Codeine	S	Transplacental		Not Reported
	Inexium	S	Unknown		Not Reported
	Inexium	S	Transplacental		Not Reported
	Speciafoldine	S	Unknown	5 Mg, Qd	Not Reported
	Cortancyl	C	Unknown		Not Reported
	Cortancyl	C	Unknown		Not Reported
	Dafalgan	C	Unknown		Not Reported
	Dafalgan	C	Unknown		Not Reported
	Lovenox	C	Unknown		Not Reported
	Lovenox	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881728	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1735572US		21 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Bruxism	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881791	EXPEDITED (15-DAY)		CA, HO, OT	US-APOTEX-2017AP016705			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Cardiac Malposition; Congenital Diaphragmatic Eventration; Deformity Thorax; Foetal Exposure During Pregnancy; Mass; Nipple Disorder; Patent Ductus Arteriosus; Rib	Topiramate			S	Transplacental	Unk		Apotex	
	Escitalopram Oxalate			S	Transplacental	Unk		Apotex	
	Tramadol Hydrochloride			S	Transplacental	Unk		Apotex	
	Oxycodone And Acetaminophen			S	Transplacental	Unk		Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

Deformity

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13882230	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1735574US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Ineffective; Feeling Abnormal; Headache; Somnolence; Suicidal Ideation; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	12523094	EXPEDITED (15-DAY)		DE, OT	JP-009507513-1606JPN012698			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Suicidal Behaviour	Mirtazapine			S	Oral	Daily Dose Unknown		Merck
	Levomepromazine Maleate			S	Oral	Daily Dosage Unknown		Not Reported
	Cymbalta			S	Oral	Daily Dosage Unknown		Not Reported
	Alprazolam			S	Oral	Daily Dosage Unknown		Not Reported
	Lexapro			S	Oral	Daily Dosage Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13043020	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2016578929		4 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Congestive Cardiomyopathy; Drug Reaction With Eosinophilia And Systemic Symptoms; Maternal Exposure During Pregnancy; Multiple Organ	Ondansetron			S	Transplacental	Unk		Pfizer
	Sertraline Hcl			S	Transplacental	Unk		Pfizer
	Progesterone			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

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Dysfunction Syndrome;
Transmission Of An
Infectious Agent Via
Product

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13814061	EXPEDITED (15-DAY)		HO	IT-ACCORD-056432		38 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Drug Abuse;	Escitalopram			S	Oral			Accord	
Dysarthria; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	1 Df Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13819993	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017005495			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Drug Abuse; Dysarthria; Somnolence	Escitalopram			S	Oral	Unk		Macleods	
	Delorazepam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13861458	EXPEDITED (15-DAY)		DE	US-ALLERGAN- 1724047US		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Toxicity To Various Agents	Lexapro			S		20 Mg, Qam		Allergan	
	Lexapro			S				Allergan	
	Xanax			S	Oral	2 Mg, Qam		Not Reported	
	Xanax			S				Not Reported	
	Xanax			S	Oral	0.5 Mg, Bid		Not Reported	
	Xanax			S				Not Reported	
	Hydrocodone			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13884328	EXPEDITED (15-DAY)		HO, OT	CA-CIPLA LTD.- 2017CA13832			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Blindness; Haemolysis; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Polyuria; Pulmonary Oedema; Renal Tubular Necrosis; Shock; Toxicity To Various Agents	Amlodipine			S	Unknown	150 Mg		Invagen
	Escitalopram			S	Unknown	60 Mg		Invagen
	Risperidone			S	Unknown	6 Mg		Cipla
	Furosemide			S	Intravenous bolus	200 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13885358	EXPEDITED (15-DAY)		LT	AT-TEVA-797220ISR		59 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myoclonus; Seizure	Fentoron 25µg/H - Transdermales Matrixpflaster			S		Every 3 Days		Actavis
	Trittico Retard 150mg - Tabletten			S		150 Milligram Daily; 0-0-1 (One In The Evening)		Not Reported
	Dibondrin- Ampullen			S	Intravenous (not otherwise specified)	2 Dosage Forms Daily; 1-0-1 (One In The Morning/Evening)		Not Reported
	Suprarenin			S		2 Dosage Forms Daily; 1-0-0(One In The Morning)Inhalative 2mg		Not Reported
	Cefepim-Mip 2g Pulver Zur Herstellung Einer Injektions-/Infusionslösun			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; 1-1-1 Iv (One In The Morning/Evening And At Noon)		Not Reported
	Aprednislon 5mg - Tabletten			S		5 Milligram Daily; 1-0-0		Not Reported

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Vendal 10mg - Ampullen	S		(One In The Morning)	Not Reported
Cipralex 10mg - Filmtabletten	S		0.5 Till 2 Amp As Needed In Case Of Pain Peaks	Not Reported
Lovenox 4.000 Ie (40mg)/0.4 MI Injektionslösung In Einer Fertigspritze	C		10 Milligram Daily; 1-0-0 (One In The Morning)	Not Reported
Pulmicort 0,5 Mg - Suspension Zur Inhalation	C		40 Milligram Daily; 0-0-1 (One In The Evening)	Not Reported
Spirono Genericon 50mg Tabletten	C		1 Milligram Daily; 1-0-1 (One In The Morning/Evening)	Not Reported
Lyrica 75mg Hartkapseln	C		25 Milligram Daily; 1/2-0-0 (Half In The Morning)	Not Reported
Berodualin - Inhalationslösung	C		150 Milligram Daily; 1-0-1 (One In The Morning/Evening)	Not Reported
Bricanyl 0.5mg - Ampullen	C	Intravenous (not otherwise specified)	40x10 Drops	Not Reported
Nexium 40mg - Magensaftresistente Tablette	C		.25 Milligram Daily; 1/2 Vial -0-0 (Half In The Morning)	Not Reported
Lasix 40mg Tabletten	C		80 Milligram Daily; 1 -0-1 (One In The Morning/Evening)	Not Reported
Advantan 0,1% - Creme	C		40 Milligram Daily; 0-1-0 (One At Noon)	Not Reported
Movicol Beutel	C		3xdaily	Not Reported
			1 Dosage Forms Daily; 0- 1-0 (One At Noon)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13886338	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-796749ACC		61 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Respiratory Tract Infection	Citalopram Escitalopram			S S	Oral			Not Reported Ivax

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13887761	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1735575US		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder; Pelvic Fracture	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Aricept			S	Oral	10 Mg, Qd		Not Reported	
	Kardegic			C	Oral	75 Mg, Qd		Not Reported	
	Movicol			C	Oral	Unk		Not Reported	
	Uvedose			C	Oral			Not Reported	
	Seresta			C	Oral	10 Mg, Qd		Not Reported	
	Paracetamol			C	Oral	500 Mg, Bid		Not Reported	
	Kayexalate			C	Oral	1 Spoon Per Day		Not Reported	
	Zopiclone			C	Oral	3.75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13896539	DIRECT		DE			75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Gun Shot Wound; Head Injury	Lexapro			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	12505480	EXPEDITED (15-DAY)		HO, LT, OT	FR-JNJFOC-20160307548		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Coma; Drug Interaction; Drug Level Increased; Myoclonus; Neuroleptic Malignant Syndrome; Status Epilepticus	Risperdal Consta			S	Intramuscular			Not Reported	
	Risperdal Consta			S	Intramuscular			Not Reported	
	Risperdal Consta			S	Intramuscular			Not Reported	
	Risperdal Consta			S	Intramuscular			Not Reported	
	Seroplex			S	Unknown			Not Reported	

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Seroplex	S	Unknown	Not Reported
Seresta	S	Unknown	Not Reported
Clozapine	S	Unknown	Not Reported
Theralene	S	Unknown	20 Drops At Night If Necessary Not Reported
Loxapine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13863457	NON-EXPEDITED			US-PFIZER INC-2017345209		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prinivil			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Salsalate			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Avapro			S		Unk		Not Reported
	Disalcid			S		Unk		Not Reported
	Forteo			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Miacalcin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13887996	EXPEDITED (15-DAY)		OT	GB-ACCORD-057361		21 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abnormal Dreams; Bruxism	Escitalopram		S	Oral				Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13890140	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2017GB14132			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13890977	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-057474		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Blindness; Hypoglycaemia; Hypokalaemia; Intentional Overdose; Optic Atrophy; Pulmonary Oedema; Shock	Amlodipine Escitalopram Risperidone			S S S				Accord Accord Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891021	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-057310		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram Escitalopram			S S	Oral			Accord Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891187	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2017M1050855			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram Escitalopram			S S	Oral	10 Mg, Unk		Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891594	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016691		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Apo-Hydro			S	Unknown	Unk		Apotex	
	Apo-Escitalopram			S	Unknown	Unk		Apotex	
	L-Thyroxine /00068001/			C	Unknown	Unk		Not Reported	
	Telmisartan			C	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891835	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2017-38935		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection	Citalopram			S	Unknown			Aurobindo	
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13892460	EXPEDITED (15-DAY)		OT	GB-TEVA-796935ACC		21 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Bruxism	Escitalopram Oxalate			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13893652	EXPEDITED (15-DAY)		LT	AT-ALLERGAN-1735877US		59 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myoclonus; Seizure	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Trittico Retard			S	Unknown	150 Mg, Qd		Not Reported	

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Fentoron	S	Unknown	1 Fentoron 25 Microgram/Hour Every 3 Days	Not Reported
Dibondrin	S	Intravenous (not otherwise specified)	2 Df, Qd	Not Reported
Suprarenin	S	Unknown	2 Mg, Qd	Not Reported
Cefepim	S	Intravenous (not otherwise specified)	3 Df, Qd	Not Reported
Aprednislon	S	Unknown	5 Mg, Qd	Not Reported
Vendal	S	Unknown	Unk	Not Reported
Lovenox	C	Unknown	40 Mg, Qd	Not Reported
Pulmicort	C	Respiratory (inhalation)	0.5 Mg, Bid	Not Reported
Spirodo	C	Unknown	25 Mg, Qd	Not Reported
Lyrice	C	Unknown	75 Mg, Bid	Not Reported
Berodualin	C	Respiratory (inhalation)	40 X 10 Drops	Not Reported
Bricanyl	C	Intravenous (not otherwise specified)	1/2 Amp - 0 - 0	Not Reported
Nexium	C	Unknown	1-0-1	Not Reported
Lasix	C	Unknown	40 Mg, Qd	Not Reported
Advantan	C	Unknown	3 X Tg1	Not Reported
Movicol	C	Unknown	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13760796	EXPEDITED (15-DAY)		DE, LT, OT	JP-ALLERGAN- 1729779US		55 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Cardio- Respiratory Arrest; Chest Pain; Malaise; Somnolence	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Effexor			S	Oral	37.5 Mg, Unk		Not Reported	
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported	

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	Lamictal		S	Oral	400 Mg, Qd			Not Reported	
	Abilify		S	Oral	3 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13790340	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-065694		16 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Incorrect Dose Administered; Oculogyric Crisis; Suicide Attempt	Abilify			S	Unknown			Bristol Myers Squibb	
	Lexapro			S	Unknown			Not Reported	
	Prozac			S	Unknown			Not Reported	
	Celexa /00582602/			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Lamictal			S	Unknown			Not Reported	
	Klonopin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13895031	NON-EXPEDITED			US-AMGEN- USASL2017124992			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Heart Rate Increased; Rash	Enbrel			S	Unknown	Unk		Amgen	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Lyrica			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Albuterol			C	Unknown	Unk		Not Reported	
	Lipitor			C	Unknown	Unk		Not Reported	
	Symbyax			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13895614	NON-EXPEDITED			US-PFIZER INC-2017363063		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13895781	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-39000		21 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Bruxism	Escitalopram			S	Oral	20 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13896054	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE-HET2017US00088		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Hetero	
	Dextromethorphan Hbr W/Promethazine Hcl			S		Unk		Not Reported	
	Labetalol			C	Unknown	100 Mg, Qd		Not Reported	
	Amlodipine			C		5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13896695	EXPEDITED (15-DAY)		HO, LT, OT	CA-LUPIN PHARMACEUTICALS INC.-2017-04714		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Depressed	Amlodipine			S	Oral	150 Mg, Unk		Lupin	

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Level Of Consciousness;	Escitalopram	S	Oral	60 Mg, Unk	Not Reported
Hypotension; Intentional Overdose; Renal Tubular Necrosis; Retinal Ischaemia; Shock; Tachycardia	Risperidone	S	Oral	6 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13897379	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1746743US			Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Anger;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
Apathy; Asthenia;	Rivotril			S	Unknown	Unk, Unknown		Not Reported
Depressed Mood;	Cisordinol Depot			S	Unknown	100 Mg Every 14 Days		Not Reported
Disturbance In Social Behaviour; Drug Dependence; Drug	Cisordinol			S	Unknown	3 X 10 Mg In The Evening		Not Reported
Ineffective; Dyskinesia;	Cisordinol			S	Unknown	10 Mg, Unk		Not Reported
Dysphagia; Dyspnoea;	Cisordinol			S	Unknown	8 Mg, Unk		Not Reported
Fatigue; Feeling	Cisordinol			S	Unknown	4 Mg, Unk		Not Reported
Abnormal; Intentional Product Use Issue;	Cisordinol			S	Unknown	6 Mg, Unk		Not Reported
Malaise; Mood Altered;	Cisordinol			S	Unknown	4x2 Mg, Qd		Not Reported
Psychotic Disorder; Restless Legs Syndrome; Somnolence; Stress; Suicidal Ideation; Suicide Attempt; Withdrawal Syndrome								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13897380	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1746563US		63 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Unk		Allergan
Bezoar; Cardiogenic Shock; Coma;	Citalopram Hydrobromide - Bp			S	Unknown			Allergan
Gastrointestinal	Zolpidem			S	Unknown			Not Reported

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Ischaemia; Hepatic Failure;	Nordazepam	S	Unknown		Not Reported
Hyperlactacidaemia; Intentional Overdose;	Lysanxia	S	Oral	420 Mg, Unk	Not Reported
Metabolic Acidosis; Multiple Organ Dysfunction Syndrome;	Sevikar	S	Oral	1.29 G, Unk	Not Reported
Overdose; Shock; Skin Necrosis; Toxicity To Various Agents	Sevikar	S	Oral	5.16 Unk, Unk	Not Reported
	Atarax	S	Oral	700 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13898828	EXPEDITED (15-DAY)		HO	CA-ELI_LILLY_AND_COMP ANY-CA201708007582		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aptyalism; Drug Ineffective; Panic Disorder	Zyprexa			S	Oral	2.5 Mg, Daily		Eli Lilly And Co
	Escitalopram			S	Oral	30 Mg, Unknown		Not Reported
	Buspirone			S	Oral	5 Mg, Daily		Not Reported
	Amitriptyline			S	Oral	20 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13900265	EXPEDITED (15-DAY)		OT	CA-IMPAX LABORATORIES, INC- 2017-IPXL-02433		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Infarction; Drug Ineffective; Hypoglycaemia; Hypokalaemia; Optic Nerve Infarction; Pulmonary Oedema	Adrenaclick			S	Other	30 Mcg/Minute		Amedra
	Adrenaclick			S	Other	40 Mcg/Minute, Unk		Amedra
	Norepinephrine			S	Other	30 Mcg/Minute		Not Reported
	Norepinephrine			S	Other	40 Mcg/Minute, Unk		Not Reported
	Norepinephrine			S	Other	25 Mcg/Minute, Unk		Not Reported
	Norepinephrine			S	Other	10 Mcg/Minutes, Unk		Not Reported
	Vasopressin			S	Other	2.4 Units/Hour		Not Reported
	Amlodipine			S		150 Mg, Unk		Not Reported

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Risperidone	S	6 Mg, Unk	Not Reported
Escitalopram	S	60 Mg, Unk	Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified) 2 G, Unk	Not Reported
Glucagon	C	Intravenous (not otherwise specified) 5 Mg, Unk	Not Reported
Dextrose	C	Intravenous (not otherwise specified) 1 Ampule Of Dextrose 50% In Water	Not Reported
Dextrose	C	Intravenous (not otherwise specified) 10% Dextrose Infusion	Not Reported
Activated Charcoal	C	Nasal 50 G, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13899065	EXPEDITED (15-DAY)		OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM- 2017-00553		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Cytotoxic Oedema; Hypoglycaemia; Hypokalaemia; Hypotension; Infarction; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Retinal Ischaemia; Shock; Tachycardia	Amlodipine Besylate			S	Unknown	150 Mg, Unk		Alkem
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	60 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13899696	EXPEDITED (15-DAY)		OT	IN-ASTRAZENECA-2017SE85304		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothyroidism	Quetiapine			S	Oral	50.0mg Unknown		Zeneca	
	Escitalopram			S	Oral	10.0mg Unknown		Not Reported	

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Amlodipine			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13900623	EXPEDITED (15-DAY)		HO	PHHY2017CA123139		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose	Amlodipine			S	Unknown	150 Mg		Novartis	
	Escitalopram			S	Unknown	60 Mg,		Not Reported	
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13902394	EXPEDITED (15-DAY)		DE, OT	FR-CIPLA LTD.- 2017FR14490			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen	
	Indapamide			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	
	Benzoic Acid			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2017	13910615	DIRECT		DS			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Hot; Palpitations; Product Substitution Issue	Escitalopram 20 Mg, Generic			S	Oral	Quantity:1 Tablet(S);		Aurobindo	
	Lexapro							Not Reported	
	Carbidopa-Levodopa			C				Not Reported	
	Lexapro			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Omega 3 Fish Oil			C				Not Reported	
	Coq10			C				Not Reported	
	Curcumin			C				Not Reported	
	Magnesium Citrate			C				Not Reported	
	Low Dose Aspirin			C				Not Reported	

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Probiotic			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13896324	EXPEDITED (15-DAY)		HO, LT, OT	CA-ALLERGAN-1735846US		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria; Blindness; Circulatory Collapse; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Mitral Valve Stenosis; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Renal Tubular Necrosis; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Escitalopram Oxalate Unk			S	Oral	60 Mg, Unk		Allergan	
	Amlodipine			S	Oral	150 Mg, Unk		Not Reported	
	Risperidone			S	Unknown	6 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13909124	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE-HET2017US00105			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carcinoid Syndrome; Condition Aggravated	Escitalopram			S	Unknown	20 Mg, Qd		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13911084	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1052792			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carcinoid Syndrome; Diarrhoea; Insomnia	Escitalopram			S	Unknown	20mg Every Day For 16 Days		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13911189	EXPEDITED (15-DAY)		DE, OT	FR-INDIVIOR LIMITED-INDV-104138-2017		30 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Death; Drug Abuse; Toxicity To Various Agents	Suboxone			S	Unknown	Unk		Reckitt Benckiser	
	Actiskenan			S	Unknown	Unk		Not Reported	
	Valium			S	Unknown	Unk		Not Reported	
	Seresta			S	Unknown	Unk		Not Reported	
	Theralene			S	Unknown	Unk		Not Reported	
	Seropram /01588502/			S	Unknown	Unk		Not Reported	
	Imovane			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13912799	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1000016435		93 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Hyperhidrosis	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qod		Allergan	
	Toprol			C		50 Mg, Qd		Not Reported	
	Norvasc			C		5 Mg, Unk		Not Reported	
	Zocor			C		20 Mg, Unk		Not Reported	
	Hytrin			C		5 Mg, Unk		Not Reported	
	Nexium			C		40 Mg, Unk		Not Reported	
	Nitroglycerin			C	Sublingual	0.4 Df, Prn		Not Reported	
	Caltrate			C		Unk		Not Reported	
	Fish Oil			C		Unk		Not Reported	
	Tobramycin			C	Ophthalmic	Unk		Not Reported	
	Hytrol			C		10 Mg, Qd		Not Reported	

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		Hytrol		C					Not Reported
		Ectrin		C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13916139	EXPEDITED (15-DAY)		HO, OT	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2017NSR000188		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Mania	Tramadol Hydrochloride			S		Unk		Northstar	
	Escitalopram			S		20 Mg, Qd		Not Reported	
	Quetiapine			C		300 Mg, Qd		Not Reported	
	Quetiapine			C		1000 Mg, Qd		Not Reported	
	Quetiapine			C		800 Mg, Qd		Not Reported	
	Oxazepam			C		Unk		Not Reported	
	Oxazepam			C		180 Mg, Qd		Not Reported	
	Alprazolam			C		Unk		Not Reported	
	Zolpidem			C		Unk		Not Reported	
	Baclofen			C		Unk		Not Reported	
	Candesartan			C		Unk		Not Reported	
	Metformin			C		Unk		Not Reported	
	Atorvastatin			C		Unk		Not Reported	
	Alfuzosin			C		Unk		Not Reported	
	Trospium			C		Unk		Not Reported	
	Acetaminophen			C		Unk		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
	Triamcinolone			C	Intramuscular	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13917735	EXPEDITED (15-DAY)		OT	US-TEVA-800887USA		63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Escitalopram			S	Unknown			Ivax	
	Lexapro			S	Unknown			Not Reported	
	Lexapro			S				Not Reported	
	Humira			S	Unknown	40mg/ 0.8ml		Not Reported	
	Fioricet			C				Not Reported	
	Gabapentin			C				Not Reported	
	Entyvio			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13917911	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1747759US		45 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Memory Impairment; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2017	13601158	EXPEDITED (15-DAY)		DE, OT	US-LUPIN (EUROPE) LIMITED-2017-02754		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence	Loperamide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Lupin	
	Meloxicam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2017	13921980	EXPEDITED (15-DAY)		HO	CA-UNICHEM LABORATORIES LIMITED-UCM201708-000219		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria;	Amlodipine			S				Unichem	
	Escitalopram			S				Not Reported	

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Circulatory Collapse; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Pulmonary Oedema; Tachycardia; Visual Impairment	Risperidone Furosemide	S C	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2017	13922661	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS- 2017M1053479		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Blindness; Cardiogenic Shock; Cerebral Infarction; Cytotoxic Oedema; Embolism; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Nerve Injury; Pulmonary Oedema; Tachycardia; Toxicity To Various Agents	Amlodipine			S	Oral	150 Mg		Not Reported
	Escitalopram			S	Oral	60 Mg		Not Reported
	Risperidone			C	Oral	6 Mg		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2017	13861559	EXPEDITED (15-DAY)		DE, HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-071227		94 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bladder Dilatation; Cachexia; Chronic Kidney Disease; Death; Failure To Thrive; Hyponatraemia; Inappropriate Antidiuretic	Eliquis			S	Oral	2.5 Mg, Daily		Bristol Myers Squibb
	Eliquis			S	Oral	2.5 Mg, Daily		Bristol Myers Squibb
	Cordarone			S	Oral	200 Mg, Daily		Not Reported

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Hormone Secretion; Off Label Use; Transaminases Increased	Tahor	S	Oral	10 Mg, Daily	Not Reported
	Seroplex	S	Oral	10 Mg, Daily	Not Reported
	Lasix /00032601/	C	Unknown	40 Mg, Unk	Not Reported
	Coversyl /00790702/	C	Unknown	Unk	Not Reported
	Inipomp	C	Unknown	Unk	Not Reported
	Forlax	C	Unknown	Unk	Not Reported
	Gaviscon /01405501/	C	Unknown	Unk	Not Reported
	Doliprane	C	Unknown	Unk	Not Reported
	Xanax	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2017	13924337	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20170824618		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy; Somnolence	Loperamide Hydrochloride		Y	S	Unknown			Not Reported	
	Loperamide Hydrochloride			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Meloxicam			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13421803	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-131889		4 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Progesterone			S	Transplacental	Unk		Not Reported	
	Sertraline			S	Transplacental			Sun	
	Ondansetron			S	Transplacental			Natco Pharma	
	Escitalopram			S	Transplacental			Not Reported	

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01-Sep-2017	13869365	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2017337244		94 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Dilatation; Cachexia; Chronic Kidney Disease; Death; Failure To Thrive; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Off Label Use; Transaminases Increased	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer	
	Tahor			S	Oral	10 Mg, Daily		Pfizer	
	Eliquis			S	Oral	2.5 Mg, 1x/Day		Not Reported	
	Eliquis			S	Oral	2.5 Mg, Daily		Not Reported	
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported	
	Lasilix			C		40 Mg, Unk		Not Reported	
	Coversyl			C		Unk		Not Reported	
	Inipomp			C		Unk		Not Reported	
	Forlax			C		Unk		Not Reported	
	Gaviscon			C		Unk		Not Reported	
	Doliprane			C		Unk		Not Reported	
	Xanax			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13926719	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015556		30 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S				Unknown	
	Vitamin D Nos			C				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13928728	EXPEDITED (15-DAY)		LT, OT	IN-TORRENT-00001330		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Quetiapine			S				Unknown	
	Escitalopram			S				Unknown	
	Amlodipine			C				Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13928925	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-CIPLA LTD.-2017US15296			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Cardiomyopathy; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Escitalopram			S	Transplacental	Unk		Invagen	
	Sertraline			S	Transplacental	Unk		Invagen	
	Ondansetron			S	Transplacental	Unk		Cipla	
	Progesterone			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13929367	DIRECT	Y	OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal	Escitalopram			S	Oral			Unknown	
	Adderall			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13930152	EXPEDITED (15-DAY)		DE, HO, LT	AT-ASTRAZENECA-2017SE89492		73 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Off Label Use; Pneumonia; Renal Impairment; Weight Decreased	Seroquel			S	Oral	25.0mg Unknown		Not Reported	
	Ciprallex			S	Unknown			Not Reported	
	Ciprallex			S	Unknown	2-0-0		Not Reported	
	Ciprallex			S	Unknown	1-0-0		Not Reported	
	Stalevo			S	Unknown	100 Mg/25 Mg/200 Mg, 1-0-0		Not Reported	
	Stalevo			S	Unknown	100 Mg/25 Mg/200 Mg, 1-1-0		Not Reported	
	Trittico			S	Unknown	0-0-0-0.5		Not Reported	

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Azilect	S	Unknown	1-0-0	Not Reported
Madopar	S	Unknown		Not Reported
Madopar	S	Unknown	50 Mg/12,5 Mg, 1-1-1	Not Reported
Lovenox	C		1 Time Daily	Not Reported
Elomel	C		1 Time Daily	Not Reported
Optinem	C			Not Reported
Lasix	C			Not Reported
Thrombo Ass	C		0-1-0	Not Reported
Spirobene	C		0-0.5-0	Not Reported
Sedacoron	C		0.5-0-0	Not Reported
Ceftriaxone Sodium	C		2 G In 200 ML, Once Daily	Not Reported
Dancor	C		1-0-1	Not Reported
Aquaphoril	C		0.5-0-0	Not Reported
Toraseamide	C		1-0-0	Not Reported
Pantoloc	C		2-0-0	Not Reported
Insulatard	C		610-0-0	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13930661	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1748733US		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Previscan (Fluindione)			S	Oral	1 Df, Qd		Allergan	
	Aldactone			C	Unknown	Unk		Not Reported	
	Lasilix			C	Unknown	Unk		Not Reported	
	Propranolol			C	Unknown	Unk		Not Reported	
	Delursan			C	Unknown	Unk		Not Reported	
	Noroxine			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2017	13930893	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-025668		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Venlafaxine			S	Unknown			Not Reported	
	Venlafaxine			S				Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S				Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Sertraline			S				Not Reported	
	Risperidone			S	Unknown	2 Mg/Day		Not Reported	
	Risperidone			S				Not Reported	
	Paroxetine			S	Unknown			Not Reported	
	Paroxetine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2017	13930997	EXPEDITED (15-DAY)		DS	DE-HETERO CORPORATE-HET2017DE00139		25 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral	20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2017	13931049	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2017005797			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During	Escitalopram			S	Transplacental	20 Mg, Qd, (0.-11. Gestational Week)		Macleods	
	Loratadin			C	Transplacental	10 Mg, Qd (0.-4.4		Not Reported	

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Pregnancy; Sinus Tachycardia; Small For Dates Baby	Saisonale	C	Transplacental	Gestational Week) Unk, (It Was Approximate Gestational Week 5 1/7, 5.1. - 5.1. Gestational Week)	Not Reported
	Folio Forte	C	Transplacental	0.8 Mg, Qd (Since October 2016, (0. - 22.2. Gestational Week))	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13931556	EXPEDITED (15-DAY)		CA, DS, OT	DE-TORRENT- 00007018			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S				Unknown
	Loratadine			C				Unknown
	Impfstoff Grippe (Saisonale)			C				Unknown
	Folio Forte			C				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13931661	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT- 00007020		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Premature Baby; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S				Unknown
	Baldrian			C				Unknown
	Protaphane			C				Unknown
	Folic Acid			C				Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13931932	EXPEDITED (15-DAY)		CA, HO, OT	DE-HETERO CORPORATE- HET2017DE00140		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported	
	Baldrian			C	Transplacental	20 Mg, Qd		Not Reported	
	Protaphane			C	Transplacental	Unk, Qd		Not Reported	
	Folsaeure			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13932447	EXPEDITED (15-DAY)		OT	US-ZYDUS-016272			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carcinoid Syndrome; Condition Aggravated; Diarrhoea; Insomnia	Escitalopram			S	Unknown			Zyduz Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13933077	EXPEDITED (15-DAY)		HO, LT, OT	US-JNJFOC- 20170900762		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Intentional Overdose; Serotonin Syndrome; Stress Cardiomyopathy	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Fentanyl			S	Transdermal			Not Reported	
	Norco			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	

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04-Sep-2017	13933148	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1748751US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan	
	Loratadin			C	Transplacental	3 Mg, Unk		Not Reported	
	Influenza Vaccine			C	Transplacental	Unk Unk, Single		Not Reported	
	Folio Forte			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13933155	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1748764US		31 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Loratadin			C	Unknown	10 Mg, Qd		Not Reported	
	Influenza Vaccine			C	Unknown			Not Reported	
	Folio Forte			C	Unknown	0.8 Mg, Qd		Not Reported	
	Folio Forte			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13934187	EXPEDITED (15-DAY)		OT	IN-HETERO CORPORATE- HET2017IN00146		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Myxoedema	Escitalopram			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13935031	EXPEDITED (15-DAY)		OT	GB-ACCORD-058025		30 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral			Accord	
	Ergocalciferol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13935142	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1054831		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported	
	Baldrian /01561601/			C	Transplacental	500 [Mg/D]/ If Required		Mylan	
	Protaphane			C	Transplacental	22 [I.E./D]		Mylan	
	Folsaeure			C	Transplacental			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13937462	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-802584USA		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria; Blindness; Cardiogenic Shock; Cerebral Infarction; Cytotoxic Oedema; Embolism; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia;	Amlodipine			S	Oral	150 Mg		Teva	
	Escitalopram			S	Oral	60 Mg		Ivax	
	Risperidone			C	Oral	6 Mg		Not Reported	

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Optic Nerve Injury;
Pulmonary Oedema;
Tachycardia; Toxicity To
Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13938096	EXPEDITED (15-DAY)		DS	DE-ALLERGAN-1749675US		25 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13938107	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1749678US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan	
	Baldrian			C	Transplacental			Not Reported	
	Protaphane			C	Transplacental	Unk, Single		Not Reported	
	Folic Acid			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13938122	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1749660US		30 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hyperhidrosis; Rash	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Unk	Allergan
Pruritic; Seborrhoea	Vitamin D2	C	Unknown	Unk	Not Reported

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05-Sep-2017	13938408	EXPEDITED (15-DAY)	CA, OT		DE-MYLANLABS-2017M1053766			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Loratadin			C	Transplacental	10 [Mg/D]		Mylan
	Grippe Impfstoff			C	Transplacental	It Was Approximate Gestational Week 5 1/7		Mylan
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ Since October 2016		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13236318	EXPEDITED (15-DAY)	OT		US-APOTEX-2017AP006772			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Resistance; Hypomania; Suicide Attempt; Therapy Cessation	Paroxetine Hydrochloride			S	Unknown			Apotex
	Aripiprazole Tablets			S				Apotex
	Haloperidol			S	Unknown			Apotex
	Duloxetine Hydrochloride Delayed-Release Capsules			S	Unknown			Apotex
	Bupropion Hydrochloride			S	Unknown			Apotex
	Carbamazepine			S	Unknown			Apotex
	Risperidone			S				Apotex
	Lamotrigine			S	Unknown			Apotex
	Quetiapine Fumarate			S	Unknown			Apotex
	Ziprasidone Hcl			S	Unknown			Apotex
	Citalopram			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex

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Trazodone Hydrochloride	S	Unknown	Apotex
Divalproex Sodium Delayed-Release Tablets Usp	S	Unknown	Apotex
Oxcarbazepine	S	Unknown	Apotex
Topiramate	S	Unknown	Apotex
Clonazepam Tablets Usp	S	Unknown	Apotex
Alprazolam	S	Unknown	Apotex
Lithium	S	Unknown	Not Reported
Clozapine	S		Not Reported
Lorazepam	S	Unknown	Not Reported
Chlorpromazine	S	Unknown	Not Reported
Loxapine	S	Unknown	Not Reported
Nefazodone	S	Unknown	Not Reported
Doxepine	S	Unknown	Not Reported
Venlafaxine	S	Unknown	Not Reported
Trihexyphenidyl	S	Unknown	Not Reported
Benzotropine	S	Unknown	Not Reported
Chloral Hydrate	S	Unknown	Not Reported
Diazepam	S	Unknown	Not Reported
Phenobarbital	S	Unknown	Not Reported
Temazepam	S	Unknown	Not Reported
Triazolam	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13805318	EXPEDITED (15-DAY)		HO, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-146182		61 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Haloperidol			S	Unknown	2 Mg, At Night		Sun
Gastrointestinal Disorder;	Clonazepam			S	Unknown	0.5 Mg, Per Night		Sun
Meige'S Syndrome								

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	Nitrazepam		S	Unknown	Unk		Not Reported		
	Lorazepam		S	Unknown	Unk		Sun		
	Paroxetine		S	Unknown	30 Mg, Daily		Sun		
	Clonazepam		S	Unknown	10 Mg, Every Night		Sun		
	Lexapro		S	Unknown	10 Mg, Daily		Not Reported		
	Flupentixol		S	Unknown	Unk		Not Reported		
	Zyprexa		S	Unknown	1.25 - 3.75 Mg Per Night		Not Reported		
	Clonazepam		S	Intravenous (not otherwise specified)	0.5 Mg, Daily		Not Reported		
	Melitracen		S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13855913	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1733775US		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Lymphocyte Stimulation Test Positive; Myalgia; Pyrexia	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan	
	Saikokeishito			S	Oral	Unk, Unknown		Not Reported	
	Triptan			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13893621	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1735906US		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	3 Gtt, Qd		Allergan	
	Bisoprolol Hemifumarate			C	Unknown			Not Reported	
	Atorvastatine			C	Unknown			Not Reported	
	Ramipril			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Alloprazol			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13938709	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017005800			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pulmonary Artery Stenosis Congenital; Selective Eating Disorder	Escitalopram			S	Transplacental	20 Mg, Qd, (0. - 36.1. Gestational Week)		Macleods	
	Baldrian			C	Transplacental	500 Mg, Qd (If Required)		Not Reported	
	Protaphane			C	Transplacental	22 Iu, Qd (22 [I.E./D]) (2 Trimester, 14. - 36.1. Gestational Week)		Not Reported	
	Folsäure			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939235	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2017005803			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral	20 Mg, Unk		Macleods	
	Vitamin D Nos			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939248	EXPEDITED (15-DAY)		LT, OT	IN-MACLEODS PHARMACEUTICALS US LTD- MAC2017005808			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dry Skin; Dysarthria; Fatigue;	Escitalopram 10 Mg Film Coated Tablet			S	Oral	10 Mg, Unk		Macleods	

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Hypokinesia; Hypothyroidism; Macroglossia; Myxoedema Coma; Oedema Peripheral; Periorbital Oedema; Somnolence	Quetiapine 50mg Tablet	S	Oral	50 Mg, Unk	Macleods
	Amlodipine Besylate Tablet	C	Oral	5 Mg, Bid	Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939361	DIRECT		DS				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Loss Of Weight; Agoraphobia; Brain Injury; Cognitive Disorder; Fear; Housebound; Impaired Driving Ability; Impaired Self-Care; Mania; Mental Impairment; Neuralgia; Pain; Paraesthesia; Physical Disability; Seizure; Suicidal Ideation; Tremor; Withdrawal Syndrome	Xanax			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyroxin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939406	EXPEDITED (15-DAY)		LT, OT	IN-ACCORD-058109		57 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram			S				Accord
	Quetiapine			S				Accord
	Amlodipine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939833	EXPEDITED (15-DAY)		CA	DE-TEVA-800304GER		< 1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram Loratadin Impfstoff Grippe (Saisonale) Folio Forte	S C C C	Transplacental Transplacental Transplacental Transplacental	20 Milligram Daily; 10 Milligram Daily;	Ivax Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13940078	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US026247		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy	Loperamide Hydrochloride			S	Oral	Unknown, Unknown		Perrigo	
	Escitalopram			S	Unknown	Unknown, Unknown		Not Reported	
	Meloxicam			S	Unknown	Unknown, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13940315	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL001308		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Furosemide			S				Validus	
	Escitalopram			S		20 Mg, Unk		Not Reported	
	Bisoprolol			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13940427	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-801409GER		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Congenital Pulmonary Hypertension; Congenital Tricuspid Valve Incompetence; Cryptorchism; Neonatal Respiratory Distress	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax	
	Baldrian			C	Transplacental	500 Mg/D / If Required		Not Reported	
	Protaphane			C	Transplacental	22 Iu (International Unit) Daily;		Not Reported	
	Folsaeure			C	Transplacental			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Pulmonary
Artery Stenosis
Congenital; Selective
Eating Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13940443	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP017713		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown			Apotex	
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13941953	EXPEDITED (15-DAY)		DE	FR-SA-2017SA160203		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown			Not Reported	
	Sotalol Hydrochloride			S	Unknown			Not Reported	
	Indapamide			S	Unknown			Not Reported	
	Benzoic Acid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13716356	EXPEDITED (15-DAY)		DE, OT	JP-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-058832		30 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Apathy; Completed Suicide; Decreased Appetite; Insomnia; Refusal Of Treatment By Patient; Suicidal Ideation	Abilify			S	Oral	24 Mg, Qd		Bristol Myers Squibb	
	Lexapro			S	Oral	10 Mg, Unk		Not Reported	
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	15 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	10 Mg, Qd		Not Reported	

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Reflex /00021218/

S

Oral

15 Mg, Qd

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13902525	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-MACLEODS PHARMACEUTICALS US LTD- MAC2017005760			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Blindness; Cerebral Infarction; Circulatory Collapse; Condition Aggravated; Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Infarction; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Amlodipine Besylate			S	Oral	150 Mg, Single (Total)		Macleods
	Escitalopram Oxalate			S	Oral	60 Mg, Single (Total)		Macleods
	Risperidone			S	Oral	6 Mg, Single (Total)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13943761	EXPEDITED (15-DAY)		OT	GB-TEVA-802244ACC		30 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral			Ivax
	Vitamin D2			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13943908	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR- APL-2017-39648			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram 20 Mg			S	Transplacental	20 Mg, Daily		Aurobindo	
	Loratadin			C	Transplacental	10 Mg, Daily		Not Reported	
	Folio Forte			C	Transplacental	0.8 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13944245	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017005843			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Qd (From 0. - 30 Gestational Week)		Macleods	
	Escitalopram			S	Transplacental	5 Mg, Qd (30 - 40.3. Gestational Week)		Macleods	
	Avitale Folsäure Plus(Nem)			C	Transplacental	0.8 Mg, Qd (0. - 40.3. Gestational Week)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13945722	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2017M1055711		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia	Escitalopram Mylan			S		Unk		Mylan	
	Rilmenidine Mylan			S		1 In The Morning		Mylan	
	Valsartan Mylan			S		80 In The Morning		Mylan	
	Alprazolam Mylan			S		Unk		Mylan	
	Spiriva			S		Once A Day		Mylan	

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Symbicort	S		Morning And Evening	Mylan
Levothyrox	S		50 And 75 Mcg Alternating Doses	Mylan
Levothyrox	S		50 And 75 Mcg Alternating Doses	Mylan
Gaviscon /00237601/	S		Unk	Mylan
Cardensiel	S		Unk (Morning And Evening)	Mylan
Escitalopram	C	Oral	Several Years 10 Mg, Noon	Mylan
Seroplex	C		In The Morning	Mylan
Arimidex	C		1 Df, Noon	Mylan
Tanakan	C		1 In The Morning And Evening	Mylan
Hyperium	C		1 In The Morning	Mylan
Nidrel	C		Unk	Mylan
Nisis	C		2 In The Evening	Mylan
Lexomil	C		One Fourth Morning And Evening	Mylan
Temesta /00273201/	C		Half At Bed-Time	Mylan
Aerus	C		If Necessary	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13946758	EXPEDITED (15-DAY)		OT	FR-SA-2017SA160629		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Galantamine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13947176	EXPEDITED (15-DAY)		HO, OT	IN-ALEMBIC PHARMACUETICALS LIMITED- 2017SCAL000721			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Activity; Depressed Level Of Consciousness; Dry Skin; Dysarthria; Heart Rate Decreased; Hyporeflexia; Hypothyroidism; Macroglossia; Myxoedema Coma; Oedema Peripheral; Periorbital Oedema; Somnolence	Quetiapine Fumarate Quetiapine Fumarate Escitalopram Amlodipine			S S S C		50 Mg, For 1 Month 10 Mg, For 3 Months 5 Mg, Bid		Alembic Alembic Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13760825	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN- 1729635US		33 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Use Disorder; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram Oxalate - Bp Melatonin			S S	Oral Oral	300 Mg 60 Mg		Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13774485	EXPEDITED (15-DAY)		DE, OT	JP-LUPIN PHARMACEUTICALS INC.-2017-03861		20 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiovascular Insufficiency; Completed Suicide; Fall; Overdose; Serotonin Syndrome; Skin Laceration; Toxicity To Various Agents	Methylphenidate Aripiprazole Flunitrazepam			S S S	Oral Oral Oral	Unk (Extended-Release Tablet) Unk Unk		Novel Labs Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Risperidone	S	Oral	Unk	Not Reported
Escitalopram	S	Oral	Unk	Not Reported
Brotizolam	S	Oral	Unk	Not Reported
Paliperidone	S	Oral	Unk	Not Reported
Chlorpromazine	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13775597	EXPEDITED (15-DAY)		HO	IT-TEVA-787627ACC		33 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram Oxalate			S	Oral			Ivax	
	Melatonin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13829992	EXPEDITED (15-DAY)		OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-146894		43 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Therapeutic Product Effect Incomplete	Cipralex			S	Unknown	Unk		Not Reported	
	Zoloft			S	Unknown			Not Reported	
	Argofan			S	Unknown	Increases To 150 Mg/Day		Not Reported	
	Leviron			S	Unknown	15 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13903405	EXPEDITED (15-DAY)		OT	BR-ALLERGAN- 1747425US			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Mydriasis; Photophobia; Pupillary Deformity;	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan	
	Lumigan Rc			C	Unknown			Allergan	

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Pupillary Reflex Impaired	Timoptol			C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13947452	EXPEDITED (15-DAY)		HO, OT	FR-CIPLA LTD.- 2017FR16090			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen	
	Escitalopram			S				Invagen	
	Sertraline			S	Unknown	Unk		Invagen	
	Sertraline			S				Invagen	
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported	
	Venlafaxine			S				Not Reported	
	Risperidone			S	Unknown	2 Mg/Day		Cipla	
	Risperidone			S				Cipla	
	Paroxetine			S	Unknown	40 Mg, Qd		Not Reported	
Paroxetine			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13948194	EXPEDITED (15-DAY)		CA, OT	DE-HETERO- HET2017DE00171		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Qd		Hetero	
	Escitalopram			S	Transplacental	5 Mg, Qd		Hetero	
	Avitale Folsäure Plus(Nem)			C	Transplacental	0.4 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13948237	EXPEDITED (15-DAY)		LT, OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-149376		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypothyroidism;	Escitalopram			S	Unknown	Unk		Not Reported	

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Myxoedema Coma	Quetiapine	S	Unknown	Unk	Sun
	Amlodipine	C	Unknown	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13948567	EXPEDITED (15-DAY)	CA, OT		DE-AUROBINDO-AUR- APL-2017-39693		365 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect;	Escitalopram 20 Mg			S	Transplacental	20 Mg, Once A Day		Aurobindo
Congenital Pulmonary	Baldrian-Dispert			C	Transplacental	500 Mg, As Directed		Not Reported
Hypertension; Congenital	Protaphane			C	Transplacental	221 U International Once A Day		Not Reported
Tricuspid Valve								
Incompetence;	Folsaeure			C	Transplacental			Not Reported
Cryptorchism; Neonatal								
Respiratory Distress								
Syndrome; Pulmonary								
Artery Stenosis								
Congenital; Selective								
Eating Disorder								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13948786	EXPEDITED (15-DAY)	HO		FR-JNJFOC- 20170900285		30 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block	Risperdal			S	Oral			Not Reported
Right; Coma;	Doliprane			S	Oral			Not Reported
Electrocardiogram Qt	Bromazepam			S	Oral			Not Reported
Prolonged; Hypokalaemia;	Seroplex			S	Oral			Not Reported
Intentional Overdose;	Nurofen			S	Oral			Not Reported
Miosis; Sinus Bradycardia	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13950220	EXPEDITED (15-DAY)	HO		FR-ALLERGAN- 1749827US		63 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Bradyphrenia; Depressed Mood; Muscular Weakness; Psychomotor Skills Impaired; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Single		Allergan	
	Paracetamol			S	Oral	8 G, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13950225	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN- 1749841US		91 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Haemorrhage; Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Every 2 Days		Allergan	
	Coveram			S	Oral	5 Mg, Qd		Not Reported	
	Previscan (Fluindione)			S	Oral	0.25 Mg, Qd		Not Reported	
	Lorazepam			C	Unknown	Unk, Unknown		Not Reported	
	Bisoprolol			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13950229	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1749149US		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Tachycardia; Vomiting	Escitalopram Oxalate Unk			S	Oral	Unk, Unknown		Allergan	
	Bromazepam			S	Oral	Unk, Unknown		Not Reported	
	Tetrazepam			S	Oral	Unk, Unknown		Not Reported	
	Zopiclone			S	Oral	Unk, Unknown		Not Reported	
	Lormetazepam			S	Oral	Unk, Unknown		Not Reported	
	Surmotil (Trimipramine)			S	Oral	Unk, Unknown		Not Reported	
	Fluoxetine			S	Oral	Unk, Unknown		Not Reported	
	Mirtazapine			C	Unknown	Unk, Unknown		Not Reported	

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08-Sep-2017	13950281	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1750055US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neoplasm Malignant; Weight Decreased	Lexapro Adderall			S C	Unknown	Unk, Unknown		Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13950294	EXPEDITED (15-DAY)		DS, OT	IT-ALLERGAN-1750618US		33 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Libido	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2017	13954373	DIRECT		DS			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia	Escitalopram			S	Oral	Quantity:1 Tablet(S); Oral		Torrent	
	Escitalopram			C				Not Reported	
	Dapagliflozin			C				Not Reported	
	Ropinirole			C				Not Reported	
	Lisinopril			C				Not Reported	
	Amlodipine Besylate			C				Not Reported	
	Glimepiride			C				Not Reported	
	Rosuvastatin			C				Not Reported	
	Welchol			C				Not Reported	
	Lantus			C				Not Reported	
	Humalog			C				Not Reported	
	Melatonin			C				Not Reported	
	Aspirin			C				Not Reported	
	D3			C				Not Reported	
	Ibuprofen			C				Not Reported	

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11-Sep-2017	11409850	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-101854			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S				Not Reported	
	Sertraline			S	Unknown			Sun	
	Sertraline			S				Sun	
	Venlafaxine			S	Unknown			Sun	
	Venlafaxine			S				Sun	
	Risperidone			S	Unknown	2 Mg/Day		Ranbaxy	
	Risperidone			S				Ranbaxy	
	Paroxetine			S	Unknown			Sun	
	Paroxetine			S				Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13762927	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2017M1042386		33 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Overdose; Pain In Extremity; Photophobia; Sopor	Escitalopram			S	Oral	300 Mg, Total		Not Reported	
	Melatonin			S	Oral	60 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13945220	EXPEDITED (15-DAY)		LT, OT	IN-ALLERGAN- 1749833US		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hypothyroidism; Myxoedema Coma	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd, 3 Months		Allergan	
	Quetiapine			S	Unknown	50 Mg, Qd Unspecified Interval		Not Reported	

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Amlodipine			C		Unknown		10 Mg Daily, 3 Months		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Sep-2017	13952019	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1054832		30 YR	Female	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram Vitamin D /00107901/			S C	Oral				Not Reported Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Sep-2017	13952258	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00007044		1 DAY	Female	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram Avitale Folsaure Plus			S C					Unknown Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Sep-2017	13953126	EXPEDITED (15-DAY)		DS	DE-AUROBINDO-AUR-APL-2017-39938		25 YR	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral	20 Mg, Daily			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Sep-2017	13953377	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-40253			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Carcinoid Syndrome; Condition Aggravated; Diarrhoea; Insomnia	Escitalopram			S	Unknown	20 Mg, Once A Day			Aurobindo	

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11-Sep-2017	13955828	NON-EXPEDITED			US-SUNOVION-2017SUN003860			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Latuda			S	Oral	Unk		Sunovion	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13957852	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1750578US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypertonia Neonatal; Tension; Tremor Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	Unk Unk, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13959065	EXPEDITED (15-DAY)		DS	DE-MYLANLABS-2017M1055240		25 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13959726	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1751121US		102 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Escitalopram Oxalate - Bp			S	Oral			Allergan	
Acute Kidney Injury;	Kardegic			S	Oral			Not Reported	
Anaemia; Gastrointestinal Haemorrhage;	Cortancyl			S	Oral			Not Reported	
Haematemesis;									

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Hypotension; Melaena; Nutritional Condition	Spironolactone	C	Unknown	Not Reported
Abnormal; Pallor; Tachycardia; Vomiting	Altizide	C	Unknown	Not Reported
	Naftidrofuryl	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13959951	EXPEDITED (15-DAY)	CA		DE-ALLERGAN-1751007US		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan	
	Avitale Folsäure Plus			C	Transplacental	0.8 Mg, Unk		Not Reported	
	Avitale Folsäure Plus			C	Transplacental	0.4 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12484667	EXPEDITED (15-DAY)	HO		US-FRI-1000085498		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Blinded Investigational Medicinal Product (Imp) Non-Partner			S	Oral	1 Mg, Qd		Not Reported	
	Lisinopril			C	Oral	40 Mg, Qd		Not Reported	
	Albuterol			C	Respiratory (inhalation)	2 Puffs , Prn		Not Reported	
	Atenolol			C	Oral	25 Mg, Qd		Not Reported	
	Simvastatin			C	Oral	20 Mg, Qd		Not Reported	
	Loratadine			C	Oral	10 Mg, Qd		Not Reported	
	Flonase			C	Nasal	50 Mg, Qd		Not Reported	
	Flomax			C	Oral	.4 Mg, Qd		Not Reported	
	Ranitidine			C	Oral	300 Mg, Qd		Not Reported	

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	Flovent		C	Respiratory (inhalation)		Unk Unk, Bid			Not Reported	
	Omeprazole		C	Oral		40 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12681166	NON-EXPEDITED				US-FRI-1000081833			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro				S		Unk			Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12681465	NON-EXPEDITED				US-FRI-1000082092		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Off Label Use	Lexapro				S	Oral	5 Mg, Qd			Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12688922	NON-EXPEDITED				US-FRI-1000084632			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Weight Increased; Wrong Technique In Product Usage Process	Lexapro				S	Oral	10 Mg, Bid			Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12690812	NON-EXPEDITED				US-FRI-1000078820		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Chills; Decreased Appetite; Dizziness; Fatigue; Hot Flush;	Lexapro				S	Oral	10 Mg, Qd			Allergan
	Lexapro				S					Allergan
	Bystolic				C	Oral	10 Mg, Qd			Not Reported

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Insomnia; Malaise; Off
Label Use; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	12690813	NON-EXPEDITED			US-FRI-1000078079		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Weight Gain;	Lexapro			S	Oral	10 Mg, Qd		Allergan
Anger; Anxiety; Cold-	Lexapro			S	Oral	10 Mg, Qd		Allergan
Stimulus Headache;	Lexapro			S	Oral	10 Mg, Qd		Allergan
Depressed Mood;	Lexapro			S		5 Mg, Qd		Allergan
Depressed Mood;	Lexapro			S		30 Mg, Qd		Allergan
Depression; Drug	Lexapro			S		.5 Mg, Unk		Not Reported
Ineffective; Dyspepsia;	Risperdal			C	Oral	500 Mg, Unk		Not Reported
Emotional Distress;	Valacyclovir			C	Oral	Unk Unk, Qd		Not Reported
Euphoric Mood; Fat	Multivitamin			C	Oral	Unk Unk, Qd		Not Reported
Tissue Increased; Fatigue;	Vit D			C	Oral	Prn		Not Reported
Feeling Abnormal; Feeling	Excedrin Otc			C	Oral			Not Reported
Hot; Feeling Hot; Feeling								
Of Relaxation; Flatulence;								
Hallucination, Auditory;								
Hypersomnia; Insomnia;								
Mental Disorder; Mood								
Swings; Paranoia;								
Peripheral Swelling;								
Peripheral Swelling; Poor								
Quality Sleep; Product								
Physical Issue;								
Screaming; Somnolence;								
Somnolence; Staring;								
Swelling; Weight								
Decreased; Weight								
Increased; Weight								
Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13753017	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2017GSK107683			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Condition Aggravated; Dizziness; Joint Swelling; Peripheral Swelling; Somnolence; Swelling Face	Breo Ellipta Inhalation Powder	S	Respiratory (inhalation)	1 Puff(S), Qd	Glaxosmithkline
	Lyrca	S		150 Mg, Tid	Not Reported
	Aspirin	S		Unk	Glaxosmithkline
	Clopidogrel	S		Unk	Not Reported
	Atorvastatin	S		Unk	Not Reported
	Metoprolol Tartrate	S		Unk	Not Reported
	Metformin Hydrochloride	S		Unk	Not Reported
	Fenofibrate	S		Unk	Not Reported
	Escitalopram	S		10 Mg, Qd	Not Reported
	Xanax	S		0.5 Mg, Tid	Not Reported
	Levothyroxine	S		50 Ug, Qd	Not Reported
	Aleve	S		2 Df, Qd	Not Reported
	Pataday	S	Ophthalmic	Once Every 3 Or So Months, Prn	Not Reported
	Nitroglycerin	S		Unk	Not Reported
	Vicodin	S		Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13855754	EXPEDITED (15-DAY)	HO		SE-PFIZER INC- 2017312706		73 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline	Xanor			S		1 Mg, Daily (At Night)		Pfizer
Phosphatase Increased;	Xanor			S		20 Mg, Unk		Pfizer
Condition Aggravated;	Escitalopram			S		Unk		Not Reported
Depression; Gastric	Levaxin			C		Unk		Not Reported
Disorder; Hyperglycaemia;	B12 /00056201/			C		Unk		Not Reported
Iron Deficiency Anaemia;	Zopiklon			C		Unk		Not Reported
Leukocytosis; Pancreatic	Zolpidem			C		Unk		Not Reported
Disorder; Pancreatic								
Steatosis; Red Blood Cell								
Sedimentation Rate								
Increased; Toxicity To								
Various Agents								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13957596	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-008854		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13958363	NON-EXPEDITED			US-PFIZER INC-2017390917		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Nexium 24hr			S		Unk		Pfizer
	Protonix			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Methylphenidate Hydrochloride			S		Unk		Pfizer
	Ampicillin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Albuterol Sulfate			S		Unk		Not Reported

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Albuterol Sulfate	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Bupropion Hcl	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Fenofibrate	S	Unk	Not Reported
Luvox	S	Unk	Not Reported
Omeprazole	S	Unk	Not Reported
Paxil /00500401/	S	Unk	Not Reported
Percocet /00867901/	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13959448	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007047			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Gestational Diabetes	Risperidone			S				Unknown
	Folio (Nem)			C				Unknown
	Tavor (Lorazepam)			C				Unknown
	Zopiclone			C				Unknown
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960102	EXPEDITED (15-DAY)		OT	DK-ROCHE-1986378			Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Anger; Apathy; Asthenia; Depressed Mood; Depression; Drug Dependence; Drug Ineffective; Dyskinesia;	Rivotril			S	Unknown			Not Reported
	Cipralext			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported
	Cisordinol			S	Unknown			Not Reported

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Dysphagia; Dyspnoea;	Cisordinol	S	Unknown	Not Reported
Fatigue; Feeling	Cisordinol	S	Unknown	Not Reported
Abnormal; Intentional	Cisordinol	S	Unknown	Not Reported
Product Use Issue;	Cisordinol	S	Unknown	Not Reported
Malaise; Maternal	Cisordinol	S	Unknown	Not Reported
Exposure During	Cisordinol Depot	S	Unknown	Not Reported
Pregnancy; Mood Altered;				
Psychotic Disorder;				
Restless Legs Syndrome;				
Social Avoidant				
Behaviour; Somnolence;				
Stress; Suicidal Ideation;				
Suicide Attempt;				
Withdrawal Syndrome				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960194	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-803255GER		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 (Mg/D)/ Dosage Reduction To 5 Mg/D From Week 30		Ivax	
	Avitale Folsaeure Plus(Nem)			C	Transplacental	0.8 (Mg/D)/ Dosage Reduction To 0.4 Mg/D		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960215	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1057381		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S		Unk		Not Reported	
	Escitalopram			S				Not Reported	
	Sertraline			S		Unk		Not Reported	
	Sertraline			S				Not Reported	
	Venlafaxine			S		225 Mg, Qd		Not Reported	
	Venlafaxine			S				Not Reported	
	Risperidone			S		2 Mg, Qd		Not Reported	

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	Risperidone	S							Not Reported
	Paroxetine	S			Unk				Not Reported
	Paroxetine	S			40 Mg, Qd				Not Reported
	Quetiapine	S			100 Mg, Qd				Not Reported
	Quetiapine	S							Not Reported
	Diazepam	S			20 Mg, Qd				Not Reported
	Diazepam	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960350	NON-EXPEDITED			US-ALLERGAN-1711369US		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hot Flush	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Lexapro			S				Allergan	
	Remeron			S	Unknown	Unk		Not Reported	
	Remeron			S				Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960351	NON-EXPEDITED			US-ALLERGAN-1711408US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dosage Administered; Rash	Lexapro			S	Unknown	.5 Df, Unknown		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960352	NON-EXPEDITED			US-ALLERGAN-1712970US		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal;	Lexapro			S	Oral	10 Mg, Qd		Allergan	
Gingival Bleeding;	Lexapro			S	Oral	20 Mg, Qd		Allergan	
Intentional Product Misuse; Off Label Use									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960353	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1711333US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Hypersensitivity; Tachycardia	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960354	NON-EXPEDITED			US-ALLERGAN-1710257US		22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Agitation; Anger; Anxiety; Drug Ineffective; Dysstasia; Gait Disturbance; Headache; Hyperhidrosis; Insomnia; Mania; Personality Change; Sinusitis	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960355	NON-EXPEDITED			US-ALLERGAN-1710122US		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate - Bp			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960357	NON-EXPEDITED			US-ALLERGAN-1710043US		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Constipation; Dizziness; Dry Mouth; Insomnia;	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Buspirone			C	Oral	300 Mg, Qd		Not Reported	

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Tremor	Disulfiram	C	Oral	Unk Unk, Qd	Not Reported
	Antabuse	C	Oral	250 Mg, Qd	Not Reported
	Prilosec	C	Oral	Unk Unk, Qd	Not Reported
	Thiamine	C	Oral	100 Mg, Qd	Not Reported
	Naltrexone	C	Oral	50 Mg, Qd	Not Reported
	Asa	C	Oral	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960358	NON-EXPEDITED			US-ALLERGAN-1710197US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Insomnia; Nausea; Nervousness	Lexapro			S		5 Mg, Unk		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lorazepam			C		0.5		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960362	NON-EXPEDITED			US-ALLERGAN-1710984US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Lexapro			S	Oral	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960363	NON-EXPEDITED			US-ALLERGAN-1709990US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960364	NON-EXPEDITED			US-ALLERGAN-1714840US		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Headache	Lexapro			S						Allergan
	Vivitrol			C	Intramuscular	30 Mg, Q Month				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960365	NON-EXPEDITED			US-ALLERGAN-1714716US		57 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Migraine	Lexapro				S	Oral	20 Mg, Qd		Allergan	
	Lexapro				S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960367	NON-EXPEDITED			US-ALLERGAN-1714852US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased; Withdrawal Syndrome	Lexapro				S	Unknown	Unk Unk, Unknown		Allergan	
	Sertraline				C	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960368	NON-EXPEDITED			US-ALLERGAN-1713987US		17 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro				S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960369	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1715426US			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis	Lexapro				S		Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960371	NON-EXPEDITED			US-ALLERGAN-1714715US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Tremor	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960372	NON-EXPEDITED			US-ALLERGAN-1712505US		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960373	NON-EXPEDITED			US-ALLERGAN-1712640US		19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Jakafi			S	Oral	10 Mg, Bid		Not Reported	
	Cholecalciferol			C		Unk		Not Reported	
	Clobetasol			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
	Docusate Sodium			C		Unk		Not Reported	
	Emla			C		Unk		Not Reported	
	Prednisone			C		Unk		Not Reported	
	Metoprolol Succinate			C		Unk		Not Reported	
	Tacrolimus			C		Unk		Not Reported	
	Bactrim Ds			C		Unk		Not Reported	
	Ativan			C		Unk		Not Reported	
	Hydromorphone			C		Unk		Not Reported	

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Oxycodone	C	Unk	Not Reported
Neurontin	C	Unk	Not Reported
Albuterol	C	Unk	Not Reported
Cetirizine	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960374	NON-EXPEDITED			US-ALLERGAN-1713203US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypoaesthesia; Paraesthesia; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Lexapro			S	Oral	Unk, Qd		Allergan	
	Lexapro			S				Allergan	
	Escitalopram Oxalate Unk			S	Oral	Unk Unk, Unknown		Allergan	
	Escitalopram Oxalate Unk			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960376	NON-EXPEDITED			US-ALLERGAN-1712144US		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Anxiety; Apathy; Distractibility; Disturbance In Attention; Irritability; Memory Impairment; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960377	NON-EXPEDITED			US-ALLERGAN-1711349US		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger	Lexapro			S		Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960378	NON-EXPEDITED			US-ALLERGAN-1712866US		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intraocular Pressure Increased	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Symbicort			C	Respiratory (inhalation)	Unk, Bid		Not Reported	
	Spiriva			C	Respiratory (inhalation)	Unk, Qd		Not Reported	
	Albuterol			C	Respiratory (inhalation)	Unk, Qid		Not Reported	
	Oxygen			C	Nasal	2 Lpm		Not Reported	
	Xanax			C	Oral	0.25mg 1/2 Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960381	NON-EXPEDITED			US-ALLERGAN-1714524US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960387	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1717316US		25 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960388	NON-EXPEDITED			US-ALLERGAN-1715886US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Burning Mouth Syndrome; Discomfort; Dysgeusia; Gingival Swelling; Hypersensitivity; Swollen Tongue		Lexapro	S		Allergan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960391	NON-EXPEDITED			US-ALLERGAN- 1714914US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Hypoacusis; Lethargy; Nerve Injury; Tinnitus; Weight Increased	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960392	NON-EXPEDITED			US-ALLERGAN- 1714320US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960393	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1716344US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fatigue; Head Discomfort; Incorrect Dose Administered; Product Solubility Abnormal; Suicidal Ideation; Wrong Technique In Product Usage Process	Lexapro			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960395	NON-EXPEDITED			US-ALLERGAN- 1718898US			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Alopecia	Lexapro			S	Unknown	Unk		Allergan	
	Humira			S	Subcutaneous			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960396	NON-EXPEDITED			US-ALLERGAN-1717177US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety	Lexapro			S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960397	NON-EXPEDITED			US-ALLERGAN-1716929US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960398	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1721897US		29 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960400	NON-EXPEDITED			US-ALLERGAN-1721539US		39 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Night Sweats	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960401	NON-EXPEDITED			US-ALLERGAN-1722749US			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gout	Lexapro			S		Unk		Allergan	
	Warfarin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960402	NON-EXPEDITED			US-ALLERGAN-1720192US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960403	NON-EXPEDITED			US-ALLERGAN-1717278US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960404	NON-EXPEDITED			US-ALLERGAN-1717763US		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alcohol Increased;	Lexapro			S		10 Mg, Unk		Allergan	
Drug Ineffective; Memory	Synthroid			C				Not Reported	
Impairment	Simvastatin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960405	NON-EXPEDITED			US-ALLERGAN-1717075US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Oral	10 Mg, Qam		Allergan	
	Lexapro			S	Oral	5 Mg, Qam		Allergan	

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	Adderall		C	Oral		20 Mg, Qam			Not Reported	
	Risperidone		C	Oral		1 Mg, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960406	NON-EXPEDITED				US-ALLERGAN-1716142US			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Inappropriate Schedule Of Product Administration; Malaise; Product Dose Omission	Lexapro				S	Oral	10 Mg, Bid			Allergan
	Propecia				C		Unk, Qd			Not Reported
	Allegra				C		Unk Unk, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960410	EXPEDITED (15-DAY)		OT		US-ALLERGAN-1722465US			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Faeces Discoloured; Melaena; Upper Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp				S		Unk			Allergan
	Humira				S	Subcutaneous	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960414	NON-EXPEDITED				US-ALLERGAN-1721230US			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Negative Thoughts; Off Label Use; Off Label Use	Lexapro				S	Unknown	Unk Unk, Qd			Allergan
	Lexapro				S	Unknown	Unk			Allergan
	Lexapro				S					Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960415	NON-EXPEDITED				US-ALLERGAN-1720156US			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>

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Diarrhoea	Lexapro	S	Allergan						
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960416	EXPEDITED (15-DAY)	HO		US-ALLERGAN-1719146US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Gastroesophageal Reflux Disease; Hyperhidrosis; Insomnia; Obesity; Serotonin Syndrome; Tardive Dyskinesia; Vitamin B6 Deficiency	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Ampyra			S	Oral	10 Mg, Q12h		Not Reported	
	Ampyra			S				Not Reported	
	Baclofen			S	Oral	10 Mg, Tid		Not Reported	
	Phentermine			S	Unknown			Not Reported	
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported	
	Celebrex			C	Unknown	200 Mg, Qd		Not Reported	
	Oxycontin			C	Unknown	30 Mg, Qhs		Not Reported	
	Oxycodone			C	Unknown	15 Mg, 4 Times A Day As Needed, Maximum Of 6 Tablets		Not Reported	
	Levemir			C	Unknown	20 Units, Qam		Not Reported	
	Levemir			C	Unknown	25 Units, Qhs		Not Reported	
	Spironolactone			C	Unknown	50 Mg, Bid		Not Reported	
	Zyrtec			C	Unknown	10 Mg, Prn		Not Reported	
	Naloxegol			C	Oral	25 Mg, Prn		Not Reported	
	Ambien			C	Unknown	10 Mg, Qhs		Not Reported	
	Vitamin D3			C	Oral	5000 Iu, Qd		Not Reported	
	Clonidine			C	Oral	0.1 Mg, Bid		Not Reported	
	Levomefolic Acid			C	Unknown			Not Reported	
	Lisinopril			C	Unknown	5 Mg, Qpm		Not Reported	
	Maalox			C	Unknown	10 Ml, 4 Times Daily		Not Reported	
	Premarin			C	Unknown	0.3 Mg, Qd		Not Reported	
	Pantoprazole			C	Unknown	40 Mg, Bid		Not Reported	
	Lipitor			C	Oral	20 Mg, Qpm		Not Reported	

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12-Sep-2017	13960417	NON-EXPEDITED			US-ALLERGAN-1720734US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Hyperhidrosis; Tremor	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960418	NON-EXPEDITED			US-ALLERGAN-1722531US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Simvastatin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960419	NON-EXPEDITED			US-ALLERGAN-1726110US		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960421	NON-EXPEDITED			US-ALLERGAN-1724037US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960423	NON-EXPEDITED			US-ALLERGAN-1723870US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective		Lexapro		S	Unknown		Unk	Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960429	NON-EXPEDITED			US-ALLERGAN-1725049US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Exposure During Pregnancy	Lexapro			S	Oral	1 Df, Qd		Allergan	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960431	NON-EXPEDITED			US-ALLERGAN-1727010US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960432	NON-EXPEDITED			US-ALLERGAN-1723253US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Disorder; Sedation	Lexapro			S		10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960433	NON-EXPEDITED			US-ALLERGAN-1725940US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Feeling Abnormal; Incorrect Dose Administered; Somnolence	Lexapro			S	Unknown			Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960434	NON-EXPEDITED			US-ALLERGAN-1725246US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960436	NON-EXPEDITED			US-ALLERGAN-1728565US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anger; Behaviour Disorder; Irritability	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lithium			C	Oral	300 Mg, Qhs		Not Reported	
	Ativan			C	Oral	0.5 Mg, Qam		Not Reported	
	Haldol			C	Oral	1 Mg, Qhs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960438	NON-EXPEDITED			US-ALLERGAN-1727615US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission; Pruritus Generalised	Lexapro			S	Unknown	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960442	NON-EXPEDITED			US-ALLERGAN-1725019US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ejaculation Delayed; Incorrect Dose Administered	Lexapro			S		10 Mg, Tid		Allergan	
	Lexapro			S				Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960443	NON-EXPEDITED			US-ALLERGAN-1723193US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960446	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1728582US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Anger; Irritability; Suicidal Ideation	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Lorazepam			C	Oral	Unk Unk, Qd		Not Reported	
	Tegretol			C	Oral	Unk Unk, Qd		Not Reported	
	Abilify			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960447	NON-EXPEDITED			US-ALLERGAN-1728662US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nightmare	Lexapro			S	Unknown			Allergan	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Alendronate Sodium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960448	NON-EXPEDITED			US-ALLERGAN-1730992US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective		Lexapro		S		Allergan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960452	NON-EXPEDITED			US-ALLERGAN-1732582US		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heat Stroke	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lorazepam			C				Not Reported	
	Crestor			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960453	NON-EXPEDITED			US-ALLERGAN-1729773US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Chest Pain; Dizziness; Palpitations; Product Dose Omission; Sensory Disturbance; Wrong Technique In Product Usage Process	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Lorazepam			C		1 Mg, Unk		Not Reported	
	Crestor			C	Unknown	5 Mg, Unk		Not Reported	
	Aspirin			C	Unknown	81 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960454	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1730585US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Off Label Use; Vomiting	Lexapro			S	Unknown	Unk		Allergan	
	Protonix			C	Unknown	Unk Unk, Qd		Not Reported	
	Metoprolol			C	Unknown	100 Mg, Qd		Not Reported	
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960455	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1731635US		11 YR	Male	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abnormal Behaviour; Hypomania; Mania; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Concerta			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960458	NON-EXPEDITED			US-ALLERGAN- 1729169US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Memory Impairment	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960461	NON-EXPEDITED			US-ALLERGAN- 1730595US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Headache	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960466	NON-EXPEDITED			US-ALLERGAN- 1735369US		38 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Flight Of Ideas; Hypomania; Insomnia	Lexapro			S	Unknown	Unk		Allergan	
	Latuda			S	Oral	20 Mg, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960468	NON-EXPEDITED			US-ALLERGAN- 1734550US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event; Off Label Use; Product Dose	Lexapro			S	Unknown	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960469	NON-EXPEDITED			US-ALLERGAN-1734600US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown			Allergan	
	Fluoxetine Hcl Unk			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960470	NON-EXPEDITED			US-ALLERGAN-1733234US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Bystolic			S	Unknown			Allergan	
	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960476	NON-EXPEDITED			US-ALLERGAN-1732856US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960477	NON-EXPEDITED			US-ALLERGAN-1733577US		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Estring			C	Unknown	Unk		Not Reported	
	Buspirone			C	Unknown	5 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960478	NON-EXPEDITED			US-ALLERGAN-1733342US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Therapeutic Response Unexpected; Weight Increased	Lexapro			S	Unknown			Allergan	
	Levoxyl			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960489	NON-EXPEDITED			US-ALLERGAN-1750355US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hip Arthroplasty; Intestinal Prolapse	Lexapro			S	Oral	290 Mg, Unk		Allergan	
	Seroquel			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960506	NON-EXPEDITED			US-ALLERGAN-1000087660			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Crying; Dizziness; Feeling Abnormal; Headache; Incorrect Dose Administered; Night Sweats; Off Label Use; Panic Attack	Lexapro			S		20 Mg, Qd		Allergan	
	Lexapro			S		30 Unk, Unk		Allergan	
	Synthroid			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960507	NON-EXPEDITED			US-FRI-1000087171			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Product Dose Omission	Lexapro	S	5 Mg/Day	Allergan
	Lexapro	S	5 Mg/Day	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960508	NON-EXPEDITED			US-FRI-1000086885			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Breast Pain;	Lexapro			S	Oral	20 Mg, Qd		Allergan
Breast Tenderness; Chest	Lexapro			S				Allergan
Pain; Drug Interaction;	Latuda			S	Oral	80 Mg, Qd		Not Reported
Dyspnoea; Fatigue;	Latuda			S	Oral	120 Mg, Qd		Not Reported
Fibromyalgia; General	Latuda			S	Oral	40 Mg, Qd		Not Reported
Physical Health	Latuda			S	Oral	60 Mg, Qd		Not Reported
Deterioration; Pain;	Latuda			S	Oral			Not Reported
Pharyngitis; Pollakiuria;	Prilosec			C		Unk		Not Reported
Sinusitis; Thirst	Risperdal			C		Unk		Not Reported
	Vitamin C With Zinc			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960509	NON-EXPEDITED			US-FRI-1000087003			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Therapeutic	Lexapro			S	Oral	20 Mg, Qd		Allergan
Response Shortened	Zoloft			C	Oral	25 Mg, Qd		Not Reported
	Xanax			C	Oral	.25 Mg, Qd		Not Reported
	Bio-Identical Progesterone			C		100 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960510	NON-EXPEDITED			US-FRI-1000086919			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Faeces Discoloured		Lexapro		S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960511	NON-EXPEDITED			US-ALLERGAN-1000087484			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960512	NON-EXPEDITED			US-ALLERGAN-1670094US		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cold Sweat; Diarrhoea; Dizziness; Headache; Nausea; Nerve Injury; Tinnitus	Lexapro			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960513	NON-EXPEDITED			US-ALLERGAN-1000087472			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Somnolence	Lexapro			S		10 Mg, Unk		Allergan	
	Lexapro			S		5 Mg, Unk		Allergan	
	Coumadin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960514	NON-EXPEDITED			US-ALLERGAN-1672112US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S		Unk		Allergan	
	Levoxyl			S		224 Mcg, Qd		Not Reported	

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Lyrica	S	Oral	150 Mg, Bid	Not Reported
Zoloft	S	Oral	100 Mg, Qd	Not Reported
Combivent	C	Respiratory (inhalation)	2 Puffs, Qid	Not Reported
Biotin	C	Oral	1000 Mg, Six Times Daily	Not Reported
Cholecalciferol	C	Oral	15000 Units, Qd	Not Reported
Clonazepam	C	Oral	1-2 Tablets, Qhs	Not Reported
Clonazepam	C			Not Reported
Cyanocobalamin	C	Oral	1000 Mcg, Qd	Not Reported
Fluocinolone	C		Unk	Not Reported
Folic Acid	C	Oral	400 Mcg, Qd	Not Reported
Norco	C	Oral	1 Tablet Every 6 Hours As Needed	Not Reported
Eskalith	C	Oral	450 Mg, Bid	Not Reported
Naratriptan	C	Oral	2.5 Mg, Prn	Not Reported
Taclonex	C	Topical	Unk	Not Reported
Trazodone	C	Oral	100 Mg, Qpm	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960515	NON-EXPEDITED			US-ALLERGAN-1000087677		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro			S		Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960516	NON-EXPEDITED			US-ALLERGAN-1670306US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Weight Increased	Lexapro			S	Oral	20 Mg, Unk		Allergan

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12-Sep-2017	13960517	NON-EXPEDITED			US-ALLERGAN-1670396US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nightmare; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
	Ibuprofen			C	Oral	Unk Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960524	NON-EXPEDITED			US-ALLERGAN-1671666US		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Potassium Decreased; Cough; Diarrhoea; Fear; Headache; Nausea	Lexapro			S		7 Mg, Unk		Allergan	
	Tyvaso			S	Respiratory (inhalation)	18 Mg, Qid		Not Reported	
	Tyvaso			S	Respiratory (inhalation)	36 Mg, Qid		Not Reported	
	Tyvaso			S	Respiratory (inhalation)	54 Mg, Qid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960525	NON-EXPEDITED			US-ALLERGAN-1672528US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Off Label Use; Product Dose Omission; Withdrawal Syndrome	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960526	NON-EXPEDITED			US-ALLERGAN-1671981US		76 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Feeling Jittery; Inappropriate Schedule Of Product Administration	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lorazepam			C	Oral	Unk		Not Reported	
	Spiriva Combi			C	Respiratory (inhalation)	Unk		Not Reported	
	Ventolin			C	Respiratory (inhalation)	Unk		Not Reported	
	Albuterol Sulfate			C	Respiratory (inhalation)	Unk		Not Reported	
	Flovent			C	Respiratory (inhalation)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960527	NON-EXPEDITED			US-ALLERGAN-1672611US		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Off Label Use	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Atenolol			C		5 Mg, Qd		Not Reported	
	Baby Aspirin			C		Unk		Not Reported	
	Lipitor			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960528	NON-EXPEDITED			US-ALLERGAN-1671413US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Off Label Use	Lexapro			S		10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960529	NON-EXPEDITED			US-ALLERGAN-1672412US		49 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alopecia; Constipation; Eye Swelling; Formication; Off Label Use; Paraesthesia	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Cardizem			C	Oral	Unk		Not Reported	
	Biotin			C	Oral	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960530	NON-EXPEDITED			US-ALLERGAN-1671723US		69 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vulvovaginal Burning Sensation; Vulvovaginal Dryness	Lexapro			S		10 Mg, Unk		Allergan	
	Lisinopril			C		Unk		Not Reported	
	Coreg			C		Unk		Not Reported	
	Crestor			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960531	NON-EXPEDITED			US-ALLERGAN-1672088US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hyperhidrosis	Lexapro			S				Allergan	
	Sertraline			C		50 Mg, Unk		Not Reported	
	Sertraline			C		100 Mg, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960532	NON-EXPEDITED			US-ALLERGAN-1671202US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Sodium Decreased; Fatigue; Implantation Complication; Insomnia; Rash	Lexapro			S	Oral	Unk		Allergan	
	Lexapro			S				Allergan	
	Pravastatin			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960538	NON-EXPEDITED			US-ALLERGAN-1673514US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Hyperhidrosis; Palpitations; Tremor	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Diazepam			C	Oral	Unk		Not Reported	
	Gabapentin			C	Oral	Unk		Not Reported	
	Progesterone			C		Unk		Not Reported	
	Progesterone			C				Not Reported	
	Estrogen			C		Unk		Not Reported	
	Estrogen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960539	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1673777US		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration; Product Dose Omission; Suicidal Ideation	Lexapro			S		10 Mg, Qd		Allergan	
	Abilify			S		10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960540	NON-EXPEDITED			US-ALLERGAN-1673272US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Depressed Level Of Consciousness; Dyspnoea; Rash; Weight Increased	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960541	NON-EXPEDITED			US-ALLERGAN-		65 YR	Female	USA

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1674141US

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Off Label Use; Vertigo	Lexapro			S		20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Horizant			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960542	NON-EXPEDITED			US-ALLERGAN-1674478US		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Abdominal Pain Upper; Diarrhoea; Nausea	Lexapro			S	Oral	20 Mg, Qd		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Trintellix			S	Oral	20 Mg, Qd		Not Reported
	Trintellix			S	Oral	10 Mg, Qd		Not Reported
	Verapamil Er			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Carisoprodol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960543	NON-EXPEDITED			US-ALLERGAN-1672698US		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression	Lexapro			S	Oral	Unk Unk, Unknown		Allergan
	Seroquel			C		Unk		Not Reported

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Concerta			C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960544	NON-EXPEDITED			US-ALLERGAN-1674720US			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypoaesthesia	Lexapro			S	Oral	10 Mg, Qd		Allergan		
	Oxycodone			C		10 Mg, Tid		Not Reported		
	Losartan			C		100 Mg, Qd		Not Reported		
	Alprazolam			C		5 Mg, Qhs		Not Reported		
	Claritin			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960545	NON-EXPEDITED			US-ALLERGAN-1674662US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anxiety; Drug Ineffective	Lexapro			S				Allergan		
	Pristiq			S				Not Reported		
	Clonidine			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960546	NON-EXPEDITED			US-ALLERGAN-1673932US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Fatigue; Irritability; Peripheral Swelling	Lexapro			S		10 Mg, Qd		Allergan		
	Ambien			C		Unk, Prn		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960547	NON-EXPEDITED			US-ALLERGAN-1674399US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

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Feeling Hot; Product Dose Omission		Lexapro	S		Unk		Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960549	NON-EXPEDITED			US-ALLERGAN-1674769US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Decreased	Lexapro			S		20 Unk, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960550	NON-EXPEDITED			US-ALLERGAN-1675551US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960551	NON-EXPEDITED			US-ALLERGAN-1676903US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Nausea; Tremor; Vomiting; Withdrawal Syndrome	Lexapro Metformin Forxiga Losartan			S C C C	Oral	20 Mg, Qd		Allergan Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960552	NON-EXPEDITED			US-ALLERGAN-1677782US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue	Lexapro			S	Oral	20 Mg, Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960553	NON-EXPEDITED			US-ALLERGAN-1678655US		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Confusional State; Dizziness; Dyskinesia; Memory Impairment; Pollakiuria; Tardive Dyskinesia; Weight Increased	Lexapro			S		Unk		Allergan	
	Abilify			S		Unk		Not Reported	
	Depakote			C				Not Reported	
	Klonopin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960554	NON-EXPEDITED			US-ALLERGAN-1677788US		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Diarrhoea; Nausea; Viral Infection; Weight Decreased	Lexapro			S		Unk		Allergan	
	Flagyl			S	Oral	Unk		Not Reported	
	Amoxicillin			S	Oral	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported	
	Tramadol			C				Not Reported	
	Lorazepam			C				Not Reported	
	Colazal			C				Not Reported	
	Zantac			C				Not Reported	
	Prilosec			C				Not Reported	
	Dicyclomine			C				Not Reported	
	Dyazide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960555	NON-EXPEDITED			US-ALLERGAN-1677112US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Decreased	Lexapro			S	Oral	10 Mg, Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960556	NON-EXPEDITED			US-ALLERGAN-1675391US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960557	NON-EXPEDITED			US-ALLERGAN-1678166US		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Feeling Abnormal; Hypoaesthesia Oral; Libido Decreased; Mood Swings; Paraesthesia Oral; Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Omeprazole			C	Unknown	Unk, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960562	NON-EXPEDITED			US-ALLERGAN-1680180US		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Insomnia	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960563	NON-EXPEDITED			US-ALLERGAN-1680011US		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Diarrhoea; Incorrect Dose Administered; Insomnia; Malaise; Nausea; Wrong	Lexapro			S	Oral	Unk, Qd		Allergan	
	Lexapro			S				Allergan	
	Bupropion			C	Oral	200 Mg, Bid		Not Reported	
	Bupropion			C				Not Reported	

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Technique In Product
Usage Process

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960564	NON-EXPEDITED			US-ALLERGAN-1679416US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960565	NON-EXPEDITED			US-ALLERGAN-1679726US		93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscular Weakness	Lexapro			S	Oral	2.5 Mg, Qd		Allergan	
	Lexapro			S		5 Mg, Unk		Allergan	
	Lexapro			S	Oral	2.5 Mg Qd		Allergan	
	Prednisone			C				Not Reported	
	Keppra			C		Unk		Not Reported	
	Depakote			C		Unk		Not Reported	
	Plavix			C				Not Reported	
	Aspirin			C				Not Reported	
	Atorvastatin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960566	NON-EXPEDITED			US-ALLERGAN-1681077US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fatigue; Feeling Abnormal; Motion Sickness	Lexapro			S	Oral	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960567	NON-EXPEDITED			US-ALLERGAN-1681413US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Cough; Decreased Appetite; Dizziness; Drug Ineffective; Dysstasia; Feeling Abnormal; Incontinence; Malaise; Nausea; Pain; Sneezing; Weight Increased; Withdrawal Syndrome	Lexapro			S	Unknown	20 Mg, Qd		Allergan	
	Metoprolol			C	Unknown	25 Mg, Unk		Not Reported	
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported	
	Protonix			C	Unknown	20 Mg, Qd Or Bid		Not Reported	
	Zantac			C	Unknown	150 Mg, Once Or Twice Daily After A Meal		Not Reported	
	Ms Contin			C	Unknown	15 Mg, Qd		Not Reported	
	Lyrica			C	Unknown	75 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960568	NON-EXPEDITED			US-ALLERGAN- 1679069US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960569	NON-EXPEDITED			US-ALLERGAN- 1679743US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960571	NON-EXPEDITED			US-ALLERGAN- 1677792US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Diarrhoea; Genital Disorder Female; Incorrect Dose Administered; Product Dose Omission; Urinary Tract Infection	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Namenda			S	Oral			Not Reported	
	Senna			C	Oral	Unk		Not Reported	

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	Neurontin	C	Oral	Unk	Not Reported
	Allopurinol	C	Oral	Unk	Not Reported
	Percocet	C	Oral		Not Reported
	Tylenol	C	Oral	Unk	Not Reported
	Valium	C	Oral		Not Reported
	Vitamin C	C	Oral	Unk	Not Reported
	Vitamin D2	C	Oral	Unk	Not Reported
	Iron	C	Oral	Unk	Not Reported
	Humalog	C		Unk	Not Reported
	Lantus	C		Unk	Not Reported
	Fish Oil	C			Not Reported
	Laxative	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960572	NON-EXPEDITED			US-ALLERGAN-1700526US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Hair Texture Abnormal; Incorrect Product Dosage Form Administered	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960574	NON-EXPEDITED			US-ALLERGAN-1681432US		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Tremor	Lexapro			S	Unknown	10 Mg, Daily		Allergan	
	Ativan			C		Unk		Not Reported	
	Mavik			C		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	
	Fioricet			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960575	NON-EXPEDITED			US-ALLERGAN-1700673US		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine	Lexapro			S	Oral	30 Mg, Qd		Allergan	
Phosphokinase Increased;	Lexapro			S	Oral	Unk Unk, Qd		Allergan	
Fatigue; Gait Disturbance;	Lexapro			S	Oral	30 Mg, Qd		Allergan	
Muscular Weakness;									
Myalgia; Off Label Use									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960576	NON-EXPEDITED			US-ALLERGAN-1682074US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Tooth	Lexapro			S	Oral	20 Mg, Unk		Allergan	
Extraction	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960577	NON-EXPEDITED			US-ALLERGAN-1700201US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960578	NON-EXPEDITED			US-ALLERGAN-1681582US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Panic Attack	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960579	NON-EXPEDITED			US-ALLERGAN-1700278US		76 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Asthenia; Decreased Appetite; Dizziness; Dry Mouth; Hyperhidrosis; Insomnia; Memory Impairment; Nausea; Somnolence; Taste Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Synthroid			C	Oral	Unk		Not Reported	
	Aspirin			C	Oral	81 Mg, Qd		Not Reported	
	B-12			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960580	NON-EXPEDITED			US-ALLERGAN-1700509US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Oral			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960581	NON-EXPEDITED			US-ALLERGAN-1700221US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use; Therapeutic Response Unexpected	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960582	NON-EXPEDITED			US-ALLERGAN-1681420US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Male Sexual Dysfunction	Lexapro			S	Oral	5 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960584	NON-EXPEDITED			US-ALLERGAN-1701209US		42 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Drug Level Increased; Road Traffic Accident	Lexapro	S	Unknown					Allergan	
	Lamotrigine	S	Unknown	20 Mg, Qd				Not Reported	
	Citalopram	S	Unknown	20 Mg, Qd				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960585	NON-EXPEDITED			US-ALLERGAN-1701071US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960589	NON-EXPEDITED			US-ALLERGAN-1701060US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Insomnia	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960594	NON-EXPEDITED			US-ALLERGAN-1702271US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Nausea	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960595	NON-EXPEDITED			US-ALLERGAN-1701467US		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Testosterone Decreased	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Gemfibrocil			C	Oral	Unk		Not Reported	
	Allopurinol			C	Oral	300 Mg, Qd		Not Reported	
	Alprazolam			C	Oral	0.5 Mg, Qd		Not Reported	

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Atorvastatin Calcium	C	Oral	40 Mg, Qd	Not Reported
Atenolol	C	Oral	50 Mg, Bid	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Qd	Not Reported
Klor-Con M20	C	Oral	Unk Unk, Qd	Not Reported
Trazodone	C	Oral	50 Mg, Qhs	Not Reported
Hydrocodone/Acetaminophen /00607101/	C	Oral	Unk Unk, Qhs	Not Reported
Hydrocodone/Acetaminophen /00607101/	C			Not Reported
Enzalutamide	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960596	NON-EXPEDITED			US-ALLERGAN-1701295US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Somnolence	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Hydrocodone/Acetaminophen			C	Unknown			Not Reported
	Omeprazole			C	Unknown	40 Mg, Qd		Not Reported
	Naproxen			C		500 Mg, Prn		Not Reported
	Lyrica			C	Unknown	Unk, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960597	NON-EXPEDITED			US-ALLERGAN-1700908US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Lexapro			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960603	NON-EXPEDITED			US-ALLERGAN-1700732US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort; Nausea; Vomiting	Lexapro	S	Unknown	10 Mg, Unk	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960604	NON-EXPEDITED			US-ALLERGAN-1701105US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug	Lexapro			S		20 Mg, Qd		Allergan
Ineffective; Hypertension;	Lexapro			S		10 Mg, Qd		Allergan
Insomnia; Panic Attack;	Chantix			C		Unk		Not Reported
Panic Attack; Suicidal	Trazodone			C		25 Mg, Prn		Not Reported
Ideation; Tobacco User	Metoprolol Tartrate			C		25 Mg, Bid		Not Reported
	Prozac			C		20 Mg, Unk		Not Reported
	Prozac			C				Not Reported
	Ativan			C		0.5 Mg, Tid		Not Reported
	Ativan			C				Not Reported
	Zoloft			C		Unk		Not Reported
	Zoloft			C				Not Reported
	Buspar			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Mirtazapine			C		Unk		Not Reported
	Mirtazapine			C				Not Reported
	Fluoxetine			C		Unk		Not Reported
	Fluoxetine			C				Not Reported
	Cymbalta			C		Unk		Not Reported
	Cymbalta			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960605	NON-EXPEDITED			US-ALLERGAN-1702170US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Depressed Mood; Insomnia;	Lexapro			S	Oral	10 Mg, Qd		Allergan

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Restlessness

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960606	NON-EXPEDITED			US-ALLERGAN-1701813US		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder;	Lexapro			S	Oral	30 Mg, Qd		Allergan	
Feeling Abnormal; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960607	NON-EXPEDITED			US-ALLERGAN-1702189US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour;	Lexapro			S		20 Mg, Qd		Allergan	
Abulia; Amnesia; Apathy;	Lexapro			S				Allergan	
Drug Ineffective; Fatigue;	Effexor			S		37.5 Mg, Qd		Not Reported	
Impulsive Behaviour;	Effexor			S		75 Mg, Qd		Not Reported	
Insomnia; Loss Of	Effexor			S		150 Mg, Qd		Not Reported	
Consciousness; Urinary	Zoloft			S		25 Mg, Qd		Not Reported	
Incontinence	Zoloft			S		25 Mg, Bid		Not Reported	
	Prozac			S		Unk		Not Reported	
	Prozac			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960609	NON-EXPEDITED			US-ALLERGAN-1702555US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia;	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
Depression; Fibromyalgia;	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported	
Gait Disturbance; Loss Of	Humira			S	Subcutaneous	40 Mg, Single		Not Reported	
Personal Independence In Daily Activities	Humira			S	Subcutaneous	40 Mg, Single		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960610	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1702277US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Inability To Afford Medication; Suicidal Ideation; Suicide Attempt	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960611	NON-EXPEDITED			US-ALLERGAN-1702970US		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Fatigue; Mental Disorder; Mood Swings	Lexapro			S		5 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960612	NON-EXPEDITED			US-ALLERGAN-1702880US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Lexapro			S				Allergan	
	Penicillin (Benzylpenicillin)			C				Not Reported	
	Wellbutrin			C				Not Reported	
	Mobic			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Simvastatin			C				Not Reported	
	Lidocaine			C				Not Reported	
	Pravastatin			C				Not Reported	
	Norco			C				Not Reported	
	Elavil			C				Not Reported	
	Effexor			C				Not Reported	
	Doxycycline			C				Not Reported	
	Viibryd			C				Not Reported	
	Lipitor			C				Not Reported	
	Sertraline			C				Not Reported	
	Azithromycin			C				Not Reported	

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	Trazodone	C		Unk				Not Reported
	Nitrostat	C						Not Reported
	Ibuprofen	C						Not Reported
	Gemfibrozil	C						Not Reported
	Lisinopril	C						Not Reported
	Methocarbamol	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960613	NON-EXPEDITED			US-ALLERGAN-1702196US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	
	Fioricet Capsules			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960614	NON-EXPEDITED			US-ALLERGAN-1701970US		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Incorrect Dose Administered; Malaise; Product Dose Omission; Therapeutic Response Unexpected; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960615	NON-EXPEDITED			US-ALLERGAN-1702240US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Hypometabolism; Weight Increased	Lexapro			S	Unknown			Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960616	NON-EXPEDITED			US-ALLERGAN-1703057US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression;	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
Disturbance In Attention;	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
Feelings Of	Lexapro			S	Unknown	30 Mg, Unk		Allergan	
Worthlessness; Irritability;	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
Memory Impairment; Off	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
Label Use; Social	Wellbutrin			S	Unknown	Unk		Not Reported	
Avoidant Behaviour;	Wellbutrin			S	Unknown	Unk		Not Reported	
Social Fear	Wellbutrin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960617	NON-EXPEDITED			US-ALLERGAN-1703738US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960618	NON-EXPEDITED			US-ALLERGAN-1702551US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Stiffness; Joint	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
Swelling; Stomatitis	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960619	NON-EXPEDITED			US-ALLERGAN-1702952US		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Rash	Lexapro			S	Oral	5 Mg, Qd		Allergan	

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Lexapro			S		Oral		10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960620	NON-EXPEDITED			US-ALLERGAN-1702579US				Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dehydration; Fatigue; Inappropriate Schedule Of Product Administration; Mental Impairment; Off Label Use; Sexual Dysfunction; Sluggishness; Thirst	Lexapro				S	Oral	10 Mg, Qd		Allergan	
	Lexapro				S	Unknown	15 Mg, Qd		Allergan	
	Lexapro				S	Unknown	30 Mg, Qd		Allergan	
	Zyrtec				C		Unk Unk, Prn		Not Reported	
	Digestive Enzymes				C				Not Reported	
	Beano				C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960622	NON-EXPEDITED			US-ALLERGAN-1703421US				Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation	Lexapro				S	Oral	15 Mg, Qd		Allergan	
	Lexapro				S	Oral	10 Mg, Qd		Allergan	
	Lexapro				S	Oral	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960623	NON-EXPEDITED			US-ALLERGAN-1703621US			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Decreased	Lexapro				S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960624	NON-EXPEDITED			US-ALLERGAN-1703728US				Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective		Lexapro		S	Oral		10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960625	NON-EXPEDITED			US-ALLERGAN-1703888US		40 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Headache; Insomnia; Pain; Peripheral Swelling; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan		
	Klonopin			S	Oral	1 Mg, Tid		Not Reported		
	Klonopin			S				Not Reported		
	Lyrica			S	Oral	50 Mg, Qhs		Not Reported		
	Lyrica			S	Oral	75 Mg, Qhs		Not Reported		
	Lyrica			S	Oral	100 Mg, Qhs		Not Reported		
	Nortriptylin			C		25 Mg, Qhs		Not Reported		
	Flexeril /00428402/			C		Unk		Not Reported		
	Treximet			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960626	NON-EXPEDITED			US-ALLERGAN-1703803US		42 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Weight Decreased; Weight Gain Poor	Lexapro			S	Oral	5 Mg, Qd		Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Sep-2017	13960627	NON-EXPEDITED			US-ALLERGAN-1703823US		73 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Memory Impairment	Lexapro			S		5 Mg, Unk		Allergan		
	Lexapro			S		10 Mg, Unk		Allergan		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960636	NON-EXPEDITED			US-ALLERGAN-1704872US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Ativan			C	Unknown	Unk		Not Reported
	Buspirone			C	Unknown	7.5 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Gabapentine			C	Unknown	100 Mg, Tid		Not Reported
	Tramadol			C	Unknown	50 Mg, Prn		Not Reported
	Meloxicam			C		15 Mg, Qhs		Not Reported
	Protonix			C	Unknown	40 Mg, Qhs		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported
	Robaxin			C	Unknown	Unk Unk, Prn		Not Reported
	Trazodone			C	Unknown	Unk Unk, Prn		Not Reported
	Doxycycline			C	Unknown	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960637	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1705410US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Depression; Fatigue; Injection Site Bruising; Joint Swelling; Musculoskeletal Pain; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Lexapro			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960638	NON-EXPEDITED			US-ALLERGAN-1705972US			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960639	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1704777US		50 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression; Malaise; Suicidal Ideation	Lexapro			S				Allergan	
	Morphine Sulfate			S		20 Mg, Bid		Not Reported	
	Percocet			C		Unk		Not Reported	
	Cymbalta			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960640	NON-EXPEDITED			US-ALLERGAN-1705236US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Feeling Abnormal; Therapeutic Product Effect Increased; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10-15 Mg		Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960641	NON-EXPEDITED			US-ALLERGAN-1705990US		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Oral			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960642	NON-EXPEDITED			US-ALLERGAN-1704706US		68 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Asthenopia; Drug Ineffective; Dry Mouth; Feeling Abnormal; Feeling Jittery; Malaise; Nervousness; Palpitations; Visual Impairment	Lexapro	S	Oral	20 Mg, Unknown	Allergan
	Lexapro	S			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960643	NON-EXPEDITED			US-ALLERGAN-1707276US		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Constipation; Decreased Appetite; Insomnia; Off Label Use; Tremor	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Primidone			C	Oral	1 Df, Qhs		Not Reported
	Methotrexate			C	Oral	2.5 Mg, Q Week		Not Reported
	Aspirin			C	Oral	Unk		Not Reported
	Amlodipine			C	Oral	Unk		Not Reported
	Folic Acid			C	Oral	Unk		Not Reported
	Iron			C	Oral	Unk		Not Reported
	Vitamin C			C	Oral	500 Mg, Unk		Not Reported
	Multivitamin			C	Oral	Unk		Not Reported
	Clonidine			C	Transdermal	Unk		Not Reported
	Metamucil			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960644	NON-EXPEDITED			US-ALLERGAN-1707811US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Lexapro			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960645	NON-EXPEDITED			US-ALLERGAN-1707296US		55 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dry Mouth; Feeling Jittery; Insomnia	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan	
	Trazodone			S	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960646	NON-EXPEDITED			US-ALLERGAN-1708019US		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Contraindication To Medical Treatment	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960647	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1706922US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Decreased Appetite; Decubitus Ulcer; Diarrhoea; Serotonin Syndrome; Somnolence	Lexapro			S	Unknown			Allergan	
	Prednisone			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin D2			C				Not Reported	
	Lasix			C				Not Reported	
	Hydrocodone/Apap			C				Not Reported	
	Lipitor			C				Not Reported	
	Magnesium Oxide			C				Not Reported	
	Vitamin C			C				Not Reported	
	Sandostatin			C				Not Reported	
Pradaxa			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960648	NON-EXPEDITED			US-ALLERGAN-1706994US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960649	NON-EXPEDITED			US-ALLERGAN-1707059US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Drug Ineffective; Dyspepsia; Hyperhidrosis; Insomnia; Retching	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960650	NON-EXPEDITED			US-ALLERGAN-1706965US		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Feeling Jittery	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960654	NON-EXPEDITED			US-ALLERGAN-1706083US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Product Dose Omission; Vision Blurred	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960655	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1709186US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Dyspnoea; Fall; Mood Altered; Skin Discolouration	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
	Chantix			S	Unknown	Unk		Not Reported	
	Klonopin			C	Unknown	1 Mg, Bid		Not Reported	
	Amitriptyline			C	Oral	20 Mg, Qhs		Not Reported	
	Ambien			C	Unknown	10 Mg, Unk		Not Reported	

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12-Sep-2017	13960656	NON-EXPEDITED			US-ALLERGAN-1709508US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Alprazolam			C	Unknown	2 Mg, Prn		Not Reported	
	Coumadin			C	Unknown	6 Mg, Bi-Weekly		Not Reported	
	Coumadin			C		4 Mg, Rest Of The Week		Not Reported	
	Clonazepam			C	Unknown	1 Mg, Bid		Not Reported	
	Levothyroxine			C	Unknown	125 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960658	NON-EXPEDITED			US-ALLERGAN-1709341US		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Escitalopram Oxalate - Bp			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960659	NON-EXPEDITED			US-ALLERGAN-1708217US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pollakiuria; Sexual Dysfunction; Tinnitus	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S		5 Mg, Qd		Allergan	
	Lexapro			S		10 Mg, Qd		Allergan	
	Lisinopril			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960660	NON-EXPEDITED			US-ALLERGAN-1709581US		61 YR	Female	USA

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Agitation; Anxiety; Dizziness; Drug Interaction	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960661	NON-EXPEDITED			US-ALLERGAN- 1706746US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960662	NON-EXPEDITED			US-ALLERGAN- 1708278US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Palpitations; Tremor	Lexapro			S		Unk		Allergan	
	Lithium			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960668	NON-EXPEDITED			US-ALLERGAN- 1709612US		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Mood Swings; Suicidal Ideation	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13960669	NON-EXPEDITED			US-ALLERGAN- 1709877US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Lexapro			S		Unk		Allergan	

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12-Sep-2017	13960670	NON-EXPEDITED			US-ALLERGAN-1709955US		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Burning Sensation; Dry Skin; Erythema; Musculoskeletal Stiffness; Taste Disorder	Lexapro			S	Oral	20 Mg At Night		Allergan	
	Lexapro			S				Allergan	
	Levothyroxine			C	Oral	0.05 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13961895	NON-EXPEDITED		HO, LT	AU-EISAI MEDICAL RESEARCH-EC-2017-031012		34 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Fycompa			S	Oral			Not Reported	
	Fycompa			S	Oral	Overdose		Not Reported	
	Carbamazepine			S		Unknown		Not Reported	
	Carbamazepine			S		Overdose		Not Reported	
	Clobazam			S		Unknown		Not Reported	
	Clobazam			S		Overdose		Not Reported	
	Clonazepam			S		Unknown		Not Reported	
	Clonazepam			S		Overdose		Not Reported	
	Escitalopram			S		Unknown		Not Reported	
	Escitalopram			S		Overdose		Not Reported	
	Ferrous Sulphate			S		Unknown		Not Reported	
	Ferrous Sulphate			S		Overdose		Not Reported	
	Levetiracetam			S		Unknown		Not Reported	
	Levetiracetam			S		3500 Mg		Not Reported	
	Topiramate			S		Unknown		Not Reported	
	Topiramate			S		200 Mg		Not Reported	

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12-Sep-2017	13961946	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1751441US		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram Oxalate - Bp			S	Oral	10, Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13962740	DIRECT		OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Barrett'S Oesophagus; Constipation; Hiatus Hernia; Vomiting; Weight Decreased	Escitalopram Tab 10mg			S	Oral	Quantity:30 Tablet(S);		Teva	
	Lansoprazole			C				Not Reported	
	Linzess			C				Not Reported	
	Daily Vitamin			C				Not Reported	
	Probiotic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13423389	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017145646		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Tahor			S	Oral	20 Mg, 1x/Day		Pfizer	
	Aromasine			S	Oral	25 Mg, 1x/Day		Pfizer	
	Bisoprolol Hemifumarate			S	Oral	3.75 Mg, 1x/Day		Not Reported	
	Pyostacine			S	Oral	500 Mg, Twice On The Morning And Twice On The Evening		Not Reported	
	Coversyl /00790703/			S	Oral	2 Mg, 1x/Day		Not Reported	
	Janumet			S		1000 Mg/500 Mg, Twice A Day		Not Reported	
	Kardegic			S	Oral	160 Mg, 1x/Day		Not Reported	

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		Diamicon		S	Oral	30 Mg, 1x/Day			Not Reported
		Seroplex		S	Oral	10 Mg, 1x/Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13551419	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1719602US		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event;	Escitalopram Oxalate - Bp			S		5 Mg, Unk		Allergan	
Cerebrovascular Accident;	Escitalopram Oxalate - Bp			S		10 Mg, Unk		Allergan	
Drug Intolerance;	Escitalopram Oxalate - Bp			S		15 Mg, Unk		Allergan	
Hypertension; Lenticular Opacities; Tremor	Tenoretic			C	Unknown	50mg/12.5mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13940389	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382872		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Amiodarone Hcl			S	Unknown	Unk		Pfizer	
Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Not Reported	
	Domperidone			S	Unknown	Unk		Not Reported	
	Aliskiren			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13940393	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382831		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Amiodarone Hcl			S	Unknown	Unk		Pfizer	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13940400	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017382874		82 YR	Male	FRA

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Drug Interaction; Electrocardiogram Qt Prolonged	Amiodarone Hcl			S	Unknown	Unk		Pfizer	
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Flecainide			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13963400	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE- HET2017DE00138			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomegaly; Dextrocardia; Encephalocele; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported	
	Loratadin			C	Transplacental	10 Mg, Qd		Not Reported	
	Seasonale			C	Transplacental			Not Reported	
	Folio Forte			C	Transplacental	0.8 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13966779	DIRECT	Y	HO, LT			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lactic Acidosis; Liver Injury; Rhabdomyolysis	Escitalopram			S	Oral		1 MTH	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13966609	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2017005937			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral	10 Mg, Unk		Macleods	

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14-Sep-2017	13966668	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2017-40000		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 Mg, Daily		Aurobindo	
	Escitalopram			S	Transplacental	5 Mg, Daily		Aurobindo	
	Folsaeure			C	Transplacental	0.8 Mg, Daily		Not Reported	
	Folsaeure			C	Transplacental	0.4 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13966730	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015603		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13967954	EXPEDITED (15-DAY)		OT	GB-ACCORD-058474		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13967966	EXPEDITED (15-DAY)		DE, HO, LT	AT-ALLERGAN-1751930US		73 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	1-0-0		Allergan	

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Artery Disease;	Azilect	S	Unknown	1-0-0	Not Reported
Dehydration; Fatigue;	Stalevo	S	Unknown	Form Strength:	Not Reported
Oedema Peripheral;				100mg/25mg/200mg	
Pneumonia; Renal	Stalevo	S	Unknown	1-1-0	Not Reported
Impairment; Weight	Stalevo	S	Unknown	Form Strength:	Not Reported
Decreased				50mg/12.5mg/200mg	
	Trittico	S	Unknown	0-0-0-0.5	Not Reported
	Seroquel	S	Unknown		Not Reported
	Madopar	S	Unknown	1-1-1	Not Reported
	Lovenox	C	Unknown	1xtgl	Not Reported
	Elomel	C	Unknown	1xtgl	Not Reported
	Optinem	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Thrombo Ass	C	Unknown	0-1-0	Not Reported
	Spirobene	C	Unknown	0-0.5-0	Not Reported
	Sedacoron	C	Unknown	0.5-0-0	Not Reported
	Eporatio	C	Unknown		Not Reported
	Ceftriaxone Sodium	C	Unknown	2 G In 200 MI, 1 X Tgl	Not Reported
	Dancor	C	Unknown	1-0-1	Not Reported
	Aquaphoril	C	Unknown	0.5-0-0	Not Reported
	Torasemide	C	Unknown	1-0-0	Not Reported
	Pantoloc	C	Unknown	2-0-0	Not Reported
	Insulatard	C	Unknown	6ie-0-0	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13970286	EXPEDITED (15-DAY)	CA		FR-ALLERGAN-1751914US		60 DAY	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Vesicoureteric Reflux; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan	
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Transplacental	Unk, Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2017	13976877	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1055963		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Small For Dates Baby	Escitalopram			S	Transplacental	15 [Mg/D]/ Dosage Reduction To 5 Mg/D From Week 30		Not Reported	
	Folsaeure			C	Transplacental	0.8 [Mg/D]/ Dosage Reduction To 0.4 Mg/D		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13971966	DIRECT		OT			1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Feeling Abnormal; Product Substitution Issue	Generic Lexapro			S	Oral	Quantity:3 Tablet(S);		Teva	
	Lorazepam			C				Not Reported	
	Norvasc			C				Not Reported	
	Lexapro			C				Not Reported	
	Daily Vitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13973503	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00320		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Spironolactone			S	Unknown			Jubilant	
	Escitalopram			S	Unknown	5 Mg		Jubilant	
	Candesartan			S	Unknown			Not Reported	
	Ivabradine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13973515	EXPEDITED (15-DAY)		OT	FR-JUBILANT CADISTA PHARMACEUTICALS-		85 YR	Female	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2017JUB00322

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Irbesartan			S	Unknown			Jubilant
	Escitalopram			S	Unknown	10 Mg		Jubilant
	Galantamine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Unspecified Diuretic			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13973589	EXPEDITED (15-DAY)		DS	DK-PFIZER INC-2017397640		18 YR	Male	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia; Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Sertraline Hcl			S	Oral	Dosage: Varying		Pfizer
	Cipralext /01588501/			S	Oral	Dosage: Varying		Not Reported
	Venlafaxin 1a Pharma			S	Oral	Dosage: Varying		Not Reported
	Valdoxan			S	Oral	Dosage: Varying		Not Reported
	Paroxetine			S	Oral	Dosage: Varying		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13974930	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1752048US		30 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bundle Branch Block	Escitalopram Oxalate - Bp	S	Oral	580 Mg Once	Allergan
Right; Coma;	Doliprane	S	Oral	12000mg Per Oral Once	Not Reported
Electrocardiogram Qt	Risperdal	S	Oral	10mg Per Oral Once	Not Reported
Prolonged; Hypokalaemia;	Bromazepam	S	Oral	60 Mg Once	Not Reported
Intentional Overdose;	Nurofen	S	Oral	Once	Not Reported
Miosis	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Oral	Once	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13976656	EXPEDITED (15-DAY)		OT	GB-TEVA-804835ACC		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13978095	NON-EXPEDITED			US-ASTRAZENECA-2017SE93490		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Nexium 24hr			S	Oral	Unk		Astrazeneca	
	Omeprazole			S	Oral	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Celebrex			S	Unknown	Unk		Not Reported	
	Protonix			S	Unknown	Unk		Not Reported	
	Septra			S	Unknown	Unk		Not Reported	
	Zolof			S	Unknown	Unk		Not Reported	
	Methylphenidate Hydrochloride			S	Unknown	Unk		Not Reported	
	Ampicillin			S	Unknown	Unk		Not Reported	
	Erythromycin			S	Unknown	Unk		Not Reported	
	Albuterol Sulfate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Albuterol Sulfate	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Bupropion Hydrochloride	S	Unknown	Unk	Not Reported
Cymbalta	S	Unknown	Unk	Not Reported
Fenofibrate	S	Unknown	Unk	Not Reported
Luvox	S	Unknown	Unk	Not Reported
Paxil /00500401/	S	Unknown	Unk	Not Reported
Percocet /00867901/	S	Unknown	Unk	Not Reported
Vicodin	S	Unknown	Unk	Not Reported
Wellbutrin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13978625	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00435		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Furosemide			S	Unknown			Prinston Pharmaceutical
	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Bisoprolol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13978632	EXPEDITED (15-DAY)		OT	FR-PRINSTON PHARMACEUTICAL INC.-2017PRN00436		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Irbesartan			S	Unknown			Prinston Pharmaceutical
	Escitalopram			S	Unknown	10mg		Prinston Pharmaceutical
	Galantamine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unspecified Diuretic			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2017	13981574	DIRECT					53 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Dry Mouth; Dyspnoea; Palpitations; Panic Reaction; Paraesthesia; Suicidal Ideation; Swollen Tongue	Escitalopram		Y	S	Oral	Quantity:30 Tablet(S);		Torrent	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13582648	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1031674		42 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum Disorder; Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown	Initial Dose Not Stated; Last Dose 5 Mg/Day Was Continued		Not Reported	
	Escitalopram			S				Not Reported	
	Carbamazepine			S	Unknown	Up To 1200 Mg/Day		Not Reported	
	Fluvoxamine			S	Unknown			Not Reported	
	Fluvoxamine			S				Not Reported	
	Mirtazapine			S	Unknown	60 Mg/Day		Not Reported	
	Mirtazapine			S				Not Reported	
	Olanzapine			S	Unknown	10 Mg/Day, The Dose Was Further Increased To 15 Mg/Day		Not Reported	
	Olanzapine			S	Unknown	15 Mg/Day		Not Reported	
	Olanzapine			S	Unknown	5 Mg/Day		Not Reported	
	Quetiapine			S	Unknown	50 Mg/Day		Not Reported	
	Risperidone			S	Unknown	3 Mg/Day		Not Reported	
	Omega 3 /01334101/			S	Unknown	700 Mg/Day, The Dose		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omega 3 /01334101/	S	Unknown	Was Further Increased To Double The Previous Dose Double The Previous Dose Of 700 Mg/Day	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13654857	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-143076		42 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased	Olanzapine			S	Unknown	10 Mg, Daily		Sun
	Olanzapine			S	Unknown	15 Mg, Daily		Sun
	Olanzapine			S	Unknown	5 Mg, Daily		Sun
	Mirtazapine			S	Unknown	60 Mg, Daily		Sun
	Carbamazepine			S	Unknown	1200 Mg, Daily		Taro
	Risperidone			S	Unknown	3 Mg, Daily		Ranbaxy
	Quetiapine			S	Unknown	50 Mg, Daily		Sun
	Fluvoxamine			S	Unknown	Unk		Sun
	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13718569	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA- 2017SE69060		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Pemphigoid	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Unknown			Not Reported
	Calcium Acetate			S	Unknown			Not Reported
	Kardegic			S	Oral			Not Reported
	Lasilix Special			S	Unknown			Not Reported
	Uvedose			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levothyrox	S	Unknown	Not Reported
Galvus	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Novonorm	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13934799	EXPEDITED (15-DAY)		LT, OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-149094		16 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Galactorrhoea; Suicide Attempt	Metoclopramide			S	Oral	Large Amount		Mutual
	Escitalopram			S	Oral	Large Amount		Not Reported
	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported
	Pseudoephedrine			S	Oral	Large Amount		Sun
	Fluoxetine			S	Unknown	20 Mg, Daily		Sun
	Fluoxetine			S	Unknown	10 Mg, Daily		Sun
	Risperidone			C	Unknown	0.5 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13974016	EXPEDITED (15-DAY)		HO, OT	FR-ALEMBIC PHARMACUETICALS LIMITED- 2017SCAL000747			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Venlafaxine Hydrochloride			S	Unknown	225 Mg, Qd		Alembic
	Venlafaxine Hydrochloride			S				Alembic
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Sertraline			S				Not Reported
	Risperidone			S	Unknown	2 Mg, Qd		Not Reported
	Risperidone			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paroxetine	S	Unk	Not Reported	
Paroxetine	S	Unknown	40 Mg, Qd	Not Reported
Diazepam	C	Unknown	20 Mg, Qd	Not Reported
Diazepam	C			Not Reported
Quetiapine	C	Unknown	100 Mg, Qd	Not Reported
Quetiapine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13980429	EXPEDITED (15-DAY)		HO, OT	NO-ASTRAZENECA-2017SE93458		21 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Aggression;	Seroquel			S	Oral	Unk		Zeneca
Agitation; Alcohol Abuse;	Seroquel			S	Oral	Unk		Zeneca
Bipolar Disorder;	Seroquel			S	Oral	Unk		Zeneca
Depression; Derealisation;	Ciprallex			S	Unknown	Unk Unk, Daily		Not Reported
Disturbance In Attention;	Efexor Depot			S	Unknown	Unk		Not Reported
Disturbance In Social	Efexor Depot			S	Unknown	Unk		Not Reported
Behaviour; Dizziness;	Efexor Depot			S	Unknown	Unk		Not Reported
Drug Abuse; Drug Abuse;	Efexor Depot			S	Unknown	Unk		Not Reported
Drug Ineffective;	Efexor Depot			S	Unknown	Unk		Not Reported
Hypomania; Impaired	Efexor Depot			S	Unknown	Unk		Not Reported
Work Ability; Irritability;	Olanzapine			S	Unknown	Unk		Not Reported
Judgement Impaired;	Zyprexa			S	Unknown	Unk		Not Reported
Logorrhoea; Malaise;	Cipramil [Citalopram			S	Unknown			Not Reported
Mania; Mania; Memory	Hydrobromide]			S	Unknown			Not Reported
Impairment; Personality	Cipramil			S	Unknown			Not Reported
Disorder; Quality Of Life	Seroxat			S	Unknown	Unk		Not Reported
Decreased; Restlessness	Seroxat			S	Unknown			Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Valproate Sodium			S	Unknown	Increasing Dose		Not Reported
	Lithionit			C		Unk		Not Reported
	Lithionit			C		Unk		Not Reported

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Sobril		C		Unk Unk, As Needed		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13980670	EXPEDITED (15-DAY)		DE, HO, LT	AT-ORION CORPORATION ORION PHARMA-ENTC2017- 0432		73 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Cardiac Failure; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Stalevo			S	Unknown	Strength: 100/25/200; 1-0-0		Not Reported	
	Stalevo			S	Unknown	Strength: 100/25/200; 1-1-0		Not Reported	
	Stalevo			S	Unknown	Strength: 50/12.5/200 Mg		Not Reported	
	Cipralext			S	Unknown	Strength: 10 Mg; 2-0-0		Not Reported	
	Cipralext			S	Unknown	Strength: 10 Mg; 1-0-0		Not Reported	
	Trittico			S	Unknown	Strength: 150 Mg; 0-0-0.5		Not Reported	
	Azilect			S	Unknown	Strength: 1 Mg; 1-0-0		Not Reported	
	Seroquel			S	Unknown	Strength: 25 Mg		Not Reported	
	Madopar			S	Unknown	Strength: 50/12.5 Mg; 1-1-1		Not Reported	
	Lovenox			C	Unknown	1xtgl		Not Reported	
	Elomel			C	Unknown	1xtgl		Not Reported	
	Optinem			C	Unknown			Not Reported	
	Lasix			C	Unknown			Not Reported	
	Thrombo Ass			C	Unknown	Strength: 100 Mg; 0-1-0		Not Reported	
	Spirobenet			C	Unknown	0-0.5-0		Not Reported	
	Sedacoron			C	Unknown	Strength: 200 Mg; 0.5-0-0		Not Reported	
	Eporatio			C	Unknown	1x/Woche		Not Reported	
	Ceftriaxone Sodium			C	Unknown	2 G In 200 ML, 1xtgl		Not Reported	
	Dancor			C	Unknown	1-0-1		Not Reported	
	Aquaphoril			C	Unknown	0.5-0-0		Not Reported	

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	Toraseamide	C	Unknown	1-0-1		Not Reported
	Pantoloc	C	Unknown	2-0-0		Not Reported
	Insulatard	C	Unknown	61e-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13983111	DIRECT		DS			62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Early Retirement; Neuralgia; Skin Disorder; Withdrawal Syndrome	Escitalopram. 20 Mg			S	Oral	Quantity:1 Tablet(S);		Accord	
	Estradiol			C				Not Reported	
	Progesterone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13983881	EXPEDITED (15-DAY)		HO, LT	PHHY2017FR137081			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Toxicity To Various Agents	Amlodipine			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Aliskiren			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13984794	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1056745		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13985504	DIRECT		DE			88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dizziness; Drug	Eliquis	S	Oral	Quantity:1 Tablet(S);	Not Reported
Interaction; Dyspnoea;	Lexapro	S			Not Reported
Fatigue; Haemorrhagic	Liquis	C			Not Reported
Stroke; Headache;	Levetiracetam (Keppra)	S			Not Reported
Paraesthesia;	Sotalol	C			Not Reported
Unresponsive To Stimuli;	Escitalopram	C			Not Reported
Vomiting	Dorzolamide	C			Not Reported
	Latanoprost	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13378115	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS- 2017-001650		10 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug	Orkambi			S	Oral	2 Df (100/125mg Each), Bid With High Fat Food		Vertex
Interaction; Pulmonary	Lexapro			S	Oral	5 Mg, Daily		Not Reported
Function Test Abnormal	Lexapro			S	Oral	2 Df (10mg Total), Qd		Not Reported
	Remeron			S	Oral	7.5mg Daily		Not Reported
	Actigall			C	Oral	1 Df, Bid		Not Reported
	Sodium Chloride			C	Respiratory (inhalation)	4 MI, Bid		Not Reported
	Miralax			C		Mix With 4-8 Oz Of Feeds, Water Or Juice. Take 2 Capfuls With Overnight Feeds & 1 Capful In Morning.		Not Reported
	Mephyton			C	Oral	0.5 Mg, Qd		Not Reported
	Pediasure			C	Oral	3 Cans Tid. 3 Cans During The Day		Not Reported
	Complete Multi Vit			C	Oral	2 Df, Qd		Not Reported
	Creon			C	Oral	5 Df, At Bedtime. Prior To Overnight Feed Starting 17-Jun-2017		Not Reported
	Creon			C		5 With Meals And 3 With		Not Reported

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Peptamen	C		Snacks	Not Reported
			2 Cans, Qd By G Tube Route	
Humulin R	C	Subcutaneous		Not Reported
Guar Gum	C	Oral	2 Packets Added To Daytime Feeds Or Via G Tube	Not Reported
Flovent Hfa	C	Respiratory (inhalation)	2 Df Inhaled (Oral) W/Spacer, Bid	Not Reported
Flonase	C	Nasal	2 Sprays In Each Nose, Qd	Not Reported
Pulmozyme	C	Respiratory (inhalation)	2.5 MI, Qd	Not Reported
Colace	C	Oral	1 Df, Qd	Not Reported
Periactin	C	Oral	1 Df, Bid	Not Reported
Vitamin D3	C	Oral	2 Df, Qd	Not Reported
Zyrtec	C		1 Df, Bid	Not Reported
Proair Hfa	C	Respiratory (inhalation)	2 Df, Qid, Prn	Not Reported
Proair Hfa	C			Not Reported
Proair Hfa	C			Not Reported
Proventil	C	Respiratory (inhalation)	2.5 Mg, Bid. May Increase To Tid With Illness	Not Reported
Ocean	C	Nasal	2 Sprays By Nostrils, Bid. Use Prior To Treatment And As Needed	Not Reported
Prevacid	C	Oral	2 Df, Qd	Not Reported
Insulin	C	Subcutaneous	1 Syringe Into The Skin Prn (6-8 Times Daily)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13740041	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2017VAL001022		87 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Pemphigoid	Furosemide			S	Oral	Unk		Validus
	Kardegic			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Phosphosorb			S	Oral	660 Mg, Bid		Not Reported
	Inexium			S	Oral	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Uvedose			S	Oral	Unk		Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Galvus			S	Oral	Unk		Not Reported
	Novonorm			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13934568	EXPEDITED (15-DAY)		HO	CN-CIPLA LTD.- 2017CN16014			Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Insomnia	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen
	Olanzapine			S	Unknown	1.25 To 3.75 Mg Per Night		Invagen
	Paroxetine			S	Unknown	30 Mg, Per Day		Not Reported
	Haloperidol			S	Unknown	2 Mg, Per Night		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S	Intravenous (not otherwise specified)	0.5 Mg, Per Day, Infusion		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Per Night, Tablets		Not Reported
	Clonazepam			S	Unknown	10 Mg, Per Qn		Not Reported
	Flupentixol			S	Unknown	Unk		Not Reported
	Melitracen			S	Unknown	Unk		Not Reported
	Tiaprider Hydrochloride			S	Unknown	100 Mg, Per Night		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13985012	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2017GB16187			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13985118	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2017-40133		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Haemorrhoids; Headache; Vulvovaginal Discomfort	Escitalopram			S	Oral			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13986445	EXPEDITED (15-DAY)		HO	JP-LUPIN (EUROPE) LIMITED-2017-05508		63 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Apathy; Diarrhoea; Dyspnoea; Hyperhidrosis; Malaise; Nausea; Palpitations; Weight Increased	Sertraline			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	50 Mg, Unk (Dose Increased)		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Duloxetine			S	Unknown	Unk		Not Reported	
	Paroxetine			S	Unknown	12.5 Mg, Qd		Lupin	
	Paroxetine			S	Unknown	37.5 Mg, Qd		Lupin	
	Paroxetine			S	Unknown	25 Mg, Qd		Lupin	
	Paroxetine			S	Unknown	37.5 Mg, Qd		Lupin	
	Lorazepam			C	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported	

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	Lorazepam	C	Unknown	3.75 Mg, Qd		Not Reported			
	Lorazepam	C	Unknown	0.5 Mg Per Week		Not Reported			
	Bromazepam	C	Unknown	2 Mg, Qd		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13986719	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-03		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Hikma	
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13987994	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2017LAN001045			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carcinoid Syndrome; Condition Aggravated	Escitalopram Oxalate			S	Unknown	20 Mg, Qd, For 16 Days		Lannett	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	10623465	EXPEDITED (15-DAY)		HO, OT	US-SA-2014SA006425		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Aubagio			S	Oral			Not Reported	
Acrophobia; Alopecia;	Aubagio			S	Oral			Not Reported	
Amnesia; Anxiety; Anxiety;	Aubagio			S	Oral			Not Reported	
Arthritis; Back Disorder;	Aubagio			S	Oral			Not Reported	
Back Pain; Balance Disorder; Decreased	Aubagio			S	Oral			Not Reported	
Appetite; Diarrhoea;	Aubagio			S	Oral			Not Reported	
Diverticulitis; Fatigue; Gait	Aubagio			S	Oral			Not Reported	
Disturbance; Gastric Ulcer; Hypersomnia;	Aubagio			S	Oral			Not Reported	

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Hypoaesthesia; Multiple Sclerosis Relapse;	Aubagio	S	Oral	Not Reported
Myalgia; Nasopharyngitis;	Aubagio	S	Oral	Not Reported
Nausea; Pain; Pain; Pain	Aubagio	S	Oral	Not Reported
In Extremity;	Aubagio	S	Oral	Not Reported
Paraesthesia; Product Use Issue; Pruritus; Pruritus	Aubagio	S	Oral	Not Reported
Generalised; Rhinorrhoea;	Aubagio	S	Oral	Not Reported
Sputum Discoloured;	Aubagio	S	Oral	Not Reported
Temperature Intolerance;	Flomax	S	Unknown	Not Reported
Tinnitus; Unevaluable Event; Vision Blurred;	Vesicare	S	Unknown	Not Reported
Vomiting	Lipitor	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	B Complex	S	Unknown	Not Reported
	Vitamin D3	S	Unknown	Not Reported
	Calcium	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Tamsulosin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	10990300	NON-EXPEDITED		OT	US-JNJFOC-20150402828			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Weight Gain; Gynaecomastia; Hyperprolactinaemia; Off Label Use; Product Use In Unapproved Indication; Sexual Dysfunction	Risperdal			S	Oral	From Mar-2004 To Apr-2004, Risperidone 0.5 Mg Twice Daily		Not Reported	
	Risperdal			S	Oral	Risperidone 0.25 Mg Twice Then Increased To 0.5 Mg Twice. Later 0.5 Mg Morning And 0.25 Mg Night		Not Reported	
	Abilify			S	Unknown			Not Reported	

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Zoloft	S	Unknown	Not Reported
Lexapro	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13989690	EXPEDITED (15-DAY)		DS	PHHY2017DK135104		18 YR	Male	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia; Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Sertraline			S	Oral	Variable		Novartis
	Paroxetine Hydrochloride			S	Oral	Variable		Not Reported
	Venlafaxin 1a Pharma			S	Oral	Variable		Not Reported
	Ciprallex			S	Oral	Variable		Not Reported
	Valdoxan			S	Oral	Variable		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13990383	EXPEDITED (15-DAY)		HO	ES-ALLERGAN- 1753522US		64 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Scleroderma	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Abasaglar			S	Subcutaneous	10 Iu, Qd		Not Reported
	Metformin			S	Oral	850 Mg, Tid		Not Reported
	Repaglinida			S	Oral			Not Reported
	Enalapril			S	Oral	1 Df, Qd		Not Reported
	Omeprazol			S	Oral	1 Df, Qd		Not Reported
	Furosemida			C	Oral	1 Df, Bid		Not Reported
	Tryptizol			C	Oral	75 Mg, Tid		Not Reported

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Brinzolamida			C		Ophthalmic	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13990408	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1752459US		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypersensitivity; Pharyngeal Swelling	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	12781558	NON-EXPEDITED			US-ALLERGAN-1663612US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Sucralfate Unk			S	Oral			Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13881626	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1735554US		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ehlers-Danlos Syndrome; Pain	Escitalopram Oxalate 20mg Tab (Tbd)			S	Oral	20 Mg, Qd		Allergan	
	Gabapentin			C	Oral	200 Mg, Tid		Not Reported	
	Fluocinonide			C	Topical	Unk		Not Reported	
	Hydrocodone Bitartrate And Acetaminophen			C	Oral	Unk Unk, Prn		Not Reported	
	Ketoconazole			C	Topical	Unk		Not Reported	
	Benadryl			C	Oral	25 Mg, Qhs		Not Reported	
	Dutasteride			C	Oral	0.5 Mg, Qd		Not Reported	
	Tretinoin			C	Topical			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13948535	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC- 2017SUN00309		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Daily		Taro
	Dextromethorphan-Promethazine			S	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported
	Labetalol			C	Unknown	100 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13995499	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-016662		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree; Chest Discomfort; Cognitive Disorder; Cough; Decreased Appetite; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Hallucination, Auditory; Hallucination, Visual; Leukocytosis; Mental Disorder; Mental Status Changes; Muscle Twitching; Myoclonus; Pain; Poor Quality Sleep; Respiratory Acidosis; Restlessness; Serotonin Syndrome; Sleep Talking; Tongue Biting; Unresponsive To Stimuli; Viral Upper Respiratory	Escitalopram			S	Unknown			Zybus Pharm
	Dextromethorphan/Promethazine			S	Unknown			Not Reported
	Naltrexone			C	Intramuscular			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Labetalol			C	Unknown			Not Reported

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Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13995707	NON-EXPEDITED			US-PFIZER INC-2017406959			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Tikosyn			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13997166	EXPEDITED (15-DAY)		HO, OT	US-NAPPMUNDI-USA-2017-0140816			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Insomnia; Neck Surgery	Oxycodone Hcl Cr Tablets (Similar To Nda 22-272)			S	Oral	80 Mg, Bid		Purdue	
	Hydrocodone Bitartrate/Acetaminophen			S	Oral	7.5/325 Mg, 2-3 A Day		Unknown	
	Hydrocodone Bitartrate/Acetaminophen			S	Oral	7.5/325 Mg, 6 Times A Day		Unknown	
	Savella			S	Unknown	100 Mg, Daily		Not Reported	
	Savella			S				Not Reported	
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported	
	Alprazolam			S	Unknown	0.5 Mg, Prn		Not Reported	
	Dicyclomine /00068601/			C	Unknown	10 Mg, Qid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13997359	EXPEDITED (15-DAY)		HO, OT	US-TEVA-808580USA		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Citalopram			S	Unknown			Actavis	
	Fentanyl			S	Unknown			Not Reported	
	Methylthioninium Chloride			S	Unknown			Not Reported	

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	Escitalopram	S	Unknown	10 Milligram Daily;	Not Reported
	Midazolam	C	Unknown		Not Reported
	Rocuronium Bromide	C	Unknown		Not Reported
	Dexmedetomidine	C	Unknown		Not Reported
	Etomidate	C	Unknown		Not Reported
	Norepinephrine	C	Unknown		Not Reported
	Epinephrine	C	Unknown		Not Reported
	Milrinone	C	Unknown		Not Reported
	Vancomycin	C	Unknown		Not Reported
	Cefepime	C	Unknown		Not Reported
	Fluconazole	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13997670	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1754109US		35 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Chills;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
Dizziness; Headache;	Thyroxine			C	Unknown	Unk		Not Reported	
Nausea; Norepinephrine									
Increased; Paraesthesia;									
Pyrexia; Tachycardia									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13998458	EXPEDITED (15-DAY)		CA, OT	IL-GLAXOSMITHKLINE-IL2017GSK142624			Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Talipes	Lamotrigine			S	Transplacental	200 Mg, Qd		Glaxosmithkline	
	Escitalopram			S	Transplacental			Glaxosmithkline	
	Folic Acid			S	Transplacental			Glaxosmithkline	
	Desipramine			S	Transplacental			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13555506	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1719863US		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Bipolar Disorder; Confusional State; Depression; Disturbance In Attention; Fatigue; Feeling Abnormal; Flashback; Impaired Quality Of Life; Influenza; Loss Of Employment; Mental Impairment; Morbid Thoughts; Night Blindness; Nightmare; Paraesthesia; Partner Stress; Post-Traumatic Stress Disorder; Renal Impairment; Sleep Disorder; Social Avoidant Behaviour; Suicidal Behaviour; Visual Impairment; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13903165	EXPEDITED (15-DAY)		HO	PHHY2017FR122536		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Not Reported	
	Prednisone			S	Oral	40 Mg, Qd		Not Reported	
	Prednisone			S	Oral	80 Mg, Qd (Morning)		Not Reported	
	Prednisone			S	Oral	60 Mg, Qd (Morning)		Not Reported	
	Prednisone			S	Oral	20 Mg, Qd (Morning)		Not Reported	
	Prednisone			S	Oral	40 Mg, Qd		Not Reported	

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Prednisone	S	Oral	20 Mg, Qd	Not Reported
Escitalopram	S	Oral	10 Mg, Qd (In The Morning)	Not Reported
Alprazolam	S	Oral	0.125 Mg, Qd (At Bed Time)	Not Reported
Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
Tramadol	S	Oral	50 Mg, Tid	Novartis
Paracetamol	S	Oral	1 G, Tid Prn	Not Reported
Seroplex	S	Oral	Unk	Not Reported
Lyrica	S	Oral	50 Mg, Unk	Not Reported
Hexomedine	S	Transdermal	Unk	Not Reported
Coltramyl	S	Oral	2 Df, Bid	Not Reported
Acupan	S	Oral	20 Mg, Q6h	Not Reported
Skenan	S	Oral	10 Mg, Bid (Midday And Evening)	Not Reported
Skenan	S	Oral	30 Mg, Bid (Midday And Evening)	Not Reported
Actiskenan	S	Oral	5 Mg, Q4h Prn	Not Reported
Actiskenan	S	Oral	10 Mg, 1 Df To 4 Df Daily	Not Reported
Actiskenan	S	Oral	10 Mg, Q6h Prn	Not Reported
Actiskenan	S	Oral	5 Mg, Q4h Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13928639	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00003318		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram			S				Unknown
Electrocardiogram Qt	Dextromethorphan/Promethazine			S				Unknown
Prolonged; Seizure;	Amlodipine Besilate			C				Unknown
Serotonin Syndrome	Labetalol Hydrochloride			C				Unknown

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Naltrexone Hydrochloride			C			Unknown			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13965920	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1056462		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Dextromethorphan			S	Unknown	Unk		Mylan	
	Promethazine			C	Unknown	Unk		Mylan	
	Amlodipine			C	Unknown	5 Mg, Qd		Mylan	
	Labetalol			C	Unknown	100 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13999926	EXPEDITED (15-DAY)		OT	FR-TEVA-807527ROM		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Dissociative Identity Disorder; Dyspnoea; Suicidal Ideation	Escitalopram Teva 20 Mg			S				Not Reported	
	Escitalopram Teva 20 Mg			S		10 Milligram Daily;		Not Reported	
	Bisoprolol Teva 10 Mg			S		1 Dosage Forms Daily;		Duramed	
	Indapamide Teva Sante			S		1 Dosage Forms Daily;		Actavis	
	Lercanidipine Teva Sante 10 Mg			S		2 Dosage Forms Daily;		Not Reported	
	Mianserine Teva 10 Mg			S		1 Dosage Forms Daily;		Not Reported	
	Inexium 40 Mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	14002018	EXPEDITED (15-DAY)		DS	DK-TEVA-806608ACC		18 YR	Male	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia;	Sertraline			S	Oral	Dosage: Varying		Not Reported	
	Paroxetine			S	Oral	Dosage: Varying		Teva	
	Ciprallex			S	Oral	Dosage: Varying		Not Reported	

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Dyspnoea; Emotional Disorder; Head Discomfort; Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder; Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Venlafaxin 1a Farma	S	Oral	Dosage: Varying	Not Reported
	Valdoxan	S	Oral	Dosage: Varying	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	14004698	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004156		35 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Feeling Guilty; Headache; Logorrhoea; Somnolence; Suicidal Ideation; Weight Increased	Respidon			S				Unknown
	Rivotril			C				Unknown
	Lithium Carbonate			C				Unknown
	Escitalopram Oxalate			S				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2017	14007133	DIRECT		HO, OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Loss Of Personal Independence In Daily Activities; Psychotic Disorder	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2017	14006181	EXPEDITED (15-DAY)		DS	DK-MYLANLABS-2017M1057997		18 YR	Male	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anxiety; Arthralgia; Body Temperature Fluctuation; Constipation; Dyspepsia;	Sertraline Mylan			S	Oral	Dosis: Varierende		Mylan
	Ciprallex			S	Oral	Dosis: Varierende		Mylan

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Dyspnoea; Emotional Disorder; Head Discomfort;	Venlafaxin	S	Oral	Dosis: Varierende	Mylan
Hyperaesthesia; Middle Insomnia; Muscle Tightness; Nervous System Disorder;	Valdoxan	S	Oral	Dosis: Varierende	Mylan
Paraesthesia; Stress; Tearfulness; Withdrawal Syndrome	Paroxetine	S	Oral	Dosis: Varierende	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13850740	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017339537		62 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Lyrica			S	Oral	50 Mg, Unk		Pfizer
	Alprazolam			S	Oral	Unk		Pfizer
	Alprazolam			S	Oral	0.125 Mg, 1x/Day		Pfizer
	Prednisone			S	Oral	40 Mg, Daily		Not Reported
	Prednisone			S		80 Mg, 1x/Day		Not Reported
	Prednisone			S		60 Mg, Daily		Not Reported
	Prednisone			S		20 Mg, Unk		Not Reported
	Prednisone			S		40 Mg, Daily		Not Reported
	Prednisone			S		20 Mg, Daily		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day, Morning		Not Reported
	Voltarene (Diclofenac Sodium)			S	Oral	15 Mg, Unk		Not Reported
	Lansoprazole			S	Oral	15 Mg, 1x/Day		Not Reported
	Tramadol Hydrochloride			S	Oral	50 Mg, 3x/Day		Not Reported
	Hexomedine /00799702/			S	Cutaneous	Unk		Not Reported
	Coltramyl			S	Oral	2 Df, 2x/Day		Not Reported
	Acupan			S	Oral	20 Mg, Every 6h		Not Reported

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Skenan	S	Oral	10 Mg, 2x/Day	Not Reported
Skenan	S		30 Mg, 2x/Day	Not Reported
Skenan	S		30 Mg, 2x/Day	Not Reported
Actiskenan	S	Oral	5 Mg, Every 4h As Needed	Not Reported
Actiskenan	S		10 Mg, 1 Up To 4/Day	Not Reported
Actiskenan	S		10 Mg, As Needed, Every 6h	Not Reported
Paracetamol	S	Oral	1 G, 3 Times A Day As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13861451	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1733980US		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Prescription Drug Used Without A Prescription; Psychotic Behaviour; Rib Fracture; Self-Injurious Ideation	Escitalopram Oxalate 20mg Tab (Tbd)			S	Unknown	20 Mg, Unknown		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13905891	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2017GSK131441		62 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd, Morning		Glaxosmithkline
	Lansoprazole			S	Oral	15 Mg, Qd		Glaxosmithkline
	Lansoprazole			S	Oral	15 Mg, Qd		Glaxosmithkline
	Paracetamol			S	Oral	1 G, Tid Prn		Glaxosmithkline
	Seroplex			S	Oral	Unk		Glaxosmithkline
	Skenan			S	Oral	10 Mg, Bid, Midday And Evening		Glaxosmithkline

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Skenan	S	Oral	30 Mg, Bid, Midday And Evening	Glaxosmithkline
Actiskenan	S	Oral	5 Mg, Q4h Prn	Glaxosmithkline
Actiskenan	S	Oral	10 Mg, 1 Df To 4 Df Daily	Glaxosmithkline
Actiskenan	S	Oral	10 Mg, Q6h Prn	Glaxosmithkline
Actiskenan	S	Oral	5 Mg, Q4h Prn	Glaxosmithkline
Prednisone	S	Oral	40 Mg, Qd	Not Reported
Prednisone	S	Oral	80 Mg, Qd, Morning	Not Reported
Prednisone	S	Oral	60 Mg, Qd, Morning	Not Reported
Prednisone	S	Oral	20 Mg, Qd, Morning	Not Reported
Prednisone	S	Oral	40 Mg, Qd	Not Reported
Prednisone	S	Oral	20 Mg, Qd	Not Reported
Alprazolam	S	Oral	0.125 Mg, Qd, At Bed Time	Not Reported
Tramadol	S	Oral	50 Mg, Tid	Not Reported
Lyrca	S	Oral	50 Mg, Unk	Not Reported
Hexomedine (Hexamidine Isethionate)	S	Transdermal	Unk	Not Reported
Coltramyl	S	Oral	2 Df, Bid	Not Reported
Acupan	S	Oral	20 Mg, Q6h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13945189	EXPEDITED (15-DAY)		DS	DE-TORRENT-00007032		25 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Libido Decreased; Male Orgasmic Disorder	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13974081	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2017ES16206			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased	Olanzapine			S	Unknown	10 Mg, Daily		Invagen
	Olanzapine			S	Unknown	15 Mg, Daily		Invagen
	Olanzapine			S	Unknown	5 Mg, Daily		Invagen
	Risperidone			S	Unknown	3 Mg, Daily		Cipla
	Escitalopram			S	Unknown	5 Mg, Per Day		Invagen
	Mirtazapine			S	Unknown	60 Mg, Daily		Cipla
	Quetiapine			S	Unknown	50 Mg, Daily		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S	Unknown	1200 Mg, Daily		Not Reported
	Fluvoxamine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	14008381	DIRECT		DS			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Memory Impairment	Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	13754360	EXPEDITED (15-DAY)		HO	FR-MERCK KGAA-2023361		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Pemphigoid	Novothyrox			S	Oral			Merck Kgaa
	Paracetamol			S				Not Reported
	Phosphosorb			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Lasilix Special			S				Not Reported
	Seroplex			S				Not Reported
	Uvedose			S	Oral			Not Reported

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Galvus	S	Oral	Not Reported
Novonorm	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14010516	EXPEDITED (15-DAY)		DS	DK-AUROBINDO-AUR- APL-2017-40865			Unknown	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Sertraline Film-Coated Tablet			S	Oral			Aurobindo
Aggression; Anxiety;	Paroxetine Film-Coated Tablet			S	Oral			Aurobindo
Arthralgia; Body	Cipralex /01588501/			S	Oral			Not Reported
Temperature Fluctuation;	Venlafaxin 1a Pharma			S	Oral			Not Reported
Constipation; Crying;	Valdoxan			S	Oral			Not Reported
Dyspnoea; Emotional								
Poverty; Functional								
Gastrointestinal Disorder;								
Hyperaesthesia; Middle								
Insomnia; Muscle								
Tightness; Nervous								
System Disorder; Pain;								
Paraesthesia; Stress;								
Tension; Withdrawal								
Syndrome								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14015205	EXPEDITED (15-DAY)		DS	DK-ALLERGAN- 1754592US		18 YR	Male	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram Oxalate - Bp			S	Oral	Dose: Varying		Allergan
Anxiety; Arthralgia; Body	Venlafaxin "1a Farna"			S	Oral	Dose: Varying		Not Reported
Temperature Fluctuation;	Valdoxan			S	Oral	Dose: Varying		Not Reported
Constipation; Dyspepsia;	Sertraline			S	Oral	Dose: Varying		Not Reported
Dyspnoea; Emotional	Paroxetine			S	Oral	Dose: Varying		Not Reported
Disorder; Head								
Discomfort;								
Hyperaesthesia; Middle								
Insomnia; Muscle								
Tightness; Nervous								
System Disorder;								

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Paraesthesia; Stress;
Tearfulness; Withdrawal
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14015670	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-150822		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased; Somnolence	Clozapine			S	Unknown	200 Mg, Daily		Sun
	Clozapine			S	Unknown	400 Mg, Daily		Sun
	Aripiprazole			S	Unknown	Unk		Not Reported
	Divalproex			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14015688	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-150798		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Obstructive Pulmonary Disease; Drug Interaction; Drug Level Increased; Hypotension; Mental Status Changes	Clozapine			S	Unknown	200 Mg, Daily		Sun
	Clozapine			S	Unknown	450 Mg, Daily		Sun
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14015704	NON-EXPEDITED		OT	US-APOTEX- 2017AP018814		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Ineffective	Citalopram			S	Unknown			Apotex
	Escitalopram Oxalate			S	Unknown			Apotex

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Bupropion Hydrochloride	S	Unknown		Apotex
Mirtazapine	S	Unknown	Unk	Apotex
Paroxetine	S	Unknown	Unk	Apotex
Sertraline Hydrochloride	S	Unknown	Unk	Apotex
Lamotrigine	S	Unknown		Apotex
Lithium Carbonate	S	Unknown		Apotex
Risperidone	S	Unknown		Apotex
Quetiapine Fumarate	S	Unknown		Apotex
Methylphenidate	S	Transdermal		Apotex
Modafinil Tablets Usp	S	Unknown		Apotex
Trazodone Hydrochloride	S	Unknown		Apotex
Buspirone Hydrochloride Tablets Usp	S	Unknown	Unk	Apotex
Venlafaxine	S	Unknown		Not Reported
Amphetamine W/Dexamphetamine	S	Unknown		Not Reported
Diazepam	S	Unknown		Not Reported
Chlordiazepoxide	S	Unknown		Not Reported
Lorazepam	S	Unknown	Unk	Not Reported
Temazepam	S	Unknown		Not Reported
Prazosin	S	Unknown		Not Reported
Hydroxyzine	S	Unknown		Not Reported
Pyridostigmine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14016838	EXPEDITED (15-DAY)		HO, OT	ES- ELI_LILLY_AND_COMP ANY-ES201709005754			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Interstitial Lung Disease; Peripheral Sensory Neuropathy; Pneumonia; Scleroderma	Abasaglar			S	Subcutaneous	10 lu, Daily		Not Reported	
	Metformin			S	Oral	850 Mg, Tid		Not Reported	
	Repaglinide			S	Oral	10 Mg, Daily		Not Reported	

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Esertia	S	Oral	10 Mg, Daily	Not Reported
Enalapril	S	Oral	Unk, Prn	Not Reported
Omeprazole	S	Oral	1 Df, Daily	Not Reported
Furosemida /00032601/	C	Oral	Unk, Bid	Not Reported
Tryptizol /00002202/	C	Oral	75 Mg, Tid	Not Reported
Brinzolamide	C	Ophthalmic	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14017049	EXPEDITED (15-DAY)			US-MORTON GROVE PHARMACEUTICALS, INC.-2027948		63 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Promethazine With Dextromethorphan Naltrexone Hydrochloride Amlodipine Labetalol Escitalopram			S C C C S				Morton Grove Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14017158	EXPEDITED (15-DAY)		HO	SG-MYLANLABS- 2017M1059781		32 YR	Male	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hyperkalaemia; Muscle Necrosis; Rhabdomyolysis	Escitalopram			S	Unknown	Every Night		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2017	14017169	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2017PRN00452		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block; Drug Interaction;	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical	

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Respiratory Distress; Serotonin Syndrome	Dextromethorphan- Promethazine	S	Unknown	Unk	Not Reported
	Dextromethorphan- Promethazine	S			Not Reported
	Dextromethorphan- Promethazine	S			Not Reported
	Amlodipine	C	Unknown	5 Mg, 2x/Day	Not Reported
	Labetalol	C	Unknown	100 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	13629903	EXPEDITED (15-DAY)		OT	ES-TEVA-775434ROM		42 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autism Spectrum Disorder; Condition Aggravated; Hepatic Enzyme Increased	Escitalopram			S	Unknown	Initial Dose Not Stated; Last Dose 5 Mg/Day Was Continued		Ivax
	Escitalopram			S				Ivax
	Mirtazapine			S	Unknown	60 Milligram Daily;		Teva
	Mirtazapine			S	Unknown			Teva
	Olanzapine 10 Mg			S	Unknown	10 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	20 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	5 Milligram Daily;		Teva
	Olanzapine 10 Mg			S	Unknown	15 Milligram Daily;		Teva
	Omega-3-Fatty-Acid			S	Unknown	700 Mg/Day, The Dose Was Further Increased To Double The Previous Dose		Teva
	Omega-3-Fatty-Acid			S	Unknown	Double The Previous Dose Of 700 Mg/Day		Teva
	Quetiapine			S	Unknown	50 Milligram Daily;		Teva
	Quetiapine			S	Unknown			Teva
	Risperidone			S	Unknown	3 Milligram Daily;		Pliva
	Risperidone			S	Unknown			Pliva
	Fluvoxamine			S	Unknown			Not Reported

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Fluvoxamine		S						Not Reported	
Carbamazepine		S		Unknown		Up To 1200 Mg/ Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14013937	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1058422		82 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Mylan Escitalopram 10			S	Oral	10 Mg, Unk		Mylan	
	Co-Tareg			S	Oral	Unk		Mylan	
	Lyrica			S	Oral	75 Mg, Unk		Mylan	
	Tellerge			S	Oral	120 Mg, Unk		Mylan	
	Navalpro			S	Oral	200 Mg, Unk		Mylan	
	Xefo Rapid			S	Oral	8 Mg, Unk		Mylan	
	Ganfort			S	Oral	5 MI, Unk		Mylan	
	Synaleve /01057301/			S	Oral	Unk		Mylan	
	Movicol			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14018881	EXPEDITED (15-DAY)		HO, OT	SG-ACCORD-059189		32 YR	Male	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Necrosis; Rhabdomyolysis	Escitalopram			S		Every Night		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14019391	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1754953US		36 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Anxiety; Asthenia; Balance Disorder; Dizziness; Dry Mouth; Dysphagia;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Lactibiane			C	Unknown			Not Reported	
	Zinc			C	Unknown			Not Reported	

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Epigastric Discomfort; Feeling Abnormal; Feeling Cold; Feeling Hot; Loss Of Consciousness; Myalgia; Nausea; Nervousness; Ocular Discomfort; Paraesthesia; Paraesthesia Oral; Productive Cough; Somnolence; Tremor	Xanax	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14019405	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754573US		41 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Level Above Therapeutic; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Baclofen			S	Oral	18 Df, Qd		Not Reported
	Seresta			S	Oral	30 Mg, Qd		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14019406	EXPEDITED (15-DAY)		HO, OT	SG-ALLERGAN-1754316US		32 YR	Male	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Necrosis; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14019409	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754599US		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Faecaloma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan

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Escitalopram Oxalate - Bp	S	Oral	15 Mg, Qd	Allergan
Risperidone	S	Oral		Not Reported
Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
Mirtazapine	S	Oral	30 Mg, Qd	Not Reported
Seresta	S	Oral	10 Mg, Qd	Not Reported
Seresta	S	Oral	50 Mg, Qd	Not Reported
Noctamide	S	Oral	2 Mg, Qd	Not Reported
Mianserine	C	Oral	30 Mg, Qd	Not Reported
Mianserine	C	Oral	60 Mg, Qd	Not Reported
Macrogol 4000 Mylan	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14019963	NON-EXPEDITED			US-ALLERGAN-1747746US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Bladder Pain; Feeling Jittery; Irritability; Mood Swings	Vraylar			S	Oral	1.5 Mg, Qd		Allergan
	Vraylar			S				Allergan
	Lexapro			S	Oral	20 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14021651	DIRECT		OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness Postural; Hypotension; Presyncope	Escitalopram (Lexapro)			S	Oral	15 Mg And 20 Mg 1 Pill Per Day By Mouth		Not Reported
	Simvastatin			C				Not Reported
	Trazodone			C				Not Reported
	Fish Oil			C				Not Reported
	E			C				Not Reported
	Saw Palmetto			C				Not Reported
	Chondroitin			C				Not Reported
	Magnesium			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2017	14022338	EXPEDITED (15-DAY)		CA	CH-ALLERGAN-1755488US		2 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract Congenital; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	13159235	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2017TUS001860			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation	Trintellix			S	Unknown	20 Mg, Unk		Takeda	
	Cipralext /01588501/			S	Unknown	Unk		Not Reported	
	Cipralext /01588501/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	13159678	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2017TUS001946			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation	Trintellix			S	Unknown	20 Mg, Unk		Takeda	
	Cipralext /01588501/			S	Unknown	Unk		Not Reported	
	Cipralext /01588501/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	13909553	NON-EXPEDITED			US-PFIZER INC-2017358715		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Effexor Xr			S	Oral	150 Mg (75 Mg Two Tablets) Daily		Pfizer	

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Effexor Xr	S	Oral	"187" Mg Daily	Pfizer
Venlafaxine Hcl	S	Oral	Unk	Pfizer
Zoloft	S	Oral	Unk	Pfizer
Gabapentin	S	Oral	Unk	Pfizer
Sildenafil Citrate	S	Oral	Unk	Pfizer
Ketamine Hcl	S	Oral	Unk	Not Reported
Mirtazapine	S	Oral	Unk	Not Reported
Clonazepam	S	Oral	Unk	Not Reported
Trazodone Hcl	S	Oral	50 Mg, 1x/Day (50mg At Night)	Not Reported
Fentanyl	S	Oral	Unk	Not Reported
Fentanyl	S	Transdermal	Unk	Not Reported
Fluoxetine Hcl	S	Oral	Unk	Not Reported
Lithium	S	Oral	Unk	Not Reported
Wellbutrin	S	Oral	Unk	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Buspirone	S	Oral	Unk	Not Reported
Abilify	S	Oral	Unk, 1x/Day At Night	Not Reported
Dextroamphetamine	S	Oral	50 Mg, 1x/Day	Not Reported
Suboxone	S	Oral	Unk	Not Reported
Famotidine	C		Unk (Dosage Via Tpn)	Not Reported
Iron & Vitamin C	C		Unk	Not Reported
Ibuprofen	C		Unk, As Needed	Not Reported
Excedrin	C		Unk, As Needed	Not Reported
Vitamin B12	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14008603	EXPEDITED (15-DAY)		HO, OT	NO-ELI_LILLY_AND_COMP ANY-NO201709005156		35 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Accident; Aggression;	Zyprexa	S	Unknown	Unk, Unknown	Eli Lilly And Co
Depression; Depression;	Olanzapine	S	Unknown	Unk, Unknown	Eli Lilly And Co
Disturbance In Attention;	Seroquel	S	Unknown	Unk	Not Reported
Dizziness; Irritability;	Seroquel	S	Unknown	Unk	Not Reported
Mania; Memory	Seroquel	S	Unknown	Unk, Unknown	Not Reported
Impairment; Restlessness	Seroquel	S	Unknown	Unk	Not Reported
	Cipralext /01588501/	S	Unknown	Unk, Daily	Not Reported
	Valproat	S	Unknown	Unk, Unknown	Not Reported
	Efexor	S	Unknown	Unk, Unknown	Not Reported
	Efexor	S	Unknown	Unk	Not Reported
	Efexor	S	Unknown	Unk	Not Reported
	Seroxat	S	Unknown	Unk, Unknown	Not Reported
	Seroxat	S	Unknown	20 Mg, Daily	Not Reported
	Seroxat	S	Unknown	20 Mg, Daily	Not Reported
	Orfiril	S	Unknown	Unk, Unknown	Not Reported
	Lamictal	S	Unknown	Unk, Unknown	Not Reported
	Lithionit	C	Unknown	Unk	Not Reported
	Lithionit	C	Unknown	Unk, Unknown	Not Reported
	Lithionit	C	Unknown	Unk	Not Reported
	Sobril	C	Unknown	Unk, Prn	Not Reported
	Cannabis	C		Unk	Not Reported
	Alcohol	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14024499	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1754955US		60 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Inexium			C	Unknown	20 Mg,		Not Reported	

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Levothyrox	C	Unknown	75 Ug	Not Reported
Forlax	C	Unknown		Not Reported
Paracetamol	C	Unknown		Not Reported
Gliclazide	C	Unknown	60, Mg, Tid	Not Reported
Gliclazide	C	Unknown		Not Reported
Fosinopril	C	Unknown		Not Reported
Atorvastatin	C	Unknown		Not Reported
Metformine	C	Unknown	1000, Mg	Not Reported
Lantus	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14024595	EXPEDITED (15-DAY)		DE, LT	PHHY2017US142131		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence	Loperamide			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Meloxicam			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14024764	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017415114		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Quetiapine			S		Unk		Not Reported	
	Bupropion			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14025798	NON-EXPEDITED			US-PFIZER INC-2017419686			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14025847	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017006008			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death; Maternal Exposure During Pregnancy	Escitalopram			S	Oral	15 Mg, Qd, (Gestational Period At The Time Of Exposure:1 Trimester, 0. - 35.6. Gestational Week)		Macleods
	Cefuroxim			C	Oral	Unk, (Gestational Period At The Time Of Exposure : 2 Trimester, 24.4. - 25.6. Gestational Week)		Not Reported
	Kadefungin			C	Vaginal	Unk, (Unknown Trimester)		Not Reported
	Salbutamol			C	Respiratory (inhalation)	Prn (Unknown Trimester)		Not Reported
	Folsäure			C	Oral	Unk, (1 Trimester, 0. - 24.4. Gestational Week)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14026689	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1754094US		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Pemphigoid	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Phosphosorb			S	Oral	660 Mg, Bid		Not Reported
	Kardegic			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Lasilix Special			S	Unknown			Not Reported

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Uvedose	S	Oral	100000 Units, Unk	Not Reported
Levothyrox	S	Oral		Not Reported
Galvus	S	Oral		Not Reported
Paracetamol	S	Oral		Not Reported
Novonorm	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14027504	EXPEDITED (15-DAY)		HO, OT	SG-LUPIN PHARMACEUTICALS INC.-2017-05664		32 YR	Male	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Necrosis; Rhabdomyolysis	Escitalopram			S	Unknown	15 Mg, Qd (Every Night)		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	12611609	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2016363715		39 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Phenytoin			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Olanzapine			S		Unk		Not Reported	
	Quetiapine			S				Not Reported	
	Bupropion			S		Unk		Not Reported	
	Primidone			S		Unk,		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14029519	NON-EXPEDITED		OT	US-JAZZ-2017-US- 010651			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Somnolence; Suicidal Ideation	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	2.25 G, Bid		Jazz	

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	Xyrem	S	Oral	Dose Adjustment	Jazz
	Xyrem	S	Oral	1 G, Bid	Jazz
	Lexapro	S			Not Reported
	Adderall	C			Not Reported
	Amitriptyline Hcl	C			Not Reported
	Effexor	C			Not Reported
	Enpresse-28	C			Not Reported
	Cymbalta	C			Not Reported
	Advil /00044201/	C			Not Reported
	Trivora	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14029884	NON-EXPEDITED			US-PFIZER INC-2017419489		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Sertraline Hcl			S		150 Mg, Unk		Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Mirtazapine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14030275	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1060086		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Death	Escitalopram			S	Oral	15 [Mg/D]		Not Reported	
	Cefuroxim			C	Oral			Mylan	
	Kadefungin			C	Vaginal			Mylan	
	Salbutamol			C	Respiratory (inhalation)	If Required		Mylan	
	Folsaeure			C	Oral			Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14031471	EXPEDITED (15-DAY)		OT	DE-TEVA-809023GER			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Death	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Cefuroxim			C	Oral			Not Reported	
	Kadefungin			C	Vaginal			Not Reported	
	Salbutamol			C	Respiratory (inhalation)	If Required		Not Reported	
	Folsaeure			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14032467	EXPEDITED (15-DAY)		HO, OT	US-JUBILANT CADISTA PHARMACEUTICALS-2017JUB00341		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Respiratory Distress; Serotonin Syndrome	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant	
	Dextromethorphan-Promethazine			S	Unknown			Not Reported	
	Dextromethorphan-Promethazine			S				Not Reported	
	Dextromethorphan-Promethazine			S				Not Reported	
	Amlodipine			C	Unknown	5 Mg, 2x/Day		Not Reported	
	Labetalol			C	Unknown	100 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	13958852	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1751116US		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Abuse; Coma; Drug Use Disorder; Hypotension; Intentional	Escitalopram Oxalate - Bp			S	Oral	15 Gtt, Unk		Allergan	
	Halcion			S	Oral			Not Reported	

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Self-Injury	Alprazolam		S		Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14007628	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1058990		70 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Drug Abuse; Hallucinations, Mixed; Overdose	Escitalopram			S	Oral	110 Gtt, Total			Not Reported
	Alprazolam			S		0.25 Mg, Pm			Not Reported
	Plendil			S		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14024520	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1755151US		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Confusional State; Decreased Appetite; Gait Disturbance; Hallucination; Parkinsonian Gait; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown			Allergan
	Azilect			S	Oral	1 Mg, Qd			Not Reported
	Stalevo			C	Unknown	Unk, Unknown			Not Reported
	Modopar			C	Unknown	Unk, Unknown			Not Reported
	Moduretic			C	Unknown	Unk, Unknown			Not Reported
	Levothyrox			C	Unknown	Unk, Unknown			Not Reported
	Ciprofibrate			C	Unknown				Not Reported
	Prazepam			C	Unknown				Not Reported
	Esomeprazole			C	Unknown				Not Reported
	Allopurinol			C	Unknown				Not Reported
	Xarelto			C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14032556	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-151160			Female	ESP

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Anxiety; Dyskinesia; Dyskinesia; Therapeutic Product Effect Incomplete	Venlafaxine			S	Unknown	75-150 Mg / Day		Sun	
	Venlafaxine			S				Sun	
	Olanzapine			S	Unknown	5 Mg, Daily		Sun	
	Olanzapine			S				Sun	
	Escitalopram			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Sun	
	Mirtazapine			S	Unknown			Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14033788	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2017-41140		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Death	Escitalopram			S	Oral	15 Mg, Once A Day		Aurobindo	
	Cefuroxim /00454602/			C	Oral	Unk		Not Reported	
	Kadefungin			C	Vaginal			Not Reported	
	Salbutamol			C				Not Reported	
	Folsaeure			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14035634	EXPEDITED (15-DAY)		HO	DK-ALLERGAN-1755493US		46 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Chronic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	12186603	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-113087		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Apnoea; Coma; Drug Interaction; Myoclonus; Neuroleptic Malignant Syndrome	Clozapine	S	Unknown	Unk	Sun
	Risperdal Consta	S	Intramuscular	Unk	Not Reported
	Risperdal Consta	S	Intramuscular	50 Mg, Fortnight (Every 14 Days)	Not Reported
	Seroplex	S	Unknown	20 Mg, Daily	Not Reported
	Theralene	S	Unknown	20 Gtt, Prn (At Night)	Not Reported
	Loxapac	C	Unknown	300 Mg, Daily	Not Reported
	Seresta	C	Unknown	10 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	12538226	EXPEDITED (15-DAY)		HO, LT, OT	FR-FRI-1000085907		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Apnoea; Clonus; Coma; Disease Recurrence; Drug Interaction; Hyperhidrosis; Hypertonia; Loss Of Consciousness; Muscle Rigidity; Myoclonus; Neuroleptic Malignant Syndrome; Off Label Use; Pulmonary Embolism; Pyrexia; Salivary Hypersecretion; Status Epilepticus; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Seresta			S	Unknown	10 Mg, Qd		Not Reported
	Theralene			S	Unknown	20 Gtt, Qhs If Needed		Not Reported
	Clozapine			S	Unknown	Unk		Not Reported
	Risperdal Consta			S	Intramuscular	50 Mg, Single (Q2weeks)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	13926727	EXPEDITED (15-DAY)		DE	FR-TAKEDA-2017TUS018236		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Brintellix			S	Oral	20 Mg, Qd		Takeda
	Seroplex			S	Oral	20 Mg, Qd		Not Reported

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Seroplex	S	Oral	10 Mg, Qd	Not Reported
Depakote	C	Unknown	1 G, Qd	Not Reported
Olanzapine	C	Unknown	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	14036995	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2017DE00227		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Death	Escitalopram			S	Oral	15 Mg, Qd		Hetero	
	Cefuroxim /00454602/			C	Oral	Unk		Not Reported	
	Kadefungin			C	Vaginal			Not Reported	
	Salbutamol			C	Topical			Not Reported	
	Folic Acid			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	14038070	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00007163		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Death	Escitalopram			S				Unknown	
	Cefuroxime			C				Unknown	
	Kadefungin			C				Unknown	
	Salbutamol			C				Unknown	
	Folsaure			C				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	14038207	EXPEDITED (15-DAY)		OT	GB-ALLERGAN- 1756117US			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Mood Swings; Suicidal Ideation; Tearfulness	Escitalopram Oxalate - Bp			S	Unknown	20 Unk, Unk		Allergan	
	Priadel			C	Unknown			Not Reported	
	Lamotrigine			C	Unknown			Not Reported	

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04-Oct-2017	14038448	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756180US		28 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Death	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Cefuroxim			C	Oral			Not Reported	
	Kadefungin			C	Unknown			Not Reported	
	Salbutamol			C	Respiratory (inhalation)			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	14045067	DIRECT		HO			34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Logorrhoea	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Risperidone			C				Not Reported	
	Bc Powder			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	13656651	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017261732		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral	10 Ml, Total		Pfizer	
	Escitalopram Oxalate			S	Oral	6 Df, Total		Not Reported	
	Carbolithium			C				Not Reported	
	Quetiapine Fumarate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	13965056	EXPEDITED (15-DAY)		HO	IT-TEVA-804857ACC		28 YR	Female	ITA

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Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral			Actavis	
	Cipralext - H. Lundbeck A/S			S	Oral			Not Reported	
	Halcion - 125 Microgrammi Comprese			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	13978702	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2017M1056089		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Gtt Total		Not Reported	
	Cipralext			S	Oral	15 Gtt Total		Mylan	
	Halcion			S	Oral	10 Df Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14017458	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS- 2017M1059836			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiotoxicity; Overdose; Toxicity To Various Agents	Amlodipine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Aliskiren			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14045077	EXPEDITED (15-DAY)		HO	FR-SA-2017SA186099		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Stilnox			S	Oral			Not Reported	
	Methadone			S	Oral			Not Reported	
	Seroplext			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14046585	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP019108		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Bupropion Hydrochloride			S	Unknown			Apotex	
	Trazodone Hydrochloride			S	Unknown			Apotex	
	Mirtazapine			S	Unknown			Apotex	
	Lamotrigine			S	Unknown			Apotex	
	Escitalopram Oxalate			S	Unknown			Apotex	
	Aripiprazole			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14046821	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1061379		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Modafinil			S	Unknown			Not Reported	
	Methylphenidate			S	Unknown			Not Reported	
	Calcium Chloride/Potassium Chloride/Sodium Lactate			S	Unknown	2 Litres		Not Reported	
	Calcium Chloride/Potassium Chloride/Sodium Lactate			S	Intravenous (not otherwise specified)	7.5 Litres		Not Reported	
	Lamotrigine			C	Unknown			Mylan	
	Synthroid			C	Unknown			Mylan	
	Vitamin D /00107901/			C	Unknown			Mylan	
	Folic Acid			C	Unknown			Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14049113	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1061908		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Meloxicam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14053265	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2017-41405			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Citalopram 20mg			S	Transplacental	20 Mg, Daily		Aurobindo	
	Escitalopram			S	Transplacental	5 Mg, Daily		Aurobindo	
	Folio /00349401/			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14054852	EXPEDITED (15-DAY)		HO, OT	CA-ALVOGEN-2016-ALVOGEN-027002		39 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S				Not Reported	
	Escitalopram			S				Not Reported	
	Olanzapine			S				Not Reported	
	Quetiapine			S				Not Reported	
	Primidone			S				Not Reported	
	Phenytoin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14055646	EXPEDITED (15-DAY)		OT	TR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-087669		16 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Creatine Phosphokinase Mb Increased; Chest Pain; Product Use In Unapproved Indication; Troponin T Increased	Aripiprazole	S	Unknown	Bristol Myers Squibb
	Escitalopram	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14056794	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1756573US		1 DAY	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Persistent Foetal Circulation	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057021	EXPEDITED (15-DAY)		CA	DE-TEVA-811201GER		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Milligram Daily;		Ivax
	Citalopram			S	Transplacental	20 Milligram Daily;		Actavis
	Folio			C	Transplacental	.4 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057082	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC-2017-IPXL-02813		23 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperammonaemic Encephalopathy; Status Epilepticus	Divalproex Sodium Er			S	Unknown	400 Mg, 2 /Day		Impax
	Carbamazepine			S	Unknown	200 Mg, 2 /Day		Not Reported
	Escitalopram			S	Unknown	0.5 Mg, 2 /Day		Not Reported
	Lacosamide			S	Intravenous (not otherwise specified)	200 Mg, Bid		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057502	EXPEDITED (15-DAY)		HO, OT	BR-ALLERGAN-1756342US		69 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Paraesthesia; Peripheral Swelling; Vasodilatation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Venalot			C	Unknown			Not Reported	
	Seroquel			C	Unknown			Not Reported	
	Acertil			C	Unknown			Not Reported	
	Propranolol			C	Unknown			Not Reported	
	Devit D3			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057516	EXPEDITED (15-DAY)		HO, OT	US-TEVA-812770USA		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Teva	
	Methylphenidate			S	Unknown			Actavis	
	Trazodone			S	Unknown			Barr	
	Escitalopram			S	Unknown			Not Reported	
	Modafinil			S	Unknown			Not Reported	
	Ringer'S Lactate			S	Unknown	2 Litres		Not Reported	
	Ringer'S Lactate			S	Intravenous (not otherwise specified)	7.5 Litres		Not Reported	
	Lamotrigine			C	Unknown			Not Reported	
	Synthroid			C	Unknown			Not Reported	
	Vitamin D Nos			C	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057602	EXPEDITED (15-DAY)		OT	US-TEVA-812722USA		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Meloxicam			S	Oral			Teva	
	Escitalopram			S	Oral			Not Reported	
	Loperamide			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057970	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2017M1062400		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothyroidism	Escitalopram			S	Unknown	10mg		Not Reported	
	Quetiapine			S	Unknown	50mg		Not Reported	
	Amlodipine			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	12643595	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000086768		39 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Phenytoin			S	Unknown	Unk		Not Reported	
	Primidone			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Bupropion			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	13781862	NON-EXPEDITED			US-PFIZER INC-2017320244		58 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Metoclopramide Hcl			S		Unk		Pfizer
	Aldactone			S		Unk		Pfizer
	Avandia			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Humalog			S		Unk		Not Reported
	Humulin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Zestril			S		Unk		Not Reported
	Levemir			S		Unk		Not Reported
	Valdecocib			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14060793	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1756580US		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Hypospadias	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan
	Citalopram Hydrobromide - Bp			S	Transplacental	Unk		Allergan
	Folio/Folic Acid			C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14061822	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2017-05422		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Psychotic Disorder; Sexual Dysfunction; Weight Increased	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Lupin
	Lorazepam			S	Unknown	2.5 Mg, Qd		Not Reported

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Alprazolam			C	Unknown	2 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14061896	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-GER/GER/17/0093841		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Citalopram			S	Transplacental			Not Reported	
	Escitalopram			S	Transplacental			Not Reported	
	Folio			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14062011	EXPEDITED (15-DAY)		HO	FR-ABBVIE-17P-056-2125390-00			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary Oedema; Medication Error; Oxygen Saturation Decreased	Depakine Chrono			S	Oral	Extended Release		Not Reported	
	Synthroid			S	Oral			Not Reported	
	Chondroitin			S	Oral			Not Reported	
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14063740	EXPEDITED (15-DAY)		CA, OT	GXKR2017DE004895		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported	
	Citalopram			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis	
	Folio			C	Transplacental	Maternal Dose: 0.4 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14064527	EXPEDITED (15-DAY)		HO	US-ACELLA PHARMACEUTICALS, LLC-2029333		63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Mental Status Changes; Serotonin Syndrome; Upper Respiratory Tract Infection	Brompheniramine Mal, Pseudoephedrine Hcl, And Dextromethorphan Hbr			S				Acella
	Amlodipine			C				Not Reported
	Labetalol			C				Not Reported
	Escitalopram			S				Not Reported
	Promethazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14066104	EXPEDITED (15-DAY)		HO, LT	FR-SA-2017SA190729		79 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Interaction; Hyponatraemia; Somnolence	Aprovel			S	Oral			Not Reported
	Aldactazine			S	Unknown			Not Reported
	Seroplex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Mianserine			C	Oral			Not Reported
	Levothyrox			C				Not Reported
	Amlor			C				Not Reported
	Flecaine			C				Not Reported
	Eupantol			C				Not Reported
	Lyrica			C				Not Reported
	Xatral			C				Not Reported
	Seresta			C				Not Reported
	Imovane			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14066992	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1756557US		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Constipation; Pruritus Generalised;	Milnacipran - Bp			S	Oral	Unk		Allergan

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Rash Macular	Escitalopram Oxalate Unk	S	Oral	Unk	Allergan
	Levothyrox	S	Oral	Unknown	Not Reported
	Levothyrox	S	Oral	25 Mg, Qd	Not Reported
	Levothyrox	S	Oral	50 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	13786795	NON-EXPEDITED			US-JNJFOC-20170613240			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Inappropriate Schedule Of Product Administration	Tylenol Extra Strength Caplet		Y	S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Topiramate			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Primidone			C	Unknown			Not Reported
	Doxepine			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Citracal			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Milk Of Magnesia			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	14014511	EXPEDITED (15-DAY)		HO, LT, OT	FR-ZYDUS-016788			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiotoxicity; Overdose; Toxicity To Various Agents	Amlodipine			S	Unknown			Zydu Pharm
	Escitalopram			S	Unknown			Zydu Pharm

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Aliskiren

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	14025527	EXPEDITED (15-DAY)		DE	JP- ELI_LILLY_AND_COMP ANY- JP201709009592AA		35 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Intentional Overdose	Strattera Capsule			S	Oral	120 Mg, Daily		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Strattera Capsule			S	Oral	Unk		Not Reported
	Serenace			S	Oral	4 Mg, Bid		Not Reported
	Biperiden			S	Oral	2 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Belsomra			S	Oral	20 Mg, Daily		Not Reported
	Contomin /00011902/			S	Oral	25 Mg, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	14068190	DIRECT		OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conjunctivitis; Vision Blurred	Escitalopram			S	Oral	1 Pill Every Day By Mouth		Mylan
	Amlodipine			C				Not Reported
	Chlorthalidone			C				Not Reported
	Carvedilol			C				Not Reported
	Coq10			C				Not Reported
	Fish Oil			C				Not Reported
	Magnesium			C				Not Reported
	Asprin			C				Not Reported
	Tumeric			C				Not Reported
	Allegra			C				Not Reported
Red Rice Yeast			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	14068925	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2017M1062516		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 [Mg/D]		Not Reported	
	Citalopram			S	Transplacental	20 [Mg/D]		Not Reported	
	Folio			C	Transplacental	0.4 [Mg/D]		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	12617491	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-121339		39 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S	Unknown			Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk		Sun	
	Phenytoin			S	Unknown	Unk		Sun	
	Primidone			S	Unknown	Unk		Mutual	
	Quetiapine			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	12687006	EXPEDITED (15-DAY)		HO, LT, OT	CH-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-069968		55 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Confusional State; Dysphagia; Hyperreflexia; Muscle Rigidity; Mutism; Neuroleptic Malignant Syndrome; Product Use In	Abilify			S	Oral	15 Mg, Qd		Bristol Myers Squibb	
	Abilify			S	Oral	5 Mg, Qd		Bristol Myers Squibb	
	Abilify Maintena			S	Intramuscular	400 Mg, Qmo		Not Reported	
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported	
	Quetiapine Actavis			C	Oral	300 Mg, Qd		Not Reported	

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Unapproved Indication; Serotonin Syndrome; Tremor	Temesta /00273201/ Amlodipin /00972401/	C C	Oral Oral	1 Mg, Tid 5 Mg, Qd	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	13899452	EXPEDITED (15-DAY)		DE, OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04764		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin	
	Indapamide			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	
	Benzoic Acid			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	13899467	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04765		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
	Galantamine			S	Unknown	Unk		Not Reported	
	Irbesartan			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	13899497	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04797		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin	
	Metoclopramide			S	Unknown	Unk		Not Reported	
	Diazepam			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	13967675	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-149393		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam			S	Oral	20 Gtt Total		Sun	
	Cipraxel			S	Oral	15 Gtt Total		Not Reported	
	Halcion 125 Micrograms			S	Oral	10 Df Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14070134	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2017006180			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral	10 Mg, Unk		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14070263	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT- 00015683		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14071664	EXPEDITED (15-DAY)		CA, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-		1 DAY	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Daily		Not Reported
	Citalopram			S	Transplacental	20 Mg, Daily		Sun
	Folio			C	Transplacental	0.4 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14073261	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1757128US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Pulmonary Oedema; Oxygen Saturation Decreased; Wrong Patient Received Product	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Single		Allergan
	Chondrosulf			S	Oral	400 Mg, Single		Not Reported
	Depakine Chrono			S	Oral	500 Mg, Single		Not Reported
	Levothyrox			S	Oral	50 Mg, Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14073489	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1757183US			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety Disorder; Chills; Discomfort; Muscle Twitching; Therapeutic Product Effect Decreased; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Tamsulosin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14073492	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1757553US		< 1 DAY	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Agitation Neonatal; Blood Glucose Decreased; Bradycardia; Drug Withdrawal Syndrome Neonatal; Insomnia; Maternal Exposure During Pregnancy; Muscle Twitching; Neonatal Seizure; Tremor Neonatal	Escitalopram Oxalate - Bp Metformin	S C	Transplacental Transplacental	Mother'S Dose Unk	Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074462	EXPEDITED (15-DAY)		HO	DK-TEVA-2014-12189		59 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pollakiuria; Suicidal Ideation; Suicide Attempt; Urinary Incontinence; Withdrawal Syndrome	Escitalopram Actavis			S	Oral			Ivax	
	Sertralin			C	Oral			Not Reported	
	Pamol			C	Oral	3000 Milligram Daily; 1-Aug-2016 To 18-Aug-2016; 20-Jul-2017 To 22-Jul-2017		Not Reported	
	Cisordinol			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074932	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2016JUB00383			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Pressure Increased; Dizziness; Limb Discomfort; Muscle Rigidity; Somnolence; Yawning	Escitalopram			S				Jubilant	
	Aspirin			S				Not Reported	
	Nortriptyline			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074934	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2016JUB00397		59 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Escitalopram			S	Oral	10 Mg, 1x/Day		Jubilant	
	Escitalopram			S			Jubilant		
	Synthroid			C			Not Reported		
	Cytomel			C			Not Reported		
	Flax Seed			C			Not Reported		
	Vitamin D Nos			C			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074936	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00098		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Escitalopram			S	Oral	20 Mg, 1x/Day		Jubilant	
	Escitalopram			S		10 Mg, 1x/Day		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074938	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00101		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Feeling Cold; Somnolence	Escitalopram			S	Oral	20 Mg, 1x/Day		Jubilant	
	Omeprazole			C		20 Mg, 1x/Day		Not Reported	
	Unspecified Vitamins			C		Unk, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074940	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00204			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Nausea; Night Sweats	Escitalopram			S	Oral	Unk		Jubilant	
	Escitalopram			S	Oral	2.5 Mg, 2x/Day Around Noon And At Bedtime		Jubilant	

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Bisoprolol Fumarate			C						Not Reported
Levothyroxine			C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14074942	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00274			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder	Escitalopram			S		Unk		Jubilant	
	Several Additional Medications			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14076478	EXPEDITED (15-DAY)		OT	NO-ALLERGAN- 1757557US			Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gestational Diabetes; Pre- Eclampsia; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Metformin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14076496	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN- 1757428US		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14077201	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE- HET2017DE00244		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd		Hetero	

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	Citalopram /00582602/		S	Transplacental	20 Mg, Qd			Not Reported	
	Folic Acid		C	Transplacental	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14077669	EXPEDITED (15-DAY)		CA	DE-TORRENT-00007194		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S				Unknown	
	Citalopram			S				Unknown	
	Folio			C				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14077754	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0093976		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Duloxetine Delayed-Release Capsules			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Lamotrigine			C	Unknown			Not Reported	
	Synthroid			C	Unknown			Not Reported	
	Trazodone			C	Unknown			Not Reported	
	Methylphenidate			C	Unknown			Not Reported	
	Modafinil			C	Unknown			Not Reported	
	Vitamin D2			C	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078837	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-813945ACC		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder;	Escitalopram			S	Oral			Ivax	

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Insomnia; Nausea;
Palpitations; Peripheral
Coldness; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14079058	EXPEDITED (15-DAY)		DE, OT	ZA-CIPLA (EU) LIMITED-2016ZA07940			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage; Death	Atolip			S	Unknown	20 Mg, Nocte		Cipla
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Xalantan			S	Unknown	Unk		Not Reported
	Cardicor			S	Unknown	2.5 Mg, Qd		Not Reported
	Tambocor Sr			S	Unknown	100 Mg, Daily		Not Reported
	Xeralto			S	Unknown	20 Mg, Daily With Meal		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14079188	EXPEDITED (15-DAY)		DE	SE-009507513- 1710SWE003541		43 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Mirtazapine			S	Oral	30 Mg, Unk		Merck
	Anafranil			S				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	12436654	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-041170		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Hydrochlorothiazide			S				Accord
	Escitalopram			S				Accord
	Metformin			S				Accord
	Levothyroxine			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported

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	Gliclazide		C			Modified Release Dosage		Not Reported	
	Insulin		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	12646279	EXPEDITED (15-DAY)		CA, OT	TR-009507513-1608TUR005013			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Limb Reduction Defect	Remeron			S	Transplacental			Merck	
	Cipralelex			S	Transplacental	Unk		Not Reported	
	Cipralelex			S	Transplacental	10 Mg/Day		Not Reported	
	Butylscopolamine Bromide			S	Transplacental	Unk		Not Reported	
	Tranko Buskas			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	13693074	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-35900		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram			S	Oral	6 Df, Total		Aurobindo	
	Lorazepam			S	Oral	10 MI, Total		Not Reported	
	Carbolithium			C	Unknown			Not Reported	
	Quetiapine Fumarate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	13693293	EXPEDITED (15-DAY)		HO	IT-TEVA-780101ACC		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Lorazepam			S	Oral			Actavis	
	Escitalopram Oxalate			S	Oral			Ivax	
	Carbolithium - 150 Mg Capsule			C				Not Reported	
	Rigide								
	Quetiapine Fumarate			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14080407	EXPEDITED (15-DAY)		HO, OT	PHHY2017IT149116		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan			S	Oral			Novartis	
	Delorazepam			S	Oral	Unk		Not Reported	
	Haldol			S	Oral	Unk		Not Reported	
	Escitalopram Accord			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14082797	EXPEDITED (15-DAY)		DE	SE-TEVA-813895ISR		43 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Escitalopram			S				Ivax	
	Mirtazapine			S	Oral			Teva	
	Anafranil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14085177	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-059817		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral			Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14085385	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2017-41545		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram 10 Mg	S	Oral	10 Mg, Unk	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14085488	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX- 2017AP020064		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Apo-Gliclazide Mr			S	Unknown	Unk		Not Reported
	Apo-Metformin - Tab 500mg			S	Unknown	1 G, Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Escitalopram			S	Unknown	Unk		Apotex
	Insulin			S	Unknown	Unk		Not Reported
	L Thyroxine			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14088672	EXPEDITED (15-DAY)		DE	NZ-SA-2017SA198029			Male	NZL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Completed Suicide	Clopidogrel Bisulfate			S	Oral			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	13675375	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1725731US		41 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram Oxalate Unk			S	Oral			Allergan	
	Lorazepam			S	Oral	10 MI, Unk		Not Reported	
	Carbolithium			C	Unknown			Not Reported	
	Quetiapine Fumarate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14091379	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.- 2017GB17914			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14091632	EXPEDITED (15-DAY)		DE, LT, OT	US-STRIDES ARCOLAB LIMITED- 2017SP013385			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt; Toxicity To Various Agents	Loperamide			S	Oral	Unk		Not Reported	
	Meloxicam			S	Oral	Unk		Strides	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14091681	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-152188		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Inappropriate Antidiuretic Hormone	Escitalopram			S	Unknown			Not Reported	

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Secretion	Hydrochlorothiazide	S	Unknown		Sun
	Gliclazide	C	Unknown	Modified-Release	Not Reported
	Insulin	C	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Telmisartan	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14091740	NON-EXPEDITED		OT	US-PFIZER INC-2017439919		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Heart Rate Decreased	Effexor			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14092482	EXPEDITED (15-DAY)		CA, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-05904		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd		Lupin
	Citalopram			S	Transplacental	20 Mg, Qd		Not Reported
	Folio /00349401/			C	Transplacental	0.4 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14093340	EXPEDITED (15-DAY)		HO, OT	US-LANNETT COMPANY, INC.-US-2017LAN001084		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Methylphenidate Hydrochloride	S	Unknown	Unk	Lannett
	Escitalopram Oxalate	S	Unknown	Unk	Lannett
	Duloxetine	S	Unknown	Unk	Not Reported
	Modafinil	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	Unk	Not Reported
	Ringers Lactate	S	Unknown	2 Liters	Not Reported
	Ringers Lactate	S	Intravenous (not otherwise specified)	7.5 Liters	Not Reported
	Ringers Lactate	S	Oral	1.2 Liters	Not Reported
	Lamotrigine	S	Unknown	Unk	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Oxygen	C		2 Liters	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14093350	DIRECT		DS, HO, OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Chills; Depersonalisation/Derealisation Disorder; Depression; Diarrhoea; Eating Disorder; Emotional Distress; Fear; Feeling Abnormal; Hallucination, Visual; Impaired Work Ability; Mental Impairment; Nausea; Panic Attack; Physical Disability; Post-Traumatic Stress Disorder; Pyrexia; Suicidal Ideation; Syncope; Tinnitus; Vision Blurred; Vomiting; Weight Decreased	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Allergan
	Klonopin			C				Not Reported
	Abilify			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14093775	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-M-EU-2012070197		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Balance Disorder; Diarrhoea; Disorientation;	Cesamet			S	Oral	0.25 Mg, Bid		Mylan	
Disturbance In Attention; Dizziness; Drug Interaction; Dyspnoea; Euphoric Mood; Gait	Escitalopram Mylan			S	Oral	20 Mg, Qd		Mylan	
Disturbance; Gait Inability; Hallucination; Headache; Hypopnoea; Muscle Spasms; Palpitations;	Escitalopram Mylan			S				Mylan	
Pulse Pressure Increased; Somnolence; Urinary Tract Infection; Vomiting	Baclofen			S		20 Mg, Tid		Mylan	
	Butrans			S	Transdermal	20 Mg, Qh		Mylan	
	Butrans			S	Transdermal	15 Mg, Qh		Mylan	
	Butrans			S	Transdermal	10 Mg, Qh		Mylan	
	Butrans			S	Transdermal	5 Mg, Qh		Mylan	
	Clonazepam			S	Oral	1 Mg, Tid		Mylan	
	Cipro XI			C	Oral	1000 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14095087	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2017M1063651		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Feeding Disorder; Insomnia; Nausea; Palpitations; Peripheral Coldness; Tremor	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13078451	EXPEDITED (15-DAY)		HO, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110446		65 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gingival Bleeding; Immune	Glucophage			S	Unknown	500 Mg, Unk		Bristol Myers Squibb	

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Thrombocytopenic Purpura; Petechiae; Tinnitus	Eutimil	S	Oral	Unk	Not Reported
	Cipralext /01588501/	S	Unknown		Not Reported
	Sereupin	S	Oral		Not Reported
	Crestor	S	Oral	10 Mg, Unk	Not Reported
	Esopral /01479301/	C	Oral	20 Mg, Unk	Not Reported
	Diamox /00016901/	C	Oral	250 Mg, Unk	Not Reported
	Stiliden	C	Oral		Not Reported
	Muscoril	C	Oral	4 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13238399	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX- 2017AP006511		39 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Withdrawal Syndrome; Arrhythmia; Condition Aggravated; Confusional State; Drug Interaction; Hyperthermia; Intentional Overdose; Intentional Product Misuse; Major Depression; Mental Status Changes; Overdose; Pneumonia; Potentiating Drug Interaction; Sepsis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Primidone			S	Oral			Not Reported
	Apo-Escitalopram			S	Oral			Apotex
	Apo-Quetiapine			S	Oral			Apotex
	Apo-Olanzapine			S	Oral			Apotex
	Apo-Citalopram			S	Unknown			Apotex
	Bupropion			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13661852	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN- 1725002US		43 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchial Obstruction; Cerebral Venous	Escitalopram Oxalate - Bp			S	Oral			Allergan

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Thrombosis; Coma; Lung Disorder; Neurological Decompensation; Respiratory Distress	Qizenday	S	Oral	100 Mg, Tid	Not Reported
	Baclofene	S	Oral	45 Mg, Qd	Not Reported
	Vesicare	S	Oral	1 Df, Qd	Not Reported
	Xatral	S	Oral	1 Df, Qd	Not Reported
	Dafalgan	S	Oral	500 Mg, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13676867	EXPEDITED (15-DAY)		HO	IT-ACCORD-052837		41 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Slow Speech; Sopor	Escitalopram			S	Oral			Accord
	Lorazepam			S	Oral	10 MI Total		Not Reported
	Carbolithium			C		Strength: 150 Mg		Not Reported
	Quetiapine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13687805	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1036720		41 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Self-Injury; Overdose; Slow Speech; Sopor	Lorazepam			S	Oral	10 MI Total		Not Reported
	Escitalopram			S	Oral	6 Df Total		Not Reported
	Carbolithium			C		Unk		Mylan
	Quetiapine Fumarate			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13923324	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-147977		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria;	Amlodipine			S	Oral	Unk		Sun

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Blindness; Circulatory Collapse; Condition Aggravated; Depressed Level Of Consciousness; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents	Escitalopram	S	Oral	Unk	Not Reported
	Risperidone	S	Oral	Unk	Ranbaxy

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14085242	NON-EXPEDITED			US-PFIZER INC-2017440319		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Drug Interaction	Lipitor			S		Unk		Pfizer
	Synthroid			S	Oral	0.112 Mg, 1x/Day		Not Reported
	Monopril			S	Oral	20 Mg, 1x/Day		Not Reported
	Valium			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S				Not Reported
	Zetia			S	Oral	10 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14096796	NON-EXPEDITED			US-PFIZER INC-2017441674		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer

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Ibuprofen	S	Unk	Pfizer
Morphine Sulfate	S	Unk	Unknown
Loperamide Hcl	S	Unk	Not Reported
Buspar	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Luvox	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Lithium	S	Unk	Not Reported
Zofran	S	Unk	Not Reported
Amoxicillin	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Benadryl	S	Unk	Not Reported
Duloxetine	S	Unk	Not Reported
Ambien	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Zyprexa	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14096866	EXPEDITED (15-DAY)		DE, LT, OT	US-HETERO- HET2017US00274		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Lethargy; Somnolence	Escitalopram			S	Oral	Unk		Hetero
	Meloxicam			S	Oral	Unk		Not Reported
	Loperamide			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14098149	EXPEDITED (15-DAY)		HO	CH-ALLERGAN- 1758680US		66 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

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Muscle	Sintrom	S	Oral	1 Mg Mitis, Unk	Not Reported
	Pantozol	C	Oral	40 Mg, Qd	Not Reported
	Bilol	C	Oral	Form Strength: 2,5	Not Reported
	Aldactone	C	Oral	50 Mg, Qd	Not Reported
	Janumet	C	Oral	50/500 Mg	Not Reported
	Cordarone Comprimes	C	Oral	100 Mg, Qd	Not Reported
	Ezetrol	C	Oral	10 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Oral	40 Mg, Qd	Not Reported
	Xanax Retard	C	Oral	0.5 Mg, Q12	Not Reported
	Remeron	C	Oral	30 Mg, Qd	Not Reported
	Trittico	C	Oral	50 Mg, Qd	Not Reported
	Zoldorm	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14100117	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1758678US		52 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Optic Neuritis	Escitalopram Oxalate - Bp			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14100264	EXPEDITED (15-DAY)		DE, HO	FR-ABBVIE-17P-056-2134034-00		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Product Administration Error	Depakine Chrono			S	Oral	Extended Release		Not Reported
	Levothyroxine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral			Not Reported

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		Modopar		S	Oral				Not Reported
		Spironolactone		C					Not Reported
		Levetiracetam		C					Not Reported
		Atarax		C					Not Reported
		Laroxyl		C					Not Reported
		Folic Acid		C					Not Reported
		Magne B6		C					Not Reported
		Chondrosulf		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14036677	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756172US		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperemesis Gravidarum; Off Label Use; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Citalopram Hydrobromide - Bp			S	Unknown	Unk, Qd		Allergan	
	L-Tyroxin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14088988	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2017-41880		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Modafinil			S	Unknown			Aurobindo	
	Trazodone			S	Unknown			Aurobindo	
	Methylphenidate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14105105	EXPEDITED (15-DAY)		DE, OT	SE-MYLANLABS-2017M1066352		43 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Escitalopram			S		Unk		Not Reported	

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	Anafranil		S			Unk			Mylan
	Mirtazapine		S	Oral		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14024516	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1755154US		37 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Depression; Dysphoria; Nausea; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Lorazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14108260	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1759248US		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Confusional State; Decreased Appetite; Disorientation; General Physical Health Deterioration; Hyponatraemia; Memory Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Inexium			S	Oral	20 Mg, Qd		Not Reported	
	Triflucan			C	Oral			Not Reported	
	Xarelto			C	Oral			Not Reported	
	Bisocce			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Novonorm			C	Unknown			Not Reported	
	Loperamide Base			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14108455	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2017LAN001121		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bradycardia; Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Lethargy; Somnolence	Escitalopram Oxalate	S	Oral	Unk	Lannett
	Loperamide	S	Oral	Unk	Not Reported
	Meloxicam	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14108568	EXPEDITED (15-DAY)		HO	FR-SA-2017SA200581		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Overdose; Tachycardia; Tachypnoea	Depakote			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14110765	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2017AP020021		54 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan Doc Generici			S	Oral	Unk		Apotex
	Delorazepam			S	Oral	Unk		Not Reported
	Haldol /00027401/			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14111134	EXPEDITED (15-DAY)		HO	FR-ABBVIE-17P-056-2136805-00		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Overdose; Tachycardia; Tachypnoea	Depakote			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14111801	DIRECT					45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue	Generic Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	14092490	EXPEDITED (15-DAY)		OT	ZA-LUPIN PHARMACEUTICALS INC.-2017-05972			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Neoplasm	Bilocor Tablets			S	Oral	5 Mg, Qd		Not Reported
	Zytomil			S	Oral	10 Mg, Qd		Lupin
	Puricos			S	Oral	300 Mg, Qd		Not Reported
	Aspavor			S	Oral	20 Mg, Qd		Not Reported
	Estro-Pause			S	Oral	1 Mg, Qd		Not Reported
	Warfarin			S	Oral	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	14116507	NON-EXPEDITED		HO	US-DEPOMED, INC.- US-2016DEP011915			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Muscle Twitching; Serotonin Syndrome; Syncope	Nucynta Er			S		250 Mg, Bid		Depomed
	Lexapro			S		Unk		Not Reported
	Subsys			C		Unk		Not Reported

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24-Oct-2017	13784442	NON-EXPEDITED			US-IMPAX LABORATORIES, INC- 2017-IPXL-01063		84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective For Unapproved Indication; Drug Interaction; Psychotic Symptom	Rytary	S	Oral	(23.75/95 Mg) Unk	Impax
	Rytary	S	Oral	(36.25/145 Mg) Unk	Impax
	Rytary	S	Oral	(48.75/195 Mg)1 Df, 2/Day	Impax
	Carbidopa-Levodopa Er	S	Unknown	Unk	Impax
	Escitalopram	S	Unknown	Unk	Not Reported
	Amiodarone	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Finasteride	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Tamsulosin	C	Unknown	Unk	Not Reported
	Requip	C	Unknown	Unk	Not Reported

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24-Oct-2017	14121946	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1760307US		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Electrocardiogram Abnormal; Hypotension; Miosis; Tachycardia; Tachypnoea	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Depakote			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14121951	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1759767US		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Product Administration Error	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Depakine Chrono			S	Oral			Not Reported
	Lamaline			S	Oral	1 Df, Unk		Not Reported
	(Acetaminophen\Belladonna Leaf\Caffeine\Opium)							

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Alprazolam	S	Oral	0.25 Mg, Unk	Not Reported
Modopar	S	Oral		Not Reported
Levothyrox	S	Oral	50 Mg, Unk	Not Reported
Atarax	C	Unknown	25 Mg, Qd	Not Reported
Atarax	C	Unknown	16 Mg, Unk	Not Reported
Spironolactone	C	Unknown		Not Reported
Levetiracetam	C	Unknown	375 Mg, Bid	Not Reported
Laroxyl	C	Unknown		Not Reported
Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
Magnesium B6	C	Unknown		Not Reported
Chondrosulf	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14017007	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1748674US		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Food Poisoning; Malaise; Nausea; Retching; Serotonin Syndrome; Vomiting	Lexapro			S	Oral	1 Df, Qhs		Allergan

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25-Oct-2017	14065972	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1757161US		57 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Increased Appetite; Overdose	Escitalopram Oxalate Unk			S	Unknown	30 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Unk		Allergan
	Escitalopram Oxalate Unk			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported

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Zyprexa Velotab	S	Unknown	10 Mg, Qd	Not Reported
Seroquel	C	Unknown	50 Mg, Qd	Not Reported
Quetiapin	C	Unknown		Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Rivotril	C	Unknown	1 Mg, Qd	Not Reported
Thyrex	C	Unknown	50 Mg, Qod	Not Reported
Combithyrex Mite	C	Unknown	1 Df, Qod	Not Reported

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25-Oct-2017	14073499	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1757433US		57 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Prescribed Overdose; Weight Increased	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Zyprexa Velotab			S	Unknown			Not Reported
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown	450 Mg, Qd		Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Seroquel Xr			S	Unknown			Not Reported

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Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Seroquel Xr	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Quetiapin	C	Unknown	Not Reported
Lamotrigin	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Temesta (Lorazepam)	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Temesta	C	Unknown	Not Reported
Rivotril	C	Unknown	Not Reported
Thyrex	C	Unknown	Not Reported
Combithyrex	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported
Molaxole	C	Unknown	Not Reported

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25-Oct-2017	14124252	EXPEDITED (15-DAY)	CA		DE-GLENMARK PHARMACEUTICALS- 2017GMK029102			Unknown	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypospadias	Escitalopram			S	Transplacental	5 Mg, Qd, Up To 13.2. Gestational Week		Not Reported	
	Citalopram Hydrobromide			S	Transplacental	20 Mg, Qd, 13.2 To 26.3 Gestational Week		Glenmark	
	Folio /00349401/			C	Transplacental	0.4 Mg, Qd, 0 To 41.2 Gestational Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14126638	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-013857			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Increased Appetite; Serotonin Syndrome	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustments		Jazz	
	Xyrem			S	Oral	5 G, Qd; First Dose		Jazz	
	Xyrem			S	Oral	4 G, Qd; Second Dose		Jazz	
	Lexapro			S		5 Mg		Not Reported	
	Lexapro			S		10 Mg		Not Reported	
	Lexapro			S		20 Mg		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
	Naltrexone			C		Unk		Not Reported	
	Tylenol Extra-Strength			C		Unk		Not Reported	
	Amitriptyline Hcl			C		Unk		Not Reported	
	Diltiazem			C		Unk		Not Reported	
	Diltiazem			C		Unk		Not Reported	
	Wellbutrin			C		Unk		Not Reported	
	Lactobacillus			C		Unk		Not Reported	
	Allegra Allergy			C		Unk		Not Reported	
	Zantac			C		Unk		Not Reported	
	Adderall			C		5 Mg		Not Reported	

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Adderall	C	25 Mg	Not Reported
Adderall	C	20 Mg	Not Reported
Adderall	C	30 Mg	Not Reported
Mestinon	C	Unk	Not Reported
Bupropion Hcl	C	Unk	Not Reported
Nuvigil	C	Unk	Not Reported
Topamax	C	25 Mg	Not Reported
Topamax	C	50 Mg	Not Reported

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26-Oct-2017	13865982	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1734194US		67 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Sedation Complication	Asenapine Maleate - Bp			S	Sublingual	10 Mg, Qd (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	7.5 Mg, Qd (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	5 Mg, (Morning And Evening)		Allergan
	Asenapine Maleate - Bp			S	Sublingual	5 Mg, Qd (Evening)		Allergan
	Olanzapine			S	Oral	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	5 Mg, Qd		Not Reported
	Olanzapine			S	Oral	10 Mg, Qd		Not Reported
	Olanzapine			S	Oral	15 Mg, Qd		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	2.5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1.5 Mg, Qd		Not Reported

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Flunitrazepam	C	Unk	Not Reported
Clonazepam	C	Unk	Not Reported
Urapidil	C	Unk	Not Reported
Dutasteride	C	Unk	Not Reported
Sertraline Hydrochloride	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	13926283	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1747950US		67 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
Phosphokinase Increased;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
Dementia; Fall; Immobile;	Dogmatyl			C	Oral	50 Mg, Unk		Not Reported
Parkinsonism;	Natrix			C	Oral	1 Mg, Unk		Not Reported
Rhabdomyolysis	Rohypnol			C	Oral	1 Mg, Unk		Not Reported

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26-Oct-2017	13967430	NON-EXPEDITED			US-PFIZER INC-2017395349		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Provera			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

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Tramadol	S	Unk	Not Reported
Zyrtec	S	Unk	Not Reported
Allegra	S	Unk	Not Reported

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26-Oct-2017	14128221	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2017-42592		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Completed Suicide; Lethargy; Somnolence; Suicide Attempt	Loperamide			S		40 Unk, Unk		Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Meloxicam			S	Unknown			Aurobindo	

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26-Oct-2017	14128595	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760596US		< 1 DAY	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan	

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26-Oct-2017	14129390	EXPEDITED (15-DAY)		DE	FR-MERCK KGAA-2031571		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Product Administration Error	Novothyrox			S	Oral			Merck Kgaa	
	Depakine Chrono			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Lamaline			S	Oral			Not Reported	
	(Acetaminophen\Belladonna Leaf\Caffeine\Opium)								
	Alprazolam			S	Oral			Not Reported	

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Modopar	S	Oral	Not Reported
Folic Acid	C		Not Reported
Magnis + B6(Dynamag)	C		Not Reported
Chondrosulf	C		Not Reported
Spironolactone	C		Not Reported
Levetiracetam	C		Not Reported
Atarax	C		Not Reported
Atarax	C		Not Reported
Laroxyl	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	13857957	EXPEDITED (15-DAY)		OT	PHHY2017FR115523		86 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14133341	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US18551			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram			S	Oral	5 Mg, Qd		Invagen
Abnormal Behaviour;	Escitalopram			S				Invagen
Decreased Appetite;								
Enuresis; Headache;								
Malaise; Nausea; Product								
Administered To Patient								
Of Inappropriate Age;								
Somnambulism;								
Somnolence								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14133705	NON-EXPEDITED			US-PFIZER INC- 2017459519		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Chromaturia;	Lipitor	S	Oral	40 Mg, 1x/Day	Pfizer
Claustrophobia; Dysuria;	Metoprolol Tartrate	S	Oral	50 Mg, 2x/Day	Not Reported
Erectile Dysfunction;	Metoprolol Tartrate	S			Not Reported
Sleep Apnoea Syndrome;	Escitalopram	S	Oral	10 Mg, 1x/Day	Not Reported
Urine Odour Abnormal	Cardizem	S	Oral	180 Mg, 1x/Day	Not Reported
	Clonazepam	S	Oral	1 Mg, 1x/Day (At Night)	Not Reported
	Clonazepam	S			Not Reported
	Seroquel	S		50 Mg, Unk	Not Reported
	Seroquel	S	Oral	150 Mg, 1x/Day	Not Reported
	Seroquel	S			Not Reported
	Abilify	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14134365	NON-EXPEDITED			US-APOTEX-2017AP016527		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During	Escitalopram Oxalate			S	Unknown	10 Mg, Per Day		Apotex
Pregnancy; Therapeutic	Escitalopram Oxalate			S				Apotex
Product Effect Incomplete								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14137237	EXPEDITED (15-DAY)		HO, LT	JP-ELI_LILLY_AND_COMP ANY-JP201710009793		27 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt	Zyprexa			S	Oral	5 Mg, Daily		Eli Lilly And Co
Prolonged; Off Label Use	Lexapro			S	Oral			Not Reported
	Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14137412	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017456084		91 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt	Cordarone	S	Unknown	Unk	Pfizer
Prolonged;	Entact	S	Oral	Unk	Not Reported
Hypertransaminasaemia;	Durogesic	C		Unk	Not Reported
Syncope					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	12649157	EXPEDITED (15-DAY)		OT	DK-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-063987			Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section;	Abilify			S	Oral	30 Mg, Qd		Bristol Myers Squibb
Maternal Exposure During	Ciprallex /01588501/			S	Oral	Unk		Not Reported
Pregnancy; Placental	Peratsin			S	Oral	Unk		Not Reported
Disorder; Premature								
Delivery; Prescribed								
Overdose; Product Use								
Issue								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	13625446	NON-EXPEDITED			US-ACCORD-048752		29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Test False	Amlodipine			S	Oral			Accord
Positive	Escitalopram Accord			S	Oral	Dose/Strength: 20 Mg		Accord
	Lisinopril			S	Oral			Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140306	NON-EXPEDITED			US-ACCORD-044366			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling	Escitalopram			S				Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140307	NON-EXPEDITED			US-ACCORD-046573		72 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Transaminases Increased	Escitalopram			S	Oral			Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140308	NON-EXPEDITED			US-ACCORD-045303			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S				Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140309	EXPEDITED (15-DAY)		OT	US-ACCORD-047083			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Expired Product Administered; Nervousness; Night Sweats; Palpitations; Poor Quality Sleep; Sexual Dysfunction	Escitalopram			S	Oral	In Oct-2015 Restarted,Discontinued In May-2016		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140310	NON-EXPEDITED			US-ACCORD-048611			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Exposure Via Breast Milk	Escitalopram			S				Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140311	NON-EXPEDITED			US-ACCORD-047499		40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Distension;	Escitalopram			S	Oral			Accord	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal Faeces; Gastrooesophageal Reflux Disease		Drisdol		C		Not Reported			
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140312	NON-EXPEDITED			US-ACCORD-050556			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Constipation; Insomnia; Nightmare	Escitalopram			S				Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140317	NON-EXPEDITED			US-ACCORD-053710		70 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pain In Extremity; Weight Increased	Escitalopram			S	Oral	Started 10 Mg Qd, Cutting Tablet In Half And Self Received 5 Mg Qd From 15-Jun-2015 To 15-Apr- 2017		Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140318	NON-EXPEDITED			US-ACCORD-056973		34 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Pain; Feeling Abnormal; Headache	Escitalopram Accord			S	Oral	Once A Day		Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140319	NON-EXPEDITED			US-ACCORD-052242		70 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash Erythematous; Rash Pruritic	Escitalopram Nifedipine			S C	Oral			Accord Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Zetia	C	Not Reported
	Pravastatin	C	Not Reported
	Metoprolol	C	Not Reported
	Irbesartan	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140320	NON-EXPEDITED			US-ACCORD-057882			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram Accord			S				Accord
	Fluoxetine			S				Not Reported
	Invega Sustenna			S				Not Reported
	Clonazepam			S				Not Reported
	Paroxetine			S				Not Reported
	Aripiprazole			S				Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Lithium			S				Not Reported
	Haloperidol			S				Not Reported
	Pramipexole			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140322	NON-EXPEDITED			US-ACCORD-050475			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Twitching; Rash	Escitalopram			S				Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140323	NON-EXPEDITED			US-ACCORD-050999			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disturbance In Attention; Feeling Abnormal; Tinnitus	Escitalopram			S				Accord

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140324	NON-EXPEDITED			US-ACCORD-051168			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram Accord			S		Strength: 10 Mg		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14140325	NON-EXPEDITED			US-ACCORD-051869		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea	Escitalopram			S	Oral			Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14141528	EXPEDITED (15-DAY)		OT	PHHY2017FR157560		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Pramipexole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14141529	EXPEDITED (15-DAY)		OT	PHHY2017FR157553		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Bisoprolol			S	Unknown	Unk		Novartis	
	Furosemide			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14142018	EXPEDITED (15-DAY)		OT	PHHY2017FR157550		56 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Candesartan Cilexetil			S	Unknown			Novartis
	Ivabradine			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	13040098	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-SA-2016SA216624		63 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Bezoar; Blood Bicarbonate Decreased; Blood Pressure Decreased; Cardiogenic Shock; Coma; Drug Level Increased; Gastrointestinal Ischaemia; Haemodynamic Instability; Heart Rate Decreased; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Overdose; Overdose; Renal Failure; Shock; Skin Necrosis; Toxicity To Various Agents	Seroplex			S	Oral	28 Tabs Of 10 Mg Each		Not Reported
	Zolpidem Tartrate			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Nordazepam			S	Unknown			Not Reported
	Olmesartan Medoxomil			S	Unknown			Not Reported
	Amlodipine (Salt Not Specified)			S	Unknown			Not Reported
	Atarax			S	Oral	28 Tabs Of 25 Mg Each		Not Reported
	Sevikar			S	Oral	129 Tabs, 10 Mg Each, 1.29g Amlodipine And 5.16g Olmesartan		Not Reported
	Lysanxia			S	Oral	42 Tabs Of 10 Mg Each		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	13828995	NON-EXPEDITED			US-APOTEX-2017AP016124		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyp2c19 Polymorphism; Cyp2c9 Polymorphism;	Mirtazapine			S	Unknown	30 Mg, Unk		Apotex

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Cyp2d6 Polymorphism; Drug Ineffective; Drug Intolerance	Risperidone	S	Unknown		Apotex
	Gabapentin	S	Unknown	200 Mg, Qd	Apotex
	Buspirone Hydrochloride Tablets Usp	S	Unknown	15 Mg, Bid	Apotex
	Citalopram	S	Unknown		Apotex
	Escitalopram Oxalate	S	Unknown	2.5 Mg, Qd	Apotex
	Paroxetine Hydrochloride	S	Unknown		Apotex
	Sertraline Hydrochloride	S	Unknown	25 Mg, Qd	Apotex
	Olanzapine	S	Unknown		Apotex
	Nortriptyline	S	Unknown	75 Mg, Qd	Not Reported
	Lorazepam	S	Unknown	0.5 Mg, Qd	Not Reported
	Venlafaxine	S	Unknown		Not Reported
	Diazepam	S	Unknown		Not Reported
	Quetiapine	S	Unknown		Not Reported
	Oxcarbazepine	S	Unknown		Not Reported
	Topiramate	S	Unknown		Not Reported
	Clonazepam	S	Unknown		Not Reported
	Flurazepam	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14145184	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC- 2016569750			Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia; Maternal Exposure During Pregnancy; Neonatal Disorder; Sepsis Neonatal; Transient Tachypnoea Of The Newborn	Temesta (Lorazepam)			S	Transplacental	1 Mg, 3x/Day In Reserve		Pfizer
	Ciprallex			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Folic Acid			C		5 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14148472	DIRECT		DS, OT			37 YR	Male	NOR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Anorgasmia; Disturbance In Attention; Erectile Dysfunction; Erectile Dysfunction; Feeling Abnormal; Hypogeusia; Hyposmia; Loss Of Libido; Memory Impairment	Cipralelex Vitamin B C D			S C C C	Oral	Quantity:1 Tablet(S);		Farmagon Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14148499	DIRECT		DS			36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14148578	DIRECT		OT			28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Apathy; Female Orgasmic Disorder; Loss Of Libido; Sensory Loss; Sexual Dysfunction	Cipralelex			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14148662	DIRECT		OT			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Loss Of Libido	Lexapro Multivitamin Spurilina D3 & K2 Probiotic			S C C C C	Oral			Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

L-Lysine			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	13418182	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-027204		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section;	Aripiprazole			S	Unknown	15 Mg, Unk		Bristol Myers Squibb	
Gestational Diabetes; Live	Aripiprazole			S	Unknown	10 Mg, Unk		Bristol Myers Squibb	
Birth; Maternal Exposure	Aripiprazole			S	Unknown	15 Mg, Unk		Bristol Myers Squibb	
During Pregnancy;	Lamictal			S	Unknown	Unk		Not Reported	
Prescribed Underdose;	Lexapro			S	Unknown	Unk		Not Reported	
Product Use Issue;	Ativan			S	Unknown	Unk		Not Reported	
Prolonged Labour									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	13418381	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-028477		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section; Fluid	Aripiprazole			S	Unknown	10 Mg, Unk		Bristol Myers Squibb	
Replacement; Gestational	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb	
Diabetes; Maternal	Lamictal			S	Unknown	Unk		Not Reported	
Exposure During	Celexa /00582602/			S	Unknown	Unk		Not Reported	
Pregnancy; Morning	Celexa /00582602/			S	Unknown	Unk		Not Reported	
Sickness; Nausea; Normal	Lexapro			S	Unknown	Unk		Not Reported	
Newborn; Oesophagitis;	Lexapro			S	Unknown	Unk		Not Reported	
Pre-Eclampsia; Prescribed	Glyburide			S	Unknown	Unk		Not Reported	
Underdose; Product Use	Ativan			S	Unknown	Unk		Not Reported	
Issue	Zofran /00955301/			S	Unknown	Unk		Not Reported	
	Compazine /00013304/			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	14148404	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1760592US		51 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Haematochezia; Intentional Dose Omission; Nausea; Poor Quality Sleep; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	14148541	EXPEDITED (15-DAY)		HO	US-APOTEX-2017AP020319		94 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Drug Intolerance; Treatment Failure	Sertraline Hydrochloride			S	Unknown	Unk		Apotex	
	Escitalopram Oxalate			S	Unknown	Unk		Apotex	
	Mirtazapine			S	Unknown	Unk		Apotex	
	Bupropion Hydrochloride			S	Unknown	Unk		Apotex	
	Trazodone Hydrochloride			S	Unknown	Unk		Apotex	
	Lamotrigine			S	Unknown	Unk		Apotex	
	Clonazepam Tablets Usp			S	Unknown	Unk		Apotex	
	Donepezil Hydrochloride Tablets Usp			S	Unknown	Unk		Apotex	
	Memantine Hydrochloride Extended Release Capsules			S	Unknown	Unk		Apotex	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Methylphenidate			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	14149266	EXPEDITED (15-DAY)		DS, OT	US-ACADIA PHARMACEUTICALS			Female	USA

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INC.-ACA-2017-006015

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Crying; Drug Ineffective; Gait Inability; Muscle Rigidity; Off Label Use	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuplazid			S				Acadia Pharmaceuticals
	Nuedexta			S	Oral	10 Mg, Unk		Not Reported
	Escitalopram			S				Not Reported
	Namenda			S		2 Mg, Bid		Not Reported
	Nortriptyline			C				Not Reported
	Prenatal Vitamins			C		500 Mg, Bid		Not Reported
	Depakote			C				Not Reported
	Seroquel			C			25 Mg, Bid	Not Reported
	Baby Aspirin			C				Not Reported
	Turmeric			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	14149518	DIRECT		DS			28 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperacusis; Sensory Disturbance; Sexual Dysfunction; Tinnitus; Withdrawal Syndrome	Escitalopram			S				Lundbeck

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	12914074	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-11087			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Insomnia	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151326	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US19120			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Escitalopram			S	Unknown	20 Mg, Qd (Camber Manufactured)		Invagen	
	Escitalopram			S	Oral	20 Mg, Qd (Cipla Manufactured)		Invagen	
	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151358	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US13729			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Reaction To Excipient; Hypersensitivity; Rash Papular	Escitalopram			S	Oral	10 Mg, Qd, One Half Tablet For One Week Every Morning		Invagen	
	Escitalopram			S	Oral	20 Mg, Qd, One Tablet Every Morning		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151359	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US11250			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Dizziness; Product Shape Issue; Product Substitution Issue; Psychomotor Hyperactivity	Escitalopram			S	Unknown	10 Mg, Qd		Invagen	
	Klonopin			C	Unknown	Unk		Not Reported	
	Vitamin B12			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151360	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US08203			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Oropharyngeal Pain	Escitalopram			S	Oral	10 Mg, Qd, One In The Morning Daily		Invagen	
	Vicodin			C	Unknown	Unk		Not Reported	
	Morphine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151377	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US12241			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Hypersomnia; Increased Appetite; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen	
	Escitalopram			S	Oral	20 Mg, Qd		Invagen	
	Toujeo			C	Unknown	50 Units Once Daily (25u And 25u)		Not Reported	
	Lisinopril			C	Unknown	5 Mg, Qd		Not Reported	
	Janumet Xr			C	Unknown	50 Mg, Qd		Not Reported	
	Janumet Xr			C	Unknown	100 Mg, Qd		Not Reported	
	Multimineral Vitamin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151382	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US12240			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Hypersomnia; Increased Appetite; Product Substitution Issue; Weight Fluctuation	Escitalopram			S	Oral	20 Mg, Unk, Other Generics For Many Years		Invagen	
	Escitalopram			S	Oral	20 Mg, Qd		Invagen	
	Tricor			C	Unknown	145 Mg, Qd		Not Reported	

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Lisinopril	C	Unknown	5 Mg, Qd	Not Reported
Pravastatin	C	Unknown	10 Mg, Qd	Not Reported
Xanax	C	Unknown	0.25 Mg, Qd	Not Reported
Insulin Humalog	C	Unknown	40 U, Bid	Not Reported
Insulin Lantus	C	Unknown	40 U, Bid (20 U And 20 U)	Not Reported
Vitamins	C	Unknown	Unk	Not Reported
Magnesium	C	Unknown	1000 Mg, Qd	Not Reported
Aspirin	C	Unknown	81 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151602	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US13650			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Throat Irritation; Tongue Discomfort	Escitalopram			S	Oral	10 Mg, Qd		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151832	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2015-06147			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Fall; Vertigo	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151848	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2015-06200			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Substitution Issue; Therapy Non-Responder	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151877	EXPEDITED (15-DAY)		OT	US-CIPLA- 2016US18259			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram			S	Oral	20 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151889	NON-EXPEDITED				US-AUROBINDO-AUR-APU-2015-06204		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Headache; Hot Flush; Muscular Weakness; Nausea; Product Substitution Issue	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151892	NON-EXPEDITED				US-AUROBINDO-AUR-APU-2015-06211		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Headache; Insomnia; Panic Attack	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151894	NON-EXPEDITED				US-AUROBINDO-AUR-APU-2015-06202		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Complaint; Therapy Non-Responder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151895	NON-EXPEDITED				US-AUROBINDO-AUR-APU-2016-09057		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151896	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2015-06201			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Complaint; Therapy Non-Responder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151908	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2016-14911			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Insomnia	Escitalopram Tablets Usp 20mg			S		Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151909	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-29546		41 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Distension;	Escitalopram Tablets Usp 20mg			S	Oral	20 Mg, Daily		Aurobindo	
Diarrhoea; Headache;	Lyrica			C	Unknown			Not Reported	
Malaise; Nausea; Product	Omeprazole			C	Unknown			Not Reported	
Substitution Issue	Venaflox			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151910	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-29297			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nausea	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151912	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-01093		55 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngeal Swelling	Escitalopram Tablets Usp 20mg			S	Unknown	2 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151977	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-40249			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain	Escitalopram Tablets Usp 5mg			S	Unknown	5 Mg, Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151978	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-36006			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Respiratory Disorder	Escitalopram Tablets Usp 10mg			S	Unknown	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14151981	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-36129			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Product Substitution Issue	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14152254	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1069810			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy; Sinus Tachycardia	Escitalopram			S		Unk		Not Reported	
	Clozapine			S		Unk		Not Reported	
	Clopine			S				Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14154012	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1761787US		37 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14154014	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1761645US		91 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertransaminasaemia; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Cardarone			S	Unknown	Unk		Not Reported	
	Durogesic			C	Transdermal	25 Mg/Hr		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14154309	EXPEDITED (15-DAY)		DE	TR-ALLERGAN-1761530US		36 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan	
	Paracetamol			S	Unknown	Unk		Not Reported	
	Tramadol			S	Unknown	Unk		Not Reported	
	Diclofenac			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	13844817	EXPEDITED (15-DAY)			US-HETERO CORPORATE-HET2017US00056		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective		Escitalopram		S	Oral		10 MI, Qd		Hetero	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
03-Nov-2017	14155011	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US01041			Unknown	USA	
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Thirst	Escitalopram				S	Oral	Unk		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
03-Nov-2017	14155012	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US18536			Unknown	USA	
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash; Skin Disorder	Escitalopram				S	Oral	20 Mg, Qd, In The Morning		Invagen	
	Insulin				C	Unknown	Unk		Not Reported	
	Levothyroxin				C	Unknown	300 Mg, Qd		Not Reported	
	Crestor				C	Unknown	20 Mg, Qd, 15 Years		Not Reported	
	Iron				C	Unknown	700m/ Once Daily, 10 Years		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
03-Nov-2017	14155013	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US02350			Unknown	USA	
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus Generalised; Skin Haemorrhage	Escitalopram				S	Oral	10 Mg, Qd		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
03-Nov-2017	14155014	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US01014			Unknown	USA	
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Glucose Increased	Escitalopram				S	Oral	20 Mg, Qd		Invagen	

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Janumet Xr	C	Unknown	100/1000mg	Not Reported
Lamotrigine	C	Unknown	150 Mg, Bid	Not Reported
Levothyroxine	C	Unknown	50 Mcg, Qd	Not Reported
Lisinopril	C	Unknown	20 Mg, Qd, One At Night	Not Reported
Simvastatin	C	Unknown	40 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155027	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US20620			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Product Substitution Issue; Pruritus	Escitalopram			S	Unknown	10 Mg, Qd, Lexapro		Invagen	
	Escitalopram			S	Unknown	10 Mg, Qd, Camber Pharma		Invagen	
	Escitalopram			S	Unknown	10 Mg, Unk, Cipla		Invagen	
	Escitalopram			S	Unknown	10 Mg, Qd, Unknown Manufacturer		Invagen	
	Escitalopram			S	Unknown	10 Mg, Unk, Cipla		Invagen	
	Omeprazole Magnesium			C	Unknown	20.6 Mg, Qd		Not Reported	
	Centrum Multivitamin			C	Unknown	Unk, Qd, Every Morning		Not Reported	
	Butalbital			C	Unknown	Unk, Prn		Not Reported	
	Acetaminophen			C	Unknown	Unk, Prn		Not Reported	
	Caffeine			C	Unknown	Unk, Prn		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155029	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US04622			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error	Escitalopram			S	Oral	5 Mg, Qd		Invagen	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155031	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US04112			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Dysphagia; Oropharyngeal Pain	Escitalopram			S	Oral	20 Mg, Qd, Quiet A Long		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155073	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US08901			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tremor	Escitalopram			S	Oral	10 Mg, Qd, In Morning		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155074	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US23377			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Nasal Congestion; Ocular Hyperaemia; Rhinorrhoea; Sneezing	Escitalopram			S	Oral	5 Mg, Unk		Invagen	
	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155076	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US01296			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue; Nausea	Escitalopram			S	Oral	5 Mg, Qd		Invagen	
	Levothyroxine			C	Unknown	112 Mcg, Qd		Not Reported	
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155077	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US23427			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety	Escitalopram			S	Unknown	20 Mg, Unk		Invagen	
	Escitalopram			S	Unknown	Tapering Down 5 Mg Every Month		Invagen	
	Escitalopram			S	Unknown	5 Mg		Invagen	
	Escitalopram			S	Unknown	10 Mg		Invagen	
	Escitalopram			S	Unknown	Tapering For 2 Months		Invagen	
	Wellbutrin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155079	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US04070			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anger; Drug Ineffective; Irritability; Medication Error	Escitalopram			S	Oral	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155080	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2016US19157			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Feeding Disorder; Product Substitution Issue	Escitalopram			S	Oral	40 Mg, Bid		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14155081	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US10341			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated	Escitalopram	S	Oral	10 Mg, Unk	Invagen				
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155084	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US04308			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Dizziness; Product Substitution Issue	Escitalopram			S	Unknown	10 Mg, Camber		Invagen	
	Escitalopram			S	Unknown	10 Mg, Every 30 Days		Invagen	
	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156999	DIRECT	Y				66 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Therapeutic Product Effect Decreased	Apokyn Inj			S	Subcutaneous	0.2-0.4ml Up To 5 Times Sq		Us Worldmeds	
	Baclofen			S				Not Reported	
	Carbidopa/Levodopa			S				Not Reported	
	Clonazepam			S				Not Reported	
	Escitalopram			S				Not Reported	
	Ropinirole			S				Not Reported	
	Trimethobenzamide			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14157011	DIRECT		DS, HO			34 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blindness; Eating Disorder; Migraine; Sleep Disorder	Lexapro			S	Oral	Quantity:6 Tablet(S);		International Labs	
	Gabapentin			C				Not Reported	
	Risperidone			C				Not Reported	
	Benadryl			C				Not Reported	
	Meloxicam			C				Not Reported	

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Linzess			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2017	14160781	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00003557		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine Besilate			S	Oral			Unknown	
	Ethanol			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	13902443	EXPEDITED (15-DAY)		DE, HO	FR-CIPLA LTD.-2017FR14768			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bezoar; Cardiogenic Shock; Coma; Gastrointestinal Ischaemia; Hyperlactacidaemia; Intentional Overdose; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Shock; Skin Necrosis; Toxicity To Various Agents	Hydroxyzine			S	Oral	25 Mg, 28 Tablets Total		Invagen	
	Escitalopram			S	Oral	10 Mg, 28 Tablets Total		Invagen	
	Citalopram			S	Unknown	Unk		Invagen	
	Zolpidem Tartarate			S	Unknown	Unk		Invagen	
	Sevikar			S	Oral	129 Tablets, 1.29 G Of Amlodipine And 5.16 G Of Olmesartan		Not Reported	
	Lysanxia			S	Oral	10 Mg, 42 Tablets Total		Not Reported	
	Nordazepam			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14100622	EXPEDITED (15-DAY)		OT	PHHY2017MX126694			Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anxiety; Behaviour Disorder; Burning Sensation; Delirium; Hallucination;	Exelon Patch			S	Transdermal	9.5 Mg, Patch 10 (Cm2) (Every Third Day)		Novartis	
	Escitalopram			S	Unknown			Not Reported	

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Impulsive Behaviour; Inappropriate Schedule Of Product Administration; Irritability; Judgement Impaired; Product Prescribing Error; Sleep Disorder; Soliloquy; Somnolence; Weight Decreased	Levothyroxine Diazepam	C C	Unknown Unknown	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14159136	EXPEDITED (15-DAY)		DS	CA-APOTEX- 2017AP020550		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Mental Status Changes	Apo-Escitalopram Apo-Lorazepam			S S	Oral Unknown	10 Mg, Unk Unk		Apotex Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14162456	EXPEDITED (15-DAY)		DE, HO, LT	AT-TEVA-822441ISR		73 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Cardiac Disorder; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Azilect 1mg			S	Unknown	One In The Morning		Teva
	Stalevo 100mg/25mg/200mg			S	Unknown	One In The Morning		Not Reported
	Stalevo 100mg/25mg/200mg			S		One In The Morning, One At Noon		Not Reported
	Cipralext 10mg - Filmtabletten			S	Unknown	Two In The Morning		Not Reported
	Cipralext 10mg - Filmtabletten			S		One In The Morning		Not Reported
	Trittico 150mg			S	Unknown	Half At Night		Not Reported
	Seroquel 25mg			S	Unknown	As Needed		Not Reported
	Madopar 50mg/12.5mg			S	Unknown	One In The Morning, One At Noon, One In The Evening		Not Reported
	Stalevo 50mg/12.5mg/200mg			S	Unknown			Not Reported

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Lovenox	C	1 Daily	Not Reported
Elomel	C	1 Daily	Not Reported
Optinem	C		Not Reported
Lasix	C		Not Reported
Thrombo Ass 100mg	C	One At Noon	Not Reported
Spirobene	C	Half At Noon	Not Reported
Sedacoron 200mg	C	Half In The Morning	Not Reported
Eporatio	C	1 Weekly	Not Reported
Ceftriaxone Sodium	C	2 G In 200 ML, 1 Daily	Not Reported
Dancor	C	One In The Morning, One In The Evening	Not Reported
Aquaphoril	C	Half In The Morning	Not Reported
Torasemide	C	One In The Morning	Not Reported
Pantoloc	C	Two In The Morning	Not Reported
Insulatard	C	6ie-0-0 (International Unit)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	11749180	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015US-106192			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Motor Dysfunction; Neurological	Escitalopram			S	Unknown	Unk		Not Reported
Decompensation; Neuromyopathy; Suicidal Ideation; Therapeutic Response Decreased	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	11749185	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015US-106193			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Motor Dysfunction; Pain In Jaw; Periodic Limb Movement Disorder; Rapid Eye Movements Sleep Abnormal	Escitalopram	S	Unknown	Unk	Not Reported
	Bupropion	C	Unknown	Unk	

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07-Nov-2017	13947490	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2017GB15701			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Rash Pruritic; Seborrhoea	Escitalopram			S	Oral	20 Mg, Unk		Invagen
	Vitamin D Nos			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14056792	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1756587US		62 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Ulcerative; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan
	Mirtazapin			S	Unknown	15 Mg, Unk		Not Reported
	Cortinson			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Brilique			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14167417	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1763755US		42 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

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Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
Amlodipine	C	Oral	Unk	Not Reported
Enalapril Maleate	C	Oral	Unk	Not Reported
Furosemide	C	Oral	Unk	Not Reported
Spironolactone	C	Oral	Unk	Not Reported
Enteronon	C	Oral	Unk	Not Reported
Bisoprolol Fumarate	C	Oral	Unk	Not Reported
Lixiana	C	Oral	Unk	Not Reported
Flunitrazepam	C	Oral	Unk	Not Reported
Belsomra	C	Oral	Unk	Not Reported
Reflex	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14168693	DIRECT	Y	LT			29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14169254	EXPEDITED (15-DAY)		DE, OT	US-TORRENT-00003677		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Duloxetine Hydrochloride			S	Oral			Unknown	
	Bupropion Hydrochloride			S	Oral	Extended Release		Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14169695	NON-EXPEDITED		OT	US-APOTEX-2017AP020633		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Treatment Noncompliance	Aripiprazole Tablets	S	Unknown	5 Mg, Q.H.S.	Apotex
	Aripiprazole Tablets	S			Apotex
	Olanzapine	S	Unknown	2.5 Mg, Q.6h As Needed	Apotex
	Olanzapine	S			Apotex
	Escitalopram Oxalate	S	Unknown	10 Mg, Daily	Apotex
	Mycophenolate Mofetil	S	Unknown	500 Mg, Bid	Apotex
	Mycophenolate Mofetil	S	Unknown	1000 Mg, Bid	Apotex
	Levothyroxine	C	Unknown	125 Mg, Unk	Not Reported
	Levothyroxine	C	Unknown	150 Mg, Unk	Not Reported
	Cefdinir	C	Oral		Not Reported
	Nitrofurantoin	C	Unknown		Not Reported
	Lorazepam	C	Oral	0.5 Mg, Q.Am	Not Reported
	Lorazepam	C	Oral	0.5 Mg, Q.H.S.	Not Reported
	Prednisone	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14169862	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US13026			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Torticollis	Escitalopram			S	Unknown	5 Mg, Daily		Invagen	
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen	
	Escitalopram			S	Unknown	15 Mg, Daily		Invagen	
	Clonazepam			C	Unknown	0.25 Mg, At Bedtime		Not Reported	
	Clonazepam			C	Unknown	0.25 Mg Qd, At Bedtime		Not Reported	
	Clonazepam			C	Unknown	0.5 Mg, At Bedtime As Needed		Not Reported	
	Clonazepam			C	Unknown	0.5 Mg, Qd, At Bedtime		Not Reported	
	Clonazepam			C	Unknown	Unk		Not Reported	

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Ibuprofen	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Tamsulosin	C	Unknown	Unk	Not Reported
Omeprazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14169977	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2016IT23059			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Diarrhoea	Escitalopram			S	Oral	10 Mg Daily		Invagen
	Cardioaspirin			C	Oral			Not Reported
	Serenase (Haloperidol)			C	Oral			Not Reported
	Quetiapine			C	Oral	25 Mg, Unk		Not Reported
	Enalapril			S	Oral	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14170067	EXPEDITED (15-DAY)		OT	FR-TEVA-822284ROM		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Not Reported
	Bisoprolol			S	Unknown			Duramed

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14170249	EXPEDITED (15-DAY)		OT	FR-TEVA-822294ROM		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Milligram Daily;		Not Reported
	Galantamine			S	Unknown			Barr
	Irbesartan			S	Unknown			Teva

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Paracetamol			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14171264	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1069569		71 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Pneumonia	Mylan Oxybutynin 5 Mg			S	Oral	5 Mg, Unk		Mylan	
	Mylan Escitalopram 10			S	Oral	10 Mg, Unk		Mylan	
	Tranqipam			S	Oral	1 Mg, Unk		Mylan	
	Epilim Cr			S	Oral	500 Mg, Unk		Mylan	
	Crestor			S	Oral	5 Mg, Unk		Mylan	
	Stilnox			S		10 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14171509	EXPEDITED (15-DAY)		OT	CH-SA-2017SA214728		39 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S	Oral			Not Reported	
	Stilnox			S	Oral			Not Reported	
	Mabthera			S	Intravenous drip			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Cipralext			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	13036197	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1680884US		27 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pregnancy	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Temesta / Lorazepam			S	Oral	1 Mg If Necessary Up To 3 Times Per Day.		Not Reported	

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Folic Acid	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported

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09-Nov-2017	14155649	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068688		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	14155658	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068709		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported
	Bisoprolol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	14157202	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068768		86 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Digoxin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	14173087	EXPEDITED (15-DAY)		OT	CH-ROCHE-2019359		39 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Maternal Exposure During	Mabthera			S	Intravenous drip			Not Reported

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Pregnancy	Mabthera	S	Intravenous drip	Not Reported
	Plaquenil	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Stilnox	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	14174611	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760600US		24 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Vacuum Extractor Delivery	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
	Tandospirone Citrate			C				Not Reported	
	Constan [Alprazolam]			C				Not Reported	
	Alprazolam			C				Not Reported	
	Metligine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	13189385	NON-EXPEDITED		DE	US-MALLINCKRODT-T201607139		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Mixed Amphetamine Salts			S	Oral			Mallinckrodt	
	Bupropion			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14025048	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2017-005341		18 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation	Orkambi			S	Oral	2 Dosage Form, Bid		Vertex	
	Lexapro			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro	S	Unknown	Unk	Not Reported
Abilify	C		Unk	Not Reported
Intuniv	C		Unk	Not Reported
Omeprazole	C		Unk	Not Reported
Pulmozyme	C		Unk	Not Reported
Zoloft	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14155637	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068690		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported	
	Bisoprolol			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14155661	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068651		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported	
	Metoclopramide			S	Unknown			Not Reported	
	Diazepam			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14157197	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2017M1068752		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest;	Escitalopram			S	Unknown			Not Reported	
Electrocardiogram Qt Prolonged	Indapamide			S	Unknown			Not Reported	
	Sotalol			S	Unknown			Not Reported	
	Benzoic Acid			S	Unknown			Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14157268	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068831		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14169912	EXPEDITED (15-DAY)		OT	FR-TEVA-822277ROM		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported	
	Bisoprolol			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14170046	EXPEDITED (15-DAY)		DE	FR-TEVA-822282ROM		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Ivax	
	Indapamide			S	Unknown			Actavis	
	Sotalol			S	Unknown			Teva	
	Benzoic Acid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14170183	EXPEDITED (15-DAY)		OT	FR-TEVA-822293ROM		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Not Reported	
	Candesartan-Cilexetil			S	Unknown			Not Reported	

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Spironolactone	S	Unknown	Actavis
Ivabradine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14170286	EXPEDITED (15-DAY)		OT	FR-TEVA-822295ROM		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Bisoprolol			S	Unknown			Teva
	Furosemide			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14170326	EXPEDITED (15-DAY)		OT	FR-TEVA-822296ROM		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Milligram Daily;		Not Reported
	Pramipexole			S	Unknown			Barr

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14170562	EXPEDITED (15-DAY)		OT	FR-TEVA-822304ROM		61 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Not Reported
	Diazepam			S	Unknown			Barr
	Metoclopramide			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14179416	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1764474US		70 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Qd	Allergan
	Salbutamol	C	Unknown	Unk	Not Reported
	Alendronic Acid	C	Unknown		Not Reported
	Bendroflumethiazide	C	Unknown	Unk	Not Reported
	Calciferol [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Morphine Sulphate	C	Unknown	Unk	Not Reported
	Tiotropium	C	Unknown	Unk	Not Reported
	Prucalopride	C	Unknown	Unk	Not Reported
	Cald3-Therapy	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2017	14180916	EXPEDITED (15-DAY)		HO, OT	CH-SA-2017SA219071			Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Stilnox			S	Transplacental			Not Reported
	Seroquel			S	Transplacental			Not Reported
	Abilify			S	Transplacental			Not Reported
	Ciprallex			S	Transplacental			Not Reported
	Lamictal			S	Transplacental			Not Reported
	Temesta (Lorazepam)			S	Transplacental	2016		Not Reported
	Brufen			S	Transplacental			Not Reported
	Dafalgan			S	Transplacental			Not Reported
	Lyrica			S	Transplacental	2016		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2017	14181076	EXPEDITED (15-DAY)		DE	US-TORRENT-00003750		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide;	Amlodipine Besilate			S		Ingst + Par		Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Toxicity To Various Agents	Enalapril Maleate	S	Ingst + Par	Unknown
	Escitalopram Oxalate	S	Ingst + Par	Unknown
	Tamsulosin Hydrochloride	S	Ingst + Par	Unknown
	Insulin	S	Ingst + Par	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2017	14181168	EXPEDITED (15-DAY)		HO, OT	CA-ALEMBIC PHARMACUEICALS LIMITED- 2017SCAL000901			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoea; Coma Scale Abnormal; Confusional State; Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Overdose; Irritability; Miosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Unresponsive To Stimuli	Quetiapine Fumarate			S		Unk		Alembic
	Temazepam			S		Unk		Not Reported
	Oxazepam			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Topiramate			S		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Ferrous Gluconate			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Spironolactone And Hydrochlorothiazide			C		Unk		Not Reported
	Fluticasone W/Salmeterol			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	8459295	EXPEDITED (15-DAY)		OT	AU-PFIZER INC- 2012064736		25 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggression; Agitation;	Sertraline Hcl	S	300 Mg, 1x/Day	Pfizer
Akathisia; Depressed	Escitalopram Oxalate	S	10 Mg, 1x/Day	Not Reported
Mood; Drug Interaction;	Escitalopram Oxalate	S		Not Reported
Ejaculation Failure;	Hypericum	S	900 Mg, 1x/Day	Not Reported
Feeling Of Despair;	Hypericum	S		Not Reported
Impulsive Behaviour;				
Mania; Overdose;				
Paranoia; Personality				
Change; Physical Assault;				
Suicide Attempt; Toxicity				
To Various Agents				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14154318	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068647		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10mg Daily		Not Reported
	Pramipexole			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14155652	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068689		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10mg Daily		Not Reported
	Galantamine			S	Unknown			Not Reported
	Irbesartan			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14155660	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1068700		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5mg Daily		Not Reported

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Candesartan	S	Unknown	Not Reported
No Drug Name	S	Unknown	Not Reported
Spironolactone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181369	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003570		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Hydrocodone Bitartrate			S	Oral			Unknown
	Tramadol Hydrochloride			S	Oral			Unknown
	Baclofen			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181380	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003618		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Diphenhydramine			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181382	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00003637		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Unknown
	Doxepin			S	Oral			Unknown
	Hydrocodone			S	Oral			Unknown

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Olmesartan	S	Oral	Unknown
Alprazolam	S	Oral	Unknown
Hydrochlorothiazide	S	Oral	Unknown
Famotidine	S	Oral	Unknown
Cetirizine Hydrochloride	S	Oral	Unknown
Pregabalin	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181659	NON-EXPEDITED			US-AMGEN- USASP2017168626			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stomatitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Lyrica			S	Unknown	100 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Nortriptyline Hcl			S	Unknown	10 Mg, Unk		Not Reported
	Amlodipine Besylate			S	Unknown	2.5 Mg, Unk		Not Reported
	Metformin Hcl			S	Unknown	500 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	7.5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Cal Gest			S	Unknown	200 (500) Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181696	DIRECT		OT			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Bupropion			S				Not Reported
	Prozac			S				Not Reported
	Lexapro			S				Not Reported
	Celexa			S				Not Reported
	Zoloft			S				Not Reported
	Effexor			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14181739	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003589		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
	Ibuprofen			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14182097	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US19687			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Electrocardiogram Qt Prolonged; Therapy Non-Responder	Olanzapine			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	
	Bupropion			S	Unknown	Unk		Invagen	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Amitriptyline			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Iloperidone			S	Unknown	Unk		Not Reported	
	Quetiapine			C	Unknown	50 Mg At Bedtime And 25 Mg During The Day		Not Reported	
	Clonazepam			C	Unknown	1 Mg, Bid		Not Reported	
	Trazodone			C	Unknown	50 Mg, At Bed Time		Not Reported	
	Warfarin			C	Unknown	6 Mg, Daily		Not Reported	
	Propranolol			C	Unknown	160 Mg, Daily		Not Reported	
	Methimazole			C	Unknown	30 Mg, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184332	NON-EXPEDITED			US-MYLANLABS-2017M1070306		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Headache; Memory Impairment; Nausea; Photosensitivity Reaction; Vomiting	Buspirone			S	Oral			Not Reported	
	Lorazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184454	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764700US		81 YR	Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Carbidopa			C	Unknown	0.5 Df, Qid		Not Reported	
	Amantadine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184455	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764705US		67 YR	Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Ropinirole			C	Unknown	Unk		Not Reported	
	Amantadine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184456	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1765156US		73 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	

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Parkinson'S Disease	Ropinirole	C	Unknown	Not Reported
	Carbidopa	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184457	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1764704US		83 YR	Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Rosagiline			C	Unknown	Unk		Not Reported	
	Carbidopa			C	Unknown	0.5 Df, Qid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184498	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1764810US		1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia Neonatal; Neonatal Behavioural Syndrome; Sepsis Neonatal; Transient Tachypnoea Of The Newborn	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Temesta / Lorazepam			S	Transplacental	1 Mg If Necessary Up To 3 Times Per Day.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184553	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2017480995		121 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy	Temesta (Lorazepam)			S	Transplacental	In Reserve 1mg 4x/Day, No Regular Intake, Stopped In Early Pregnancy		Pfizer	
	Lyrica			S	Transplacental	100mg, 3x/Day (Treatment Stopped In Early Pregnancy)		Pfizer	

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Seroquel	S	Transplacental	50 Mg, Daily (In Reserve In The Evening Until The Beginning Of The Pregnancy)	Not Reported
Seroquel	S	Transplacental	100 Mg At Bedtime + 25 Mg In Reser	Not Reported
Abilify	S	Transplacental	10mg 2x/Day, Treatment Taken Until Delivery	Not Reported
Ciprallex /01588501/	S	Transplacental	20 Mg, Daily	Not Reported
Ciprallex /01588501/	S	Transplacental	20mg/D Decreased To 10mg/D Until Delivery	Not Reported
Stilnox	S	Transplacental	10 Mg, Daily	Not Reported
Stilnox	S	Transplacental	12.5 Mg, Daily	Not Reported
Lamictal	S	Transplacental	150mg Daily (Treatment Taken Until Delivery)	Not Reported
Brufen	S	Transplacental	400mg, 3x/Day (Treatment Stopped During Pregnancy)	Not Reported
Dafalgan	S	Transplacental	1g, 2x/Day (According To Catamnesis In Reserve)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184658	NON-EXPEDITED			PHEH2017US036190			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Delusion; Lacrimation Increased; Mydriasis; Personality Change; Product Use In Unapproved Indication	Gilenya			S	Oral	0.5 Mg, Qd		Novartis	
	Gilenya			S				Novartis	
	Etodolac			S	Unknown	Unk		Not Reported	
	Osartan			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Rosuvastatin			S	Unknown			Not Reported	
	Nortriptyline			C	Unknown			Not Reported	
	Azithromycin			C	Unknown	250 Mg, Unk		Not Reported	

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Vitamin D3	C	Unknown	50000 U, Unk	Not Reported
Zetia	C	Unknown	10 Mg, Unk	Not Reported
Diazepam	C	Unknown	5 Mg/ML, Unk	Not Reported
Lisinopril	C	Unknown		Not Reported
Hydrocodone/Acetaminophen	C	Unknown		Not Reported
Cephalexin	C	Unknown		Not Reported
Trazodone Hcl	C	Unknown		Not Reported
Methocarbamol	C	Unknown		Not Reported
Amlodipine Besylate	C	Unknown		Not Reported
Metoprolol Succinate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	13662423	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017005237			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse;	Escitalopram			S	Unknown	6 Df, Unk		Macleods	
Electrocardiogram Qt	Lorazepam			S	Oral	10 MI, Unk		Not Reported	
Prolonged; Intentional	Quetiapine			C	Unknown	Unk		Macleods	
Self-Injury; Slow Speech;	Carbaolthium			C	Unknown	Unk		Not Reported	
Somnolence; Suicidal									
Ideation									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186398	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201711- 006359		39 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Plaquenil			S	Oral			Concordia	
Exposure During	Stilnox			S	Oral			Not Reported	
Pregnancy	Mabthera			S	Intravenous drip			Not Reported	

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Prednisone	S	Oral	Not Reported
Cipraxel	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186962	NON-EXPEDITED			US-PFIZER INC-2017488946		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stomatitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Lyrice			S	Unknown	100 Mg, Unk		Pfizer
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Nortriptyline Hcl			S	Unknown	10 Mg, Unk		Not Reported
	Amlodipine Besilate			S	Unknown	2.5 Mg, Unk		Pfizer
	Metformin Hcl			S	Unknown	500 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	7.5 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Cal Gest			S	Unknown	200 (500) Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186987	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1765143US		39 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Plaquenil			S	Unknown	200 Mg, Q12h		Not Reported
	Mabthera			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Stilnox			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14188121	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1764290US			Male	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Operation; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14064266	EXPEDITED (15-DAY)		OT	US-ACORDA-ACO_142563_2017			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anger; Asthenia; Back Pain; Balance Disorder; Dyssomnia; Fall; Fatigue; Gait Disturbance; Hemiparesis; Hypersomnia; Hypertonic Bladder; Hypoaesthesia; Intermittent Claudication; Joint Lock; Multiple Sclerosis Relapse; Muscle Spasms; Muscular Weakness; Neck Pain; Paraesthesia; Peroneal Nerve Palsy; Rash; Stent Placement; Temperature Intolerance; Vertigo	Ampyra			S	Unknown	Unk		Acorda	
	Tecfidera			S	Oral	240 Mg, Bid		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Rebif			S	Unknown	Unk		Not Reported	
	Topiramate			C	Oral	100 Mg, Qd		Not Reported	
	Zofran			C	Intravenous (not otherwise specified)	4 Mg, Prn		Not Reported	
	Abilify			C	Oral	10 Mg, Qd		Not Reported	
	Donepezil			C	Oral	5 Mg, Qam With Meal		Not Reported	
	Nuvigil			C	Oral	150 Mg, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14134778	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1760607US		29 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Overdose; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	120 Mg Once		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14190033	EXPEDITED (15-DAY)		OT	FR-STRIDES ARCOLAB LIMITED-2017SP013985			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Electrocardiogram Qt Prolonged	Pramipexole Dihydrochloride	S	Unknown	Unk	Strides
	Escitalopram	S	Unknown	10 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2017	14190782	EXPEDITED (15-DAY)		HO, OT	CH-GLAXOSMITHKLINE-CH2017170465		< 1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Seroquel			S	Transplacental	50 Mg, Unk		Glaxosmithkline	
	Cipralelex			S	Transplacental	10 Mg, Unk		Glaxosmithkline	
	Lamictal			S	Transplacental	150 Mg, Unk		Glaxosmithkline	
	Dafalgan			S	Transplacental	1 G, Bid		Glaxosmithkline	
	Abilify			S	Transplacental	10 Mg, Bid		Not Reported	
	Stilnox			S	Transplacental	10 Mg, Unk		Not Reported	
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Unk		Not Reported	
	Brufen			S	Transplacental	400 Mg, Tid		Not Reported	
	Lyrica			S	Transplacental	100 Mg, Tid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2017	14193146	EXPEDITED (15-DAY)		HO, OT	CH-MYLANLABS-2017M1071575		< 1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Brufen			S	Transplacental			Mylan	
	Seroquel			S	Transplacental	50 Mg, Qd		Mylan	
	Abilify			S	Transplacental	10 Mg, Qd		Mylan	
	Cipralelex			S	Transplacental	20 Mg, Qd		Mylan	
	Cipralelex			S	Transplacental	10 Mg, Qd		Mylan	
	Stilnox			S	Transplacental	10 Mg, Qd		Mylan	
	Lamictal			S	Transplacental	150 Mg, Qd		Mylan	
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Qid		Mylan	

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	Dafalgan		S	Transplacental					Mylan
	Lyrica		S	Transplacental					Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	13836098	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1733201US		54 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brugada Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Zacras			C	Oral	Unk		Not Reported	
	Zacras			C	Oral	Unk		Not Reported	
	Belsomra			C	Oral	Unk		Not Reported	
	Belsomra			C				Not Reported	
	Tasmolin			C	Oral	Unk		Not Reported	
	Tasmolin			C	Unknown			Not Reported	
	Boiogito			C	Oral			Not Reported	
	Boiogito			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14161061	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003574		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride			S	Oral			Unknown	
	Clonazepam			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
	Amphetamine/Dextroamphetamine (Extended Release)			S	Oral			Unknown	
	Ethanol			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14193633	NON-EXPEDITED		HO, OT	GR-LUPIN PHARMACEUTICALS		76 YR	Male	GRC

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14194093	EXPEDITED (15-DAY)		HO	PHHY2017FR166383		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Embolism; Thrombophlebitis	Exelon			S	Transdermal	1 Df, Qd		Novartis
	Escitalopram			S	Oral	Unk Unk, Qd		Not Reported
	Paracetamol			S	Oral	Unk Unk, Prn		Not Reported
	Temesta (Lorazepam)			S	Oral	1 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14194798	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004162		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Clonazepam			S	Oral			Unknown
	Trazodone Hydrochloride			S	Oral			Unknown
	Oxybutynin			S	Oral			Unknown
	Quetiapine			S	Oral			Unknown
	Lamotrigine			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Finasteride			S	Oral			Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14196390	NON-EXPEDITED			US-PFIZER INC-2017495320		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Sertraline Hcl			S		Unk		Pfizer	
	Bupropion Hcl			S		Unk		Not Reported	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Fluoxetine Hcl			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14196598	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1765583US		33 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Sexual Arousal; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14061827	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS INC.-2017-05202		49 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Affective Disorder; Anxiety; Apathy; Irritability; Sexual Dysfunction; Weight Increased	Paroxetine			S	Unknown	20 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Bupropion			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported	
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported	
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported	
	Reboxetina			C	Unknown	Unk		Not Reported	
	Lamotrigine			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14198168	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004252		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown	
	Temazepam			S	Oral			Unknown	
	Lorazepam			S	Oral			Unknown	
	Primidone			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
	Benzatropine Mesilate			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14198274	EXPEDITED (15-DAY)		DE	US-TORRENT-00004058		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S		Ingestion Plus Aspiration		Unknown	
	Zonisamide			S		Ingestion Plus Aspiration		Unknown	
	Lorazepam			S		Ingestion Plus Aspiration		Unknown	
	Escitalopram Oxalate			S		Ingestion Plus Aspiration		Unknown	
	Lovastatin			S		Ingestion Plus Aspiration		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199066	EXPEDITED (15-DAY)		DE	US-TORRENT-00004300		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Zolpidem			S		Ingestion Plus Inhalation (Extended Release)		Unknown	
	Ethanol			S		Ingestion Plus Inhalation		Unknown	
	Metamfetamine			S		Ingestion Plus Inhalation		Unknown	

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Escitalopram			S		Ingestion Plus Inhalation			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199146	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004160		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Verapamil Hydrochloride			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
	Codeine			S	Oral			Unknown	
	Topiramate			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199976	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003891		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral			Unknown	
	Ethanol			S	Oral			Unknown	
	Methocarbamol			S	Oral			Unknown	
	Oxycodone			S	Oral			Unknown	
	Lorazepam			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199981	EXPEDITED (15-DAY)		DE	US-TORRENT-00004015		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Unknown	
	Atomoxetine Hydrochloride			S	Oral			Unknown	
	Sertraline			S	Oral			Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199993	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004062		34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Amitriptyline Hydrochloride			S	Oral			Unknown
	Tramadol			S	Oral			Unknown
	Hydrocodone			S	Oral			Unknown
	Ondansetron Hydrochloride			S	Oral			Unknown
	Linaclotide			S	Oral			Unknown
	Diclofenac			S	Oral			Unknown
	Lubiprostone			S	Oral			Unknown
	Zolpidem Tartrate			S	Oral			Unknown
	Liothyronine Sodium			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Sertraline Hydrochloride			S	Oral			Unknown
	Gabapentin			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14200001	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00004056		28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Gabapentin			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14200009	EXPEDITED (15-DAY)		DE	US-TORRENT-00004079		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Completed Suicide; Toxicity To Various Agents	Promethazine	S	Oral	Unknown
	Verapamil Hydrochloride	S	Oral	Unknown
	Escitalopram Oxalate	S	Oral	Unknown
	Acetaminophen; Hydrocodone Bitartrate	S	Oral	Unknown
	Diazepam	S	Oral	Unknown
	Topiramate	S	Oral	Unknown
	Esomeprazole Magnesium	S	Oral	Unknown
	Diclofenac	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14200058	EXPEDITED (15-DAY)		DE	US-TORRENT-00003913		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Diphenhydramine Hydrochloride/Paracetamol			S	Oral			Unknown
	Warfarin			S	Oral			Unknown
	Olanzapine			S	Oral			Unknown
	Lisinopril			S	Oral			Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Prednisone			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14200076	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003945		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Toxicity To Various Agents	Oxycodone			S		Inhalation And Ingestion		Unknown
	Cyclobenzaprine Hydrochloride			S		Inhalation And Ingestion		Unknown
	Metoprolol			S		Inhalation And Ingestion		Unknown
	Clonidine			S		Inhalation And Ingestion		Unknown
	Glyceryl Trinitrate			S		Inhalation And Ingestion		Unknown

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	Lisinopril	S	Oral	Inhalation And Ingestion	Unknown
	Escitalopram Oxalate	S		Inhalation And Ingestion	Unknown
	Ibuprofen	S	Oral	Inhalation And Ingestion	Unknown
	Diclofenac	S		Inhalation And Ingestion	Unknown
	Azithromycin	S		Inhalation And Ingestion	Unknown
	Cefalexin	S		Inhalation And Ingestion	Unknown
	Doxycycline	S		Inhalation And Ingestion	Unknown
	Methylprednisolone	S		Inhalation And Ingestion	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14201672	EXPEDITED (15-DAY)		OT	PHHY2017AU169146		63 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myeloid Leukaemia;	Famciclovir			S	Unknown			Novartis
Anion Gap Increased;	Baclofen			S	Unknown			Not Reported
Blood Albumin Decreased;	Pantoprazole			S	Unknown			Not Reported
Blood Lactate	Idarubicin			S	Unknown			Not Reported
Dehydrogenase	Escitalopram			S	Unknown			Not Reported
Increased; Bundle Branch	Allopurinol			S	Unknown			Not Reported
Block Left; Dysplasia;	Duodart			S	Unknown			Not Reported
Fungal Infection;								
Haematocrit Decreased;								
Haemoglobin Decreased;								
Lung Infection;								
Myelodysplastic								
Syndrome; Platelet Count								
Decreased; Red Blood								
Cell Count Decreased;								
Red Cell Distribution								
Width Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14201982	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1766182US		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Circulatory Collapse; Coma; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp	S	Oral	160 Mg, Single	Allergan
	Baclofen	S	Oral	160 Mg, Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14202526	EXPEDITED (15-DAY)		OT	FR-ROCHE-2026651		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Mabthera			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Cotareg			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	13411746	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170303422		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Emotional Disorder; Gynaecomastia; Increased Appetite; Initial Insomnia; Obesity; Sleep Disorder	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	0.5 Mg Every Morning And 1 Mg Every Night Time		Not Reported

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	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported
	Strattera	S	Unknown	Not Reported
	Abilify	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14205187	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1072679		32 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Escitalopram			S	Oral			Not Reported	
	Trimipramin			S	Oral			Mylan	
	Trimipramin			S	Oral	75 Mg, Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14205924	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1766611US			Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Aromasin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14205928	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1766394US		1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan	
	Seroquel Xr			S	Transplacental	50 Mg, Qd		Not Reported	
	Seroquel Xr			S	Transplacental	100 Mg, Qd		Not Reported	

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Seroquel Xr	S	Transplacental	25 Mg, Unk	Not Reported
Abilify	S	Transplacental	10 Mg, Unk	Not Reported
Abilify	S	Transplacental	20 Mg, Unk	Not Reported
Abilify	S	Transplacental	10 Mg, Unk	Not Reported
Stilnox	S	Transplacental	10 Mg, Qd	Not Reported
Stilnox	S	Transplacental	12.5 Mg, Qd	Not Reported
Lamictal	S	Transplacental	150 Mg, Unk	Not Reported
Temesta (Lorazepam)	S	Transplacental	4 Df, Qd	Not Reported
Brufen	S	Transplacental	3 Df, Qd	Not Reported
Dafalgan	S	Transplacental	2 Df, Qd	Not Reported
Lyrica	S	Transplacental	3 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	9678754	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- 19721703		< 1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Jaundice Neonatal; Neonatal Hypoxia; Tremor	Abilify			S	Transplacental	10 Mg, Qd		Bristol Myers Squibb
	Seroplex			S	Transplacental	20 Mg, Qd		Not Reported
	Seresta			S	Transplacental	25 Mg, Bid		Not Reported
	Tercian			S	Transplacental	25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	13430940	EXPEDITED (15-DAY)		OT	IT- ELI_LILLY_AND_COMP ANY-IT201704002431		86 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Sedation Complication	Olanzapine			S	Oral	2.5 Mg, Daily		Eli Lilly And Co
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14208328	DIRECT		DE, HO, OT				Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Interaction; Gun Shot Wound	Escitalopram Oxalate			S				Not Reported	
	Clonazepam			S				Not Reported	
	Ambien			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14210918	EXPEDITED (15-DAY)		CA, HO	FR-SA-2017SA227373		273 DAY	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder	Stilnox			S	Transplacental			Not Reported	
	Seroplex			S	Unknown			Not Reported	
	Seresta			S	Transplacental			Not Reported	
	Donormyl (Doxylamine\Sodium Bromide\Sodium Phosphate, Dibasic, Anhydrous\Sodium Sulfate)			S	Transplacental			Not Reported	
	Xanax			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14184502	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1764786US		40 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Arrhythmia; Blood Pressure Increased; Extrasystoles; Libido Decreased; Palpitations; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

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Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
Escitalopram Oxalate - Bp	S	Oral	2.5 Mg, Qd	Allergan
Estazolam	C	Unknown	1 Tablet, Qd	Not Reported
Estazolam	C			Not Reported
Trazodone Hydrochloride	C	Unknown	30 Mg, Qd	Not Reported
Lorazepam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14186989	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1765178US		28 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperacusis; Pain In Jaw; Restless Legs Syndrome; Sensory Disturbance; Sexual Dysfunction; Therapy Cessation; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Losartan			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14213551	EXPEDITED (15-DAY)		HO	US-SCIEGEN PHARMACEUTICALS INC-2017SCILIT00686		2 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product By Child; Aggression; Asthenia; Ataxia; Depressed Level Of Consciousness; Dysstasia; Hypersomnia; Hypertonia; Hypophagia; Irritability; Mental Status Changes; Nuchal Rigidity; Slow Response To Stimuli; Urine Output Decreased	Aripiprazole			S	Unknown	Unk		Sciegen
	Ziprasidone			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14214408	NON-EXPEDITED			US-PFIZER INC-2017497283		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition	Xanax			S		Unk		Pfizer	
Aggravated; Drug	Xanax			S				Pfizer	
Ineffective; Human	Xanax			S				Pfizer	
Papilloma Virus Test	Lexapro			S		Unk		Not Reported	
Positive; Hyperphagia;	Lexapro			S				Not Reported	
Loss Of Personal	Lexapro			S				Not Reported	
Independence In Daily	Lexapro			S				Not Reported	
Activities; Mental Disorder;	Wellbutrin			S		Unk		Not Reported	
Panic Disorder; Weight	Wellbutrin			S				Not Reported	
Increased	Wellbutrin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14216296	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMP ANY-US201711006465			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Failure	Cymbalta			S	Unknown	30 Mg, Unknown		Eli Lilly And Co	
	Lexapro			S	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14216763	EXPEDITED (15-DAY)		DE, HO, OT	DE-ABBVIE-17S-062-2164899-00		1 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Flatulence;	Synagis			S	Intramuscular			Not Reported	
Immobile; Oxygen	Varivax			S	Intramuscular			Not Reported	
Saturation Decreased;	Topiramate			S	Unknown			Not Reported	
Pain; Pneumonia;	Phenobarbital			S	Unknown			Not Reported	
Respiratory Failure	Sildenafil Citrate			S	Unknown			Not Reported	

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Exodus//Escitalopram Oxalate	S	Unknown	Not Reported
Spironolactone	S	Unknown	Not Reported
Nutrition With Nutriini Mixed With Water	C	Other	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	13410533	NON-EXPEDITED			US-JNJFOC-20170300007		15 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Emotional Disorder; Fatigue; Gynaecomastia; Initial Insomnia; Off Label Use; Product Use In Unapproved Indication	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Risperdal			S	Oral	At Variable Doses Of 0.25mg, 0.5 Mg And 1 Mg		Not Reported
	Lexapro			S	Unknown	10 Mg And Then 20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	13412845	NON-EXPEDITED			US-JNJFOC-20170309370		12 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Sedation Complication; Treatment Noncompliance	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported

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	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Risperidone	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	14217973	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-06704		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Amitriptyline			C	Unknown	10 Mg, Qd, At Bedtime		Not Reported	
	Fentanyl			C	Unknown	75 Mcg, Every 72 Hrs		Not Reported	
	Hydromorphone			C	Unknown	4 Mg, Prn, Every 4 Hours		Not Reported	
	Ondansetron			C	Unknown	4 Mg, Prn, Every 8 Hours		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	14218409	EXPEDITED (15-DAY)		OT	FR-SCIEGEN PHARMACEUTICALS INC-2017SCILIT00678		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Pramipexole Dihydrochloride Tablets			S	Unknown	Unk		Sciegen	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2017	14220405	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2017504719		63 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myeloid Leukaemia; Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Myelodysplastic Syndrome; Platelet Count Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased	Pantoprazole			S	Unknown	Unk		Pfizer	
	Idarubicin Hcl			S	Unknown	Unk		Pfizer	
	Famciclovir			S	Unknown	Unk		Not Reported	
	Baclofen			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Allopurinol			S	Unknown	Unk		Not Reported	
	Dutasteride And Tamsulosin Hydrochloride			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2017	14224083	DIRECT		DS			32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Mood Swings; Penile Pain; Premature Ejaculation; Restlessness	Lexapro 20mg			S	Oral	Quantity:1 Tablet(S);		Forest	
	Omeprazole			C				Not Reported	
	Calcium			C				Not Reported	
	Magnesium			C				Not Reported	
	Zinc			C				Not Reported	
	Folic Acid			C				Not Reported	
	Coenzyme Q-10			C				Not Reported	
	L-Arginine			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14224968	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-106828		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Bristol Myers Squibb	
	Aripiprazole			S	Oral	5 Mg, Qd		Bristol Myers Squibb	
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	L-Thyroxin /00068001/			C	Oral	100 Mg, Qd		Not Reported	
	Metformin			C	Oral	1500 Mg, Qd		Not Reported	
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd		Not Reported	
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported	
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported	
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14226884	DIRECT		OT			9 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enuresis; Somnambulism	Escitalopram 5mg Tablets Cipla			S	Oral			Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14227057	DIRECT	Y	OT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Product Substitution Issue; Escitalopram 20mg Syncope		S		Oral		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14228166	DIRECT		DE, HO, OT				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram Oxalate			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14239044	DIRECT					56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Incorrect Dose Administered	Escitalopram Gabapentin			S C					Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	13415084	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17- 01			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Escitalopram			S	Unknown	For The Final Trimester			Hikma
	Ondansetron			S	Unknown				Hikma
	Progesterone			S	Unknown	For The Final Trimester			Hikma
	Sertraline			S	Unknown	For The Initial Two Trimester			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14211332	EXPEDITED (15-DAY)		OT	CA-ALLERGAN- 1766411US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Emotional Distress; Suicide Attempt		Escitalopram Oxalate - Bp		S	Unknown	Unk	Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14240018	DIRECT		DS				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Auditory; Hyperhidrosis; Pyrexia	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Not Reported	
	Nature Made Vitamin C			C				Not Reported	
	Calcium			C				Not Reported	
	Iron			C				Not Reported	
	Prenatal Capsules			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2017	14237486	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS- 2017AMN01009			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram			S				Amneal	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	13007210	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS- 2016M1053128		63 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bezoar; Cardiogenic Shock; Hyperlactacidaemia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents	Zolpidem			S	Unknown			Not Reported	
	Sevikar			S	Oral	129 Tablets: Olmesartan Medoxomil 5.16g/Amlodipine 1.29g		Mylan	
	Seroplex			S	Oral	280 Mg		Mylan	
	Atarax /00058401/			S	Oral	700 Mg		Mylan	
	Lysanxia			C	Oral	420 Mg		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	13103372	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-16245		26 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Poisoning; Sopor	Simvastatin			S	Unknown	14 Df, Total		Aurobindo	
	Aspirina			S	Unknown	Unk		Not Reported	
	Deursil			S	Oral	14 Df, Total		Not Reported	
	Entact			S	Oral	28 Df, Total		Not Reported	
	Igroton			S	Oral	15 Df, Total		Not Reported	
	Rivotril			S	Oral	10 MI, Total		Not Reported	
	Torvast			S	Oral	8 Df, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	13873933	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1734937US		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dizziness; Hyperhidrosis; Nausea; Pain; Pain In Jaw	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Topamax			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	14240115	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1768222US		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury; Hyponatraemia; Overdose	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Paracetamol			S	Oral	8 G, Qd		Not Reported	
	Oxynormoro			C		Unk		Not Reported	
	Imovane			C	Unknown	0.5 Df, Unk		Not Reported	
	Nasonex			C	Unknown	Unk		Not Reported	
	Kardegic			C	Unknown	Unk		Not Reported	

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Lercan	C	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Aldactazine	C	Unknown	Unk	Not Reported
Alprazolam	C		0.25 Mg, Tid	Not Reported
Movicol	C		1 Df, Bid	Not Reported
Amoxicillin	C		Unk	Not Reported
Oxycontin Lp	C		1 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	14240126	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1768112US		7 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Headache; Medication Error; Myalgia; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Zovirax			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	14240171	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1768385US		33 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Abilify			S	Oral	Unk		Not Reported
	Levemir			C	Unknown	Unk		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2017	14240686	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMP ANY-US201711009829		65 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Atrial Fibrillation; Panic Attack; Sexual Dysfunction; Sleep Apnoea Syndrome; Wrong Technique In Product Usage Process	Cialis 5mg			S	Unknown	5 Mg, Unk		Eli Lilly And Co	
	Cialis 20mg			S	Unknown	5 Mg, Unk		Eli Lilly And Co	
	Lexapro			S	Unknown			Not Reported	
	Zoloft			S	Unknown			Not Reported	
	Klonopin			S	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2017	14243801	DIRECT		DS			54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anger; Anxiety; Benign Prostatic Hyperplasia; Drug Interaction; Emotional Disorder; Personality Change	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla	
	Tamsulosin			S	Oral	Quantity:1 Capsule(S);		Zydus Pharm	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14248115	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1768515US		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14248267	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2017GSK183357		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S	Oral			Glaxosmithkline	
	Escitalopram			S	Oral			Glaxosmithkline	

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04-Dec-2017	14248281	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183376		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Overdose	Bupropion			S	Oral	Unk		Glaxosmithkline	
	Amlodipine			S	Oral	Unk		Glaxosmithkline	
	Escitalopram			S	Oral	Unk		Glaxosmithkline	
	Losartan			S	Oral	Unk		Glaxosmithkline	
	Levothyroxine			S	Oral	Unk		Glaxosmithkline	
	Ethanol			S	Oral	Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14249032	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK183383		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Glaxosmithkline	
	Escitalopram			S	Oral	Unk		Glaxosmithkline	
	Venlafaxine			S	Oral	Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14249824	DIRECT	Y	HO			19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Amnesia; Paranoia	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	12331971	NON-EXPEDITED			US-PFIZER INC-2016242099		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity	Morphine Sulfate	S	Unk	Unknown
	Celebrex	S	Unk	Pfizer
	Tramadol	S	Unk	Not Reported
	Duloxetine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250074	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21778			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
	Acetaminophen			S	Oral	Unk		Cipla	
	Hydrocodone			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250490	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2017US21802			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Respiratory Arrest; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Bupropion			S	Oral	Unk		Invagen	
	Ethanol			S	Oral	Unk		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250491	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21801			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Acetaminophen			S	Oral	Unk		Cipla	

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		Trazodone		S	Oral	Unk			Not Reported
		Hydrocodone		S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250881	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21803			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Alprazolam			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
	Acetaminophen			S	Oral	Unk		Cipla	
	Quetiapine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250883	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21806			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Quetiapine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250906	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21804			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Lamotrigine			S	Oral	Unk		Cipla	
	Citalopram			S	Unknown	Unk		Invagen	
	Gabapentin			S	Oral	Unk		Invagen	
	Alprazolam			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	

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Carbon Black			S	Oral	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250908	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21805			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Cyclobenzaprine			S	Oral	Unk		Invagen	
	Bupropion			S	Oral	Unk		Invagen	
	Acetaminophen			S	Oral	Unk		Cipla	
	Ethanol			S	Oral	Unk		Not Reported	
	Nifedipine			S	Oral	Unk		Cipla	
	Piroxicam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14251092	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1768823US		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Loss Anaemia; International Normalised Ratio Increased; Melaena	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Previscan (Fluindione)			C	Oral	15 Mg, Qd		Allergan	
	Previscan (Fluindione)			C	Unknown	Unk		Allergan	
	Bromazepam			C	Unknown			Not Reported	
	Celiprolol			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Fumafer			C	Unknown			Not Reported	
	Pravastatin			C	Unknown			Not Reported	
	Seretide			C	Unknown			Not Reported	
	Titanoreine			C	Rectal			Not Reported	
	Transipeg (Macrogol 3350)			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14251914	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2016US10549			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Meloxicam			S	Oral	Unk		Cipla	
	Celecoxib			S	Oral	Unk		Cipla	
	Acetaminophen			S	Oral	Unk		Cipla	
	Propoxyphene			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14254325	EXPEDITED (15-DAY)		DE, HO, OT	US- GLAXOSMITHKLINE- US2017GSK183970		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Propranolol			S		Unk		Glaxosmithkline	
	Escitalopram			S		Unk		Glaxosmithkline	
	Lamotrigine			S		Unk		Glaxosmithkline	
	Buspirone Hcl			S		Unk		Glaxosmithkline	
	Activated Charcoal			S		Unk		Glaxosmithkline	
	Cyclobenzaprine			S		Unk		Not Reported	
	Mirtazapine			S		Unk		Not Reported	
	Clonazepam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14254338	EXPEDITED (15-DAY)		DE, OT	US- GLAXOSMITHKLINE- US2017GSK184039		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Carvedilol			S	Oral	Unk		Glaxosmithkline	

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Escitalopram	S	Oral	Unk	Glaxosmithkline
Phenytoin	S	Oral	Unk	Glaxosmithkline
Valproic Acid	S	Oral	Unk	Not Reported
Sitagliptin	S	Oral	Unk	Not Reported
Mirtazapine	S	Oral	Unk	Not Reported
Primidone	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14254342	EXPEDITED (15-DAY)		DE, HO, OT	US- GLAXOSMITHKLINE- US2017GSK183407		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Death; Drug Abuse	Bupropion			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Ethanol			S	Unknown	Unk		Glaxosmithkline	
	Cocaine			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14254365	EXPEDITED (15-DAY)		DE, OT	US- GLAXOSMITHKLINE- US2017GSK184037		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Propranolol			S	Oral	Unk		Glaxosmithkline	
	Escitalopram			S	Oral	Unk		Glaxosmithkline	
	Lamotrigine			S	Oral	Unk		Glaxosmithkline	
	Ibuprofen			S	Oral	Unk		Glaxosmithkline	
	Singular			S	Oral	Unk		Glaxosmithkline	
	Acyclovir			S	Oral	Unk		Glaxosmithkline	
	Oxycodone And Acetaminophen			S	Oral	Unk		Not Reported	
	Ondansetron			S	Oral	Unk		Not Reported	

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Alprazolam			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14107503	EXPEDITED (15-DAY)		OT	GR-LUPIN PHARMACEUTICALS INC.-2017-06040		60 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Micturition Urgency; Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14228009	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1767438US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Contraindicated Product Prescribed	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Phenelzine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14252680	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2016US10561			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine Besylate			S	Oral	Unk		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
	Atenolol			S	Oral	Unk		Not Reported	
	Duloxetine			S	Oral	Unk		Cipla	
	Losartan			S	Oral	Unk		Not Reported	
	Trazodone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14253096	NON-EXPEDITED		HO	US-AUROBINDO-AUR- APL-2015-06984			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Toraseamide 20mg			S	Oral	20 Mg, Daily		Aurobindo
	Ascorbic Acid			S	Oral	1000 Mg, Daily		Not Reported
	Lexapro			S		5 Mg, Daily		Not Reported
	Magnesium Oxide			S		400 Mg, Daily		Not Reported
	Vasotec /00574902/			S	Oral	2.5 Mg, Daily		Not Reported
	Vitamin D3			S	Oral	Unk, Daily		Not Reported
	Glucosamine			C	Oral	1 Capsule, Daily		Not Reported
	Fish Oil			C	Oral	1 Tablet, Daily		Not Reported
	Aspirin			C	Oral	81 Mg, Daily		Not Reported
	Mvi			C	Oral	1 Tab, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14255091	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17- 04			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma	Escitalopram			S	Oral			Hikma
	Phenelzine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14256041	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA- 2017SF22811		62 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Triatec (Ramipril)			S	Oral	Unk		Not Reported
	Triatec (Ramipril)			S	Oral	2.5 Mg 2/Day		Not Reported
	Brilique			S	Oral	90 Mg 2/Day		Not Reported
	Brilique			S	Oral			Not Reported
	Seroplex			S	Oral	5 Mg/Day		Not Reported

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Seroplex	S	Oral	Unk	Not Reported
Diffu-K	S	Oral	Unk	Not Reported
Diffu-K	S	Oral	Unk	Not Reported
Bisoprolol Fumarate	S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening	Not Reported
Bisoprolol Fumarate	S	Oral		Not Reported
Tahor	S	Oral	40 Mg/Day	Not Reported
Tahor	S	Oral	Unk	Not Reported
Inexium	C		20 Mg/Day	Not Reported
Kardegic	C		75 Mg/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14256268	EXPEDITED (15-DAY)		DE	FR-ANIPHARMA-2017- FR-000080		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Death; Electrocardiogram Qt Prolonged	Indapamide (Non-Specific)			S				Ani
	Escitalopram			S				Not Reported
	Sotalol			S				Not Reported
	Benzoic Acid			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14256269	EXPEDITED (15-DAY)		OT	FR-ANIPHARMA-2017- FR-000081		61 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Metoclopramide (Non-Specific)			S				Ani
	Escitalopram			S				Not Reported
	Diazepam			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14257260	NON-EXPEDITED		DS, OT	US-ASTRAZENECA- 2017SF21487		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Amnesia; Crying; Drug Ineffective; Gait Inability; Muscle Rigidity; Off Label Use	Seroquel	S	Oral			Zeneca
	Escitalopram	S	Unknown	10.0mg	Unknown	Not Reported
	Nuedexta	S	Unknown			Not Reported
	Namenda	S	Unknown			Not Reported
	Nortriptyline	C				Not Reported
	Prenatal Vitamine	C				Not Reported
	Depakote	C				Not Reported
	Baby Aspirin	C				Not Reported
	Turmeric	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14257583	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004507		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral			Unknown
	Carvedilol			S	Oral			Unknown
	Bupropion Hydrochloride			S	Oral			Unknown
	Hydrocodone/Acetaminophen			S	Oral			Unknown
	Citalopram Hbr			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14257603	EXPEDITED (15-DAY)		DE	US-TORRENT-00004545		93 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Amlodipine Besylate			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14257776	EXPEDITED (15-DAY)		DE	US-TORRENT-00004457		86 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Hydrocodone - Acetaminophen			S	Oral			Unknown	
	Isosorbide Mononitrate			S	Oral			Unknown	
	Amlodipine			S	Oral			Unknown	
	Escitalopram			S	Oral			Unknown	
	Warfarin			S	Oral			Unknown	
	Furosemide			S	Oral			Unknown	
	Levothyroxine			S	Oral			Unknown	
	Doxazosin			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14260476	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1766907US		50 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Off Label Use; Parkinsonism; Road Traffic Accident	Milnacipran - Bp			S	Oral	Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Tramcet			S	Oral			Not Reported	
	Cymbalta			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14260569	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201710229		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Chills; Hyperhidrosis; Myalgia; Restlessness; Serotonin Syndrome	Linezolid (Manufacturer Unknown)			S	Unknown			Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14260745	EXPEDITED (15-DAY)		DE, HO, OT	US-		56 YR	Female	USA

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GLAXOSMITHKLINE-
US2017GSK183859

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Lamotrigine			S	Oral	Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14261168	DIRECT		OT			21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Alopecia; Confusional State; Fatigue; Impaired Work Ability; Insomnia; Scar; Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Calcium			C				Not Reported
	Multivitamin			C				Not Reported
	Opc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14225685	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT- 00007334		32 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Dyskinesia; Extrapyramidal Disorder; Muscle Twitching; Muscle Twitching; Restlessness	Trimipramin			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14261949	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Therapy Change	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14263154	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20171205190		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Rezolsta			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Kivexa			S	Unknown			Not Reported	
	Minias			S	Unknown			Not Reported	
	Tavor [Lorazepam]			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Ethanol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14263897	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171202971		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	11277218	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2015_000019			Unknown	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Obesity; Weight Increased	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka	
	Aripiprazole			S	Oral	15 Mg, Qd		Otsuka	
	Seroquel			S	Oral	800 Mg, Qd		Not Reported	
	Cipralext			S	Oral	20 Mg, Qd		Not Reported	
	Quetiapine			S	Oral	800 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	

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Simvastatin	C	Unknown	Unk	Not Reported
Simvastatin	C			Not Reported
Valium	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	Unk	Not Reported
Lorazepam	C	Oral	2.5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	13678507	EXPEDITED (15-DAY)	DE		FR-PFIZER INC-2017263969		79 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Revatio			S		Unk		Pfizer
	Aldactone			S		Unk		Pfizer
	Selexipag			S	Oral	1400 Ug, Daily		Not Reported
	Uptravi			S	Oral	1400 Ug, Daily		Not Reported
	Tracleer			S		Unk		Not Reported
	Lasilix /00032601/			S		Unk		Not Reported
	Previscan /00789001/			S		Unk		Not Reported
	Seroplex			S		Unk		Not Reported
	Inexium /01479302/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	13703042	EXPEDITED (15-DAY)	DE		FR-ASTRAZENECA-2017SE66255		79 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Inexium			S	Oral			Astrazeneca
	Seroplex			S	Unknown			Not Reported
	Tracleer			S	Unknown	Unknown Daily Dose		Not Reported
	Revatio			S	Unknown	Unknown Daily Dose		Not Reported
	Lasilix			S	Unknown			Not Reported
	Aldactone			S	Unknown			Not Reported

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Previscan (Fluindione)			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14268384	EXPEDITED (15-DAY)		HO	IN-LANNETT COMPANY, INC.-IN- 2017LAN001228		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothyroidism	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Lannett	
	Quetiapine			S	Unknown	50 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14268536	EXPEDITED (15-DAY)		DE	US-PERRIGO- 17US030994		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Naproxen			S	Oral	Unk		Perrigo	
	Glucophage			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14268636	EXPEDITED (15-DAY)		DE	US-SA-200911019EU		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Pulmonary Congestion; Toxicity To Various Agents	Dextromethorphan Hydrobromide			S		Dose As Used: Unk		Not Reported	
	Ambien			S		Dose As Used: Unk		Not Reported	
	Temazepam			S		Dose As Used: Unk		Not Reported	
	Zyprexa			S		Dose As Used: Unk		Not Reported	
	Lexapro			S		Dose As Used: Unk		Not Reported	
	Ethanol			S		Dose As Used: Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269139	EXPEDITED (15-DAY)		CA, HO, OT	FR-OTSUKA-DJ20115169		4 DAY	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysmorphism; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Large For Dates Baby; Respiratory Distress	Abilify			S	Transplacental	Unk		Otsuka	
	Tercian			S	Transplacental	Unk		Not Reported	
	Imovane			S	Transplacental	Unk		Not Reported	
	Seroplex			S	Transplacental	Unk		Not Reported	
	Zopiclone			S	Transplacental	Unk		Not Reported	
	Lexapro			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269142	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030736		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Loratadine			S	Oral	Unknown		Perrigo	
	Ethylene Glycol			S	Oral	Unknown		Not Reported	
	Escitalopram			S	Oral	Unknown		Not Reported	
	Furosemide			S	Oral	Unknown		Not Reported	
	Levothyroxine			S	Oral	Unknown		Not Reported	
	Folic Acid			S	Oral	Unknown		Not Reported	
	Vitamin B1 /00056101/			S	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269165	EXPEDITED (15-DAY)		DE	US-SA-A01200902224		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Pneumonia; Pulmonary Congestion; Toxicity To	Dextromethorphan Hydrobromide			S	Unknown			Not Reported	
	Zolpidem Tartrate			S	Unknown			Not Reported	

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Various Agents	Temazepam	S	Unknown	Not Reported
	Zyprexa	S	Unknown	Not Reported
	Lexapro	S	Unknown	Not Reported
	Ethanol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269192	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-OTSUKA-2017_025156			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Death; Product Use In Unapproved Indication	Abilify			S	Unknown	Unk		Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269222	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_016002		27 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Suicidal Ideation; Weight Increased	Abilify Maintena			S	Intramuscular	400 Mg, Unk		Otsuka	
	Abilify			S	Oral	15 Mg, Unk		Otsuka	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported	
	Zuclopenthixol			S	Intramuscular	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Intramuscular	Unk		Not Reported	
	Haloperidol			S	Intramuscular	Unk		Not Reported	
	Paliperidone			S	Oral	Unk		Not Reported	
	Paliperidon			S	Unknown	100 Mg, Unk		Not Reported	
	Paliperidon			S	Unknown	150 Mg, Unk		Not Reported	
	Clozapine			S	Unknown	100 Mg, Bid		Not Reported	
	Fluvoxamine			S	Unknown	50 Mg, Unk		Not Reported	

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Fluvoxamine	S	Unknown	50 Mg, Unk	Not Reported
Olanzapine	S	Intramuscular	Unk	Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Paliperidone	S	Oral	Unk	Not Reported
Haloperidol	S	Intramuscular	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	4x1 Mg, Later 2x1 Mg	Not Reported
Lorazepam	C	Unknown	4 Mg, Unk	Not Reported
Lorazepam	C	Unknown	2 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269294	EXPEDITED (15-DAY)		OT	KR-OTSUKA-2016_014339AA		40 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Facial Paralysis; Palpitations	Abilify			S	Unknown	2 Mg, Unk		Otsuka	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Valproic Acid			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269407	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-DJ20122817			Unknown	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Abilify 3mg			S	Oral			Otsuka	
	Seroquel			S	Unknown			Not Reported	
	Cipralex			S	Oral			Not Reported	

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Quilonorm	S	Oral		Not Reported
Quetiapine	S		50 Mg, Unk	Not Reported
Lexapro	S	Oral	10 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269625	EXPEDITED (15-DAY)		DE, OT	CH-OTSUKA-DJ20111145		1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death Neonatal; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	15 Mg, Qd		Otsuka	
	Cipralext			S	Transplacental	10 Mg, Bid		Not Reported	
	Stilnox			S	Transplacental	12.5 Mg, Qd		Not Reported	
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported	
	Zyprexa			S	Transplacental	7.5 Mg, Qd		Not Reported	
	Zolpidem			S	Transplacental	12.5 Mg, Qd		Not Reported	
	Lorazepam			S	Transplacental	Unk		Not Reported	
	Lexapro			S	Transplacental	10 Mg, Bid		Not Reported	
	Olanzapine			S	Transplacental	7.5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269690	EXPEDITED (15-DAY)		OT	CA-OTSUKA-2015_016863		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Abilify			S	Oral	2 Mg, Qd		Otsuka	
	Cipralext			S	Unknown	30 Mg, Qd		Not Reported	
	Cipralext			S	Unknown	20 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	30 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269693	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20090225			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Abilify 3mg			S	Unknown			Otsuka
	Abilify 3mg			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Lexapro			S		30 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269809	EXPEDITED (15-DAY)		HO	IT-OTSUKA-21247325		69 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extrapyramidal Disorder; Product Use In Unapproved Indication	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Valsartan			C	Oral	Tabs		Not Reported
	Cardioaspirin			C	Oral	Tabs		Not Reported
	Delorazepam			C	Oral	Tabs		Not Reported
	Cotareg			C	Oral	Tabs		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14269893	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201308463		< 1 DAY	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Jaundice Neonatal; Neonatal Hypoxia; Tremor	Abilify			S	Transplacental	10 Mg, Qd		Otsuka
	Seroplex			S	Transplacental	20 Mg, Qd (20mg Film Coated Tabs)		Not Reported
	Seresta			S	Transplacental	25 Mg, Bid (Dose Value:50mg,20mg Scored Tab)		Not Reported
	Tercian			S	Transplacental	25 Mg, Qd (Film Coated Tabs,Dose Value 12.5mg)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro			S		Transplacental		20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2017	14269913	EXPEDITED (15-DAY)		HO	DE-OTSUKA-DJ20112967			Female	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abortion Induced; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes	Abilify			S	Unknown	10 Mg, Qd		Otsuka		
	Ciprallex			S	Unknown	10 Mg, Unk		Not Reported		
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported		
	Antipsychotics			C	Unknown	Unk		Not Reported		
	Folsan			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2017	14270304	EXPEDITED (15-DAY)		OT	DK-OTSUKA-2016_020938			Male	DNK	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Depressed Mood; Intentional Overdose; Restlessness; Sedation; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Weight Increased	Abilify			S	Oral	10 Mg, Unk		Otsuka		
	Ciprallex			S	Oral	10 Mg, Unk		Not Reported		
	Imoclon			S	Oral	7.5 Mg, Unk		Not Reported		
	Oxapax			S	Oral	Unk		Not Reported		
	Seroquel			S	Oral	100 Mg, Unk		Not Reported		
	Seroquel			S	Unknown	300 Mg, Unk		Not Reported		
	Truxal			S	Oral	265 Mg, Unk		Not Reported		
	Zeldox			S	Oral	1 Df, Unk		Not Reported		
	Solian			S	Oral	1 Df, Unk		Not Reported		
	Solian			S	Unknown	50 Mg, Unk		Not Reported		
	Risperidon			S	Oral	Unk, 1/2 Mg At Night		Not Reported		
	Risperidon			S	Oral	1 Mg, Unk		Not Reported		
	Seroquel Prolong			S	Oral	200 Mg, Unk		Not Reported		
	Zopiclone			S	Oral	7.5 Mg, Unk		Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quetiapine	S	Oral	100 Mg, Unk	Not Reported
Quetiapine	S	Unknown	300 Mg, Unk	Not Reported
Risperidone	S	Oral	Unk, 1/2 Mg At Night	Not Reported
Risperidone	S	Oral	1 Mg, Unk	Not Reported
Escitalopram	S	Oral	10 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14270314	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_017398		19 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Off Label Use	Abilify Maintena			S	Intramuscular	400 Mg, Monthly		Otsuka
	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Orfiril			S	Oral	1000 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Bid		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14270468	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20115158			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Failure; Suicide Attempt	Abilify 3mg			S	Unknown			Otsuka
	Abilify 3mg			S				Otsuka
	Lexapro			S	Unknown			Not Reported
	Topamax			S	Unknown			Not Reported
	Lexapro			S		Started 6 Years Ago		Not Reported
	Lexapro			S				Not Reported
	Imitrex			C	Unknown			Not Reported
	Trazodone Hcl			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trazodone Hydrochloride			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14270488	EXPEDITED (15-DAY)		HO	AU-OTSUKA-DJ20070799			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Laryngospasm	Abilify 3mg			S	Oral			Otsuka	
	Escitalopram			S	Oral			Not Reported	
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271071	EXPEDITED (15-DAY)		LT, OT	IT-OTSUKA-2016_012556		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Prescribed Underdose	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Ciprallex			S	Oral	5 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271149	EXPEDITED (15-DAY)		OT	AT-OTSUKA-BMS-2016-010026		47 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Galactorrhoea	Aripiprazole			S	Unknown	2.5 Mg, Unk		Otsuka	
	Aripiprazole			S	Unknown	5 Mg, Unk		Otsuka	
	Clonazepam			S	Unknown	2 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	2.5 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	1.5 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	1.25 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	1 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trazodone Hydrochloride	S	Unknown	150 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	150 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	200 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	250 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	200 Mg, Qd	Not Reported
Trazodone Hydrochloride	S	Unknown	250 Mg, Qd	Not Reported
Quetiapine	S	Unknown	50 Mg, Qd	Not Reported
Quetiapine	S	Unknown	1 Df, Qd	Not Reported
Quetiapine	S	Unknown	100 Mg, Qd	Not Reported
Quetiapine	S	Unknown	75 Mg, Qd	Not Reported
Quetiapine	S	Unknown	50 Mg, Qd	Not Reported
Quetiapine	S	Unknown	25 Mg, Qd	Not Reported
Paroxetine	S	Unknown	40 Mg, Qd	Not Reported
Cymbalta	S	Unknown	60 Mg, Qd	Not Reported
Risperidone	S	Unknown	1 Mg, Qd	Not Reported
Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
Escitalopram	S	Unknown	30 Mg, Qd	Not Reported
Gewacalm	S	Unknown	30 Mg, Qd	Not Reported
Gewacalm	S	Unknown	20 Mg, Qd	Not Reported
Gewacalm	S	Unknown	10 Mg, Qd	Not Reported
Gewacalm	S	Unknown	5 Mg, Qd	Not Reported
Anafranil	S	Unknown	75 Mg, Qd	Not Reported
Ixel	S	Unknown	50 Mg, Qd	Not Reported
Ixel	S	Unknown	100 Mg, Qd	Not Reported
Ixel	S	Unknown	150 Mg, Qd	Not Reported
Ixel	S	Unknown	200 Mg, Qd	Not Reported
Molaxole	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oleovit D3	S	Unknown	30 G, Qwk	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	1 Df, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	75 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	25 Mg, Qd	Not Reported
Cymbalta	S	Unknown	60 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271575	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_003560		29 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Ciprallex			S	Oral	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271599	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201309326		33 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Oligohydramnios; Vomiting	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Ciprallex			S	Unknown	29jan13 29jan13		Not Reported
	Escitalopram			S	Unknown	29jan13 29jan13		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271714	EXPEDITED (15-DAY)		OT	FR-OTSUKA-J201300907		35 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Rhabdomyolysis	Abilify			S	Oral	15 Mg, Qd		Otsuka	
	Seroplex			S	Unknown	Unknown		Not Reported	
	Atacand			S	Unknown	Unknown		Not Reported	
	Baclofen			S	Unknown	Unknown		Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271771	EXPEDITED (15-DAY)		OT	FR-OTSUKA- J201408698			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section; Delirium; Hypertension; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Unknown	15 Mg, Unk		Otsuka	
	Seroplex			S	Unknown	Unk		Not Reported	
	Parkinane			S	Unknown	Unk		Not Reported	
	Tenoretic			S	Unknown	1 Df, Qd		Not Reported	
	Tercian			S	Unknown	1 Df, Qd		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Loxen (Nicardipine Hydrochloride)			C	Unknown	Unk		Not Reported	
	Loxen (Nicardipine Hydrochloride)			C				Not Reported	
	Loxapac			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271914	EXPEDITED (15-DAY)		OT	US-OTSUKA- 2016_009602		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Bipolar Disorder; Depression; Dizziness; Drug Ineffective; Dry Mouth; Mania; Rash	Abilify			S	Oral	5 Mg, Qd		Otsuka	
	Abilify			S	Oral	2.5 Mg, Qd		Otsuka	
	Carbamazepine			S	Unknown	600 Mg, Qd (200mg Tablet In The Morning And Two		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro	S	Unknown	200mg Tablets In The Evening)	Not Reported
Wellbutrin	S	Unknown	10 Mg, Qd	Not Reported
Prozac	S	Unknown	Unk	Not Reported
Zoloft	S	Unknown	Unk	Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
			600 Mg, Qd (200mg Tablet In The Morning And Two 200mg Tablets In The Evening)	Not Reported
Sertraline	S	Unknown		Not Reported
Lexapro	S	Unknown	10 Mg, Qd	Not Reported
Fluoxetine Hydrochloride	S	Unknown		Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Simvastatin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272116	EXPEDITED (15-DAY)		OT	US-OTSUKA-BMS-2016-077166			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Cardiac Flutter; Feeling Abnormal; Major Depression; Sleep Disorder; Suicidal Ideation; Therapeutic Response Decreased	Aripiprazole			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272844	EXPEDITED (15-DAY)		OT	IT-OTSUKA-2017_005459		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Drug	Abilify			S	Oral	1 Df, Unk		Otsuka

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Abuse; Hypokinesia; Movement Disorder	Efexor	S	Oral	1 Df, Unk	Not Reported
	Tavor [Lorazepam]	S	Oral	1 Df, Unk	Not Reported
	Cipralext	S	Unknown	60 Mg, Unk	Not Reported
	Talofen	S	Oral	5 Gtt, Unk	Not Reported
	Lorazepam	S	Oral	1 Df, Unk	Not Reported
	Venlafaxine Xr	S	Oral	1 Df, Unk	Not Reported
	Escitalopram	S	Unknown	60 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272865	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2017_008051			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Blood Glucose Increased; Drug Abuse; Heart Rate Increased; Sinus Disorder; Suicidal Ideation	Abilify			S	Unknown	Unk		Otsuka	
	Latuda			S	Oral	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Sudafed /00076302/			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272950	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201407960		28 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section; Maternal Exposure During Pregnancy; Metrorrhagia; Off Label Use; Premature Delivery; Premature Rupture Of Membranes	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Abilify			S				Otsuka	
	Latuda			S	Unknown	40 Mg, Qd		Not Reported	
	Latuda			S				Not Reported	
	Cipralext			S	Oral	20 Mg, Qd		Not Reported	
	Cipralext			S				Not Reported	
	Seropram (Citalopram Hydrobromide)			S	Unknown	20 Mg, Qd		Not Reported	
	Seropram (Citalopram Hydrobromide)			S				Not Reported	

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	Edronax	S	Oral	4 Mg, Qd	Not Reported
	Edronax	S			Not Reported
	Lexapro	S	Oral	20 Mg, Qd	Not Reported
	Lexapro	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272970	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_002594			Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breech Presentation; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	15 Mg, Qd		Otsuka
	Ciprallex			S	Transplacental	20 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	Unk		Not Reported
	Lorazepam			S	Transplacental	Unk		Not Reported
	Lexapro			S	Transplacental	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14272982	EXPEDITED (15-DAY)		CA, OT	FR-OTSUKA-DJ20096035		< 1 DAY	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Abilify			S	Transplacental	10 Mg, Unk		Otsuka
	Seroplex			S	Transplacental	20 Mg, Unk		Not Reported
	Dipiperon			S	Transplacental	1 Df, Qd		Not Reported
	Ikaran			S	Transplacental	10 Mg, Unk		Not Reported
	Seresta			S	Transplacental	75 Mg, Unk		Not Reported
	Havlane			S	Transplacental	Unk Unk, Qd		Not Reported
	Tranxene			S	Transplacental	40 Mg, Unk		Not Reported
	Lexapro			S	Transplacental	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14273313	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033625		68 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Diltiazem			S	Oral			Not Reported	
	Metformin			S	Oral			Santarus	
	Lorazepam			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Glyburide			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Levothyroxine			S	Oral			Not Reported	
	Losartan			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14273711	EXPEDITED (15-DAY)		CA, OT	FR-OTSUKA-DJ201408616		3 DAY	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Trisomy 21; Ventricular Septal Defect	Abilify			S	Transplacental	15 Mg, Qd		Otsuka	
	Seroplex			S	Transplacental	1 Df, Qd		Not Reported	
	Parkinane			S	Transplacental	1 Df, Unk		Not Reported	
	Tenoretic			S	Transplacental	1 Df, Qd		Not Reported	
	Tercian			S	Transplacental	1 Df, Qd		Not Reported	
	Lexapro			S	Transplacental	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14273718	EXPEDITED (15-DAY)		DE, LT, OT	JP-OTSUKA-2017_015179		55 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Cardio-Respiratory Arrest; Chest Pain; Somnolence	Abilify 3mg			S	Oral	3 Mg, Qd		Otsuka	
	Effexor			S	Oral	Unk		Not Reported	
	Effexor			S	Oral	37.5 Mg, Qd		Not Reported	
	Lexapro			S	Oral	20 Mg, Daily		Not Reported	

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Lamictal	S	Oral	400 Mg, Daily	Not Reported
Lamotrigine	S	Oral	400 Mg, Daily	Not Reported
Venlafaxine Xr	S	Oral	37.5 Mg, Qd	Not Reported
Lexapro	S	Oral	20 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14273953	EXPEDITED (15-DAY)		OT	JP-OTSUKA-BJ201304295		36 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section; Live Birth; Maternal Exposure During Pregnancy; Off Label Use	Abilify 3mg			S	Oral	3 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	6 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	9 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	15 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	12 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	18 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	24 Mg, Qd		Otsuka
	Abilify 3mg			S	Oral	30 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Bid		Not Reported
	Silece			S	Oral	2 Mg, Qd		Not Reported
	Contomin			S	Oral	25 Mg, Bid		Not Reported
	Seroquel			S	Oral	25 Mg, Qd		Not Reported
	Cymbalta			S	Oral	30 Mg, Bid		Not Reported
	Pyrethia			C	Oral	25 Mg, Qd		Not Reported
	Anesthetics, General			C	Unknown	Unk		Not Reported
	Tasmolin			C	Oral	1 Mg, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14274095	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-DJ20105191		37 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Anxiety; Electrocardiogram Qt Prolonged; Mood Altered	Abilify	S	Oral		Otsuka
	Prazine (Promazine Hydrochloride)	S	Oral	Unk	Not Reported
	Haldol Decanoate	S	Unknown	3 Mg, Unk	Not Reported
	Haldol Decanoate	S			Not Reported
	Risperdal	S	Oral	2 Mg, Unk	Not Reported
	Risperdal	S			Not Reported
	Cipralex	S	Oral		Not Reported
	Cipralex	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	20 Mg, Qd	Not Reported
	Stilnox	C	Unknown		Not Reported
	Stilnox	C	Unknown		Not Reported
	Rivotril	C	Oral	4 Mg, Intermittent	Not Reported
	Entumine	C	Unknown		Not Reported
	Zolpidem	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14274213	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_015748		16 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Incorrect Dose Administered; Oculogyric Crisis; Suicide Attempt	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported
	Prozac			S	Unknown	Unk		Not Reported
	Celexa			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Klonopin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Fluoxetine Hydrochloride			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14274292	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA-DJ20072544		66 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospitalisation; Serotonin Syndrome	Abilify 3mg			S	Oral			Otsuka
	Cipralex			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Lexapro			S	Oral	Daily Dosage:From 18-Jul-07 To 23-Jul-07 Is 5 Mg		Not Reported
	Lamotrigin			C	Unknown	Unk		Not Reported
	Trileptal			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Oral	150 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14274412	EXPEDITED (15-DAY)		DE, HO, OT	DE-OTSUKA-DJ20100215		55 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Abilify 3mg			S	Oral	15 Mg, Unknown		Otsuka
	Abilify 3mg			S	Oral	20 Mg, Unk		Otsuka
	Cipralex /01588502/			S	Oral	10 Mg, Unk		Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Tavor [Lorazepam]			S	Oral	6 Mg, Unk		Not Reported
	Tavor			S	Oral	2 Mg, Unk		Not Reported
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Eferox			C	Unknown	Unk		Not Reported
	Simeticone			C	Unknown	Unk		Not Reported

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Movicol			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2017	14275117	EXPEDITED (15-DAY)		OT	AU-OTSUKA-DJ201308012		40 YR	Female	AUS	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abortion Spontaneous; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Qd		Otsuka		
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported		
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2017	14275281	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ20111147		32 YR	Female	CHE	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Premature Delivery	Abilify			S	Unknown	15 Mg, Qd		Otsuka		
	Cipralext			S	Unknown	10 Mg, Bid		Not Reported		
	Stilnox			S	Unknown	12.5 Mg, Qd		Not Reported		
	Temesta (Lorazepam)			S	Unknown	Unk		Not Reported		
	Zyprexa			S	Unknown	7.5 Mg, Qd		Not Reported		
	Zolpidem			S	Unknown	12.5 Mg, Qd		Not Reported		
	Lorazepam			S	Unknown	Unk		Not Reported		
	Lexapro			S	Unknown	10 Mg, Bid		Not Reported		
	Olanzapine			S	Unknown	7.5 Mg, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2017	14275445	EXPEDITED (15-DAY)		HO	AT-OTSUKA-J20127883		27 YR	Male	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Akathisia; Off Label Use	Abilify			S	Unknown	10 Mg:23aug12		Otsuka		
	Abilify			S				Otsuka		

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	Abilify	S							Otsuka
	Ciprallex	S	Unknown	03aug12 Until 19aug12,10mg 20aug12 Until 31aug12. 20mg 10mg:01sep-04sep12					Not Reported
	Ciprallex	S							Not Reported
	Ciprallex	S							Not Reported
	Zyprexa	S	Unknown	10aug12 Until 20aug12, 20mg 21aug12 Until 22aug12, 10mg 5mg:23aug12					Not Reported
	Zyprexa	S							Not Reported
	Zyprexa	S							Not Reported
	Rivotril	S	Unknown	Unk					Not Reported
	Dibondrin	S	Unknown	Unk					Not Reported
	Clonazepam	S	Unknown						Not Reported
	Lexapro	S	Unknown	03aug12 Until 19aug12,10mg 20aug12 Until 31aug12. 20mg 10mg:01sep-04sep12					Not Reported
	Lexapro	S							Not Reported
	Lexapro	S							Not Reported
	Olanzapine	S	Unknown	10aug12 Until 20aug12, 20mg 21aug12 Until 22aug12, 10mg 5mg:23aug12					Not Reported
	Olanzapine	S							Not Reported
	Olanzapine	S							Not Reported
	Diphenhydramine Hcl	C	Unknown	Unk					Not Reported
	Clonazepam	C	Unknown	Unk					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14275507	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20113215			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Failure To Thrive; Foetal	Abilify			S	Transplacental	2.5 Mg, Qd		Otsuka	

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Exposure During Pregnancy;	Lexapro	S	Transplacental	20 Mg, Qd	Not Reported
Gastroesophageal Reflux Disease; Maternal Exposure During Breast Feeding; Menstrual Disorder	Lexapro	S	Transplacental	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14275739	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2015_016226			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation	Abilify			S	Unknown	Unk, Qd		Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14275783	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2016_016049		38 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Normal Newborn; Off Label Use	Abilify			S	Oral	15 Mg, Qd		Otsuka	
	Lexapro			S	Oral	20 Mg, Qd		Not Reported	
	Ciprallex			S	Oral	20 Mg, Qd		Not Reported	
	Lyrica			S	Oral	150 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14275919	EXPEDITED (15-DAY)		OT	AU-OTSUKA-2016_027754		40 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use Issue	Abilify			S	Oral	20 Mg, Qd		Otsuka	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	

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11-Dec-2017	14275950	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-J201405746		28 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gestational Diabetes; Live Birth; Major Depression; Maternal Exposure During Pregnancy; Off Label Use	Abilify			S	Unknown	10 Mg, Qd		Otsuka	
	Topamax			S	Unknown	100 Mg, Qd		Not Reported	
	Temesta (Lorazepam)			S	Unknown	Unk		Not Reported	
	Cipralext			S	Unknown	10 Mg, Qd		Not Reported	
	Seroquel			S	Unknown	200 Mg, Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Unknown	200 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14275992	EXPEDITED (15-DAY)		HO	US-OTSUKA-BMS-2015-010390		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes	Aripiprazole			S	Oral	15 Mg, Bid		Otsuka	
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported	
	Ibuprofen			S	Oral	800 Mg, Tid		Not Reported	
	Clonazepam			S	Oral	1 Mg, Bid		Not Reported	
	Venlafaxine			S	Oral	50 Mg, Qd		Not Reported	
	Lexapro			S	Oral	20 Mg, Unk		Not Reported	
	Fluticasone			S	Unknown	1 Df= 2 Sprays, Qd		Not Reported	
	Vicodin			S	Oral	1 Df= 5/500 Units Nos, Prn		Not Reported	
	Zestoretic			S	Oral	1 Df= 20/12.5 Units Nos, Qd		Not Reported	
	Vivelle /00045401/			S	Transdermal	0.1 Mg, Unk		Not Reported	
	Lyrica			S	Oral	75 Mg, Qd		Not Reported	

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	Loratadine	S	Oral	10 Mg, Qd	Not Reported
	Robaxin	S	Oral	750 Mg, Tid	Not Reported
	Desvenlafaxine	S	Oral	50 Mg, Qd	Not Reported
	Lexapro	S	Oral	20 Mg, Unk	Not Reported
	Ambien	S	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276065	EXPEDITED (15-DAY)		CA, OT	CH-OTSUKA-DJ20083115		< 1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breech Presentation; Dysmorphism; Ear Malformation; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Multiple Congenital Abnormalities; Selective Eating Disorder	Abilify			S	Transplacental	30 Mg, Qd		Otsuka	
	Ciprallex			S	Transplacental	10 Mg, Qd		Not Reported	
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276085	EXPEDITED (15-DAY)		OT	US-OTSUKA-2016_022933		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission; Suicidal Ideation; Treatment Noncompliance	Abilify			S	Unknown	10 Mg, Qd		Otsuka	
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported	
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276402	EXPEDITED (15-DAY)		OT	BE-OTSUKA-DJ20127101		28 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Systemic Lupus Erythematosus	Abilify			S	Unknown	2.5 Mg, Unk		Otsuka	

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Escitalopram	S	Unknown	Unknown	Not Reported
Escitalopram	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276455	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2016_001345		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose	Abilify			S	Oral	7 Tab, Unk		Otsuka
	Valium			S	Oral	1 Df, Unk		Not Reported
	Theralene			S	Oral	1 Df, Unk		Not Reported
	Theralene			S	Oral	50 Tab, Unk		Not Reported
	Stilnox			S	Oral	30 Tab, Unk		Not Reported
	Seresta			S	Oral	80 Tab, Unk		Not Reported
	Seroplex			S	Oral	15 Tab, Unk		Not Reported
	Zolpidem			S	Oral	30 Tab, Unk		Not Reported
	Lexapro			S	Oral	15 Tab, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276651	EXPEDITED (15-DAY)		OT	AU-OTSUKA-DJ20106192		1 DAY	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	30 Mg, Qd		Otsuka
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276730	EXPEDITED (15-DAY)		OT	CH-OTSUKA-2015_010341			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During	Aripiprazole			S	Transplacental	10 Mg, Qd		Otsuka

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Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Ciprallex	S	Transplacental	5 Mg, Qd	Not Reported
	Escitalopram	S	Transplacental	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14276809	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-2017_014193		32 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Lung Disorder; Toxicity To Various Agents	Abilify			S	Oral	Unk		Otsuka
	Xanax			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Risperidone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14277640	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2017_005158		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis; Surgery	Abilify			S	Oral	Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Innohep			C	Unknown	0.8 MI, Qd		Not Reported
	Ogastoro			C	Unknown	Unk Unk, Qd		Not Reported
	Gaviscon /00237601/			C	Unknown	Unk, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14278411	EXPEDITED (15-DAY)		OT	CH-OTSUKA-DJ201405802			Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Foetal Exposure During Pregnancy; Foetal Macrosomia; Hypoglycaemia Neonatal	Abilify	S	Transplacental	Unk	Otsuka
	Temesta (Lorazepam)	S	Transplacental	Unk	Not Reported
	Ciprallex	S	Transplacental	Unk	Not Reported
	Topamax	S	Transplacental	Unk	Not Reported
	Seroquel	S	Transplacental	Unk	Not Reported
	Lorazepam	S	Transplacental	Unk	Not Reported
	Quetiapine	S	Transplacental	Unk	Not Reported
	Lexapro	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14278439	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-OTSUKA-2016_012076		28 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Abilify			S	Unknown	Unk		Otsuka
	Ciprallex			S	Unknown	Unk		Not Reported
	Xeplion			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14278504	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ201403271			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Abilify 3mg			S	Unknown			Otsuka
	Lexapro			S	Unknown			Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14272292	NON-EXPEDITED			US-PFIZER INC-2017525488		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Ciprofloxacin			S		Unk		Unknown
	Advair			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14273153	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004822		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Citalopram			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral			Unknown
	Bupropion			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Tadalafil			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14273239	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005027		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Quetiapine			S	Oral			Unknown

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Citalopram	S	Oral	Unknown
Escitalopram	S	Oral	Unknown
Hydroxyzine Hydrochloride	S	Oral	Unknown
Buspirone	S	Oral	Unknown
Cyclobenzaprine Hydrochloride	S	Oral	Unknown
Levothyroxine Sodium	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14273268	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005036		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Risperidone			S	Oral			Unknown
	Propranolol			S	Oral			Unknown
	Oxycodone			S	Oral			Unknown
	Trazodone			S	Oral			Unknown
	Clonazepam			S	Oral			Unknown
	Hydroxyzine			S	Oral			Unknown
	Temazepam			S	Oral			Unknown
	Benztrapine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Ondansetron			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14273275	EXPEDITED (15-DAY)		DE	US-TORRENT-00005260		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Phenobarbital			S	Oral			Unknown
	Quetiapine			S	Oral			Unknown
	Trazodone			S	Oral			Unknown
	Zolpidem			S	Oral			Unknown

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	Phenytoin	S	Oral	Unknown
	Escitalopram	S	Oral	Unknown
	Oxycodone	S	Oral	Unknown
	Emtricitabine Tenofovir	S	Oral	Unknown
	Methylphenidate	S	Oral	Unknown
	Metformin	S	Oral	Unknown
	Ondansetron	S	Oral	Unknown
	Pregabalin	S	Oral	Unknown
	Metoclopramide	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14275034	EXPEDITED (15-DAY)		DE	US-TORRENT-00005275		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Zolpidem Tartrate			S	Oral			Unknown	
	Escitalopram			S	Oral			Unknown	
	Duloxetine			S	Oral			Unknown	
	Temazepam			S	Oral			Unknown	
	Ethanol			S	Oral			Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14275050	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005268		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Toxicity To Various Agents	Sertraline Hydrochloride			S	Unknown			Unknown	
	Doxepin Hcl			S	Unknown			Unknown	
	Ethanol			S	Unknown			Unknown	
	Clonazepam			S	Unknown			Unknown	
	Clonidine Hydrochloride			S	Unknown			Unknown	
	Sildenafil			S	Unknown			Unknown	

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Duloxetine	S	Unknown	Unknown
Diphenhydramine Hydrochloride	S	Unknown	Unknown
Oxybutynin Chloride	S	Unknown	Unknown
Escitalopram	S	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14275146	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203253		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276235	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005183		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral			Unknown
	Venlafaxine			S	Oral			Unknown
	Ethanol			S	Oral			Unknown
	Citalopram			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276255	EXPEDITED (15-DAY)		DE	US-TORRENT-00005231		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide;	Lamotrigine			S	Oral			Unknown

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Toxicity To Various Agents	Clonazepam	S	Oral	Unknown
	Escitalopram	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276276	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005282		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Desipramine Hcl			S	Oral			Unknown
	Diltiazem			S	Oral	Extended Release		Unknown
	Venlafaxine			S	Oral			Unknown
	Lamotrigine			S	Oral			Unknown
	Hydrochlorothiazide			S	Oral			Unknown
	Armodafinil			S	Oral			Unknown
	Potassium Chloride			S	Oral			Unknown
	Trifluoperazine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Pantoprazole			S	Oral			Unknown
	Lansoprazole			S	Oral			Unknown
	Naproxen			S	Oral			Unknown
	Nitrofurantoin			S	Oral			Unknown
	Diclofenac			S	Oral			Unknown
	Hydrocodone - Acetaminophen			S	Oral			Unknown
	Propoxyphene Napsylate And Acetaminophen			S	Oral			Unknown
	Solifenacin Succinate			S	Oral			Unknown
	Ciprofloxacin			S	Oral			Unknown
	Rosuvastatin			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276366	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203000		36 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276620	EXPEDITED (15-DAY)		DE	US-JNJFOC-20171203128		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Ibuprofen		Y	S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Oxycodone W/Paracetamol			S	Oral			Not Reported
	Singulair			S	Oral			Not Reported
	Ondansetron			S	Oral			Not Reported
	Acyclovir			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276780	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20171203053		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Completed Suicide; Toxicity To Various Agents	Diphenhydramine	Y	S	Oral		Not Reported
	Risperidone		S	Oral		Not Reported
	Fluoxetine		S	Oral		Not Reported
	Escitalopram		S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14277293	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017- ALVOGEN-094295		39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Bupropion			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Ethanol			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14279704	EXPEDITED (15-DAY)		OT	FR-NOVAST LABORATORIES, LTD- FR-2017NOV000079		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Butalbital, Acetaminophen, And Caffeine			S				Novast
	Escitalopram			S		Unk		Not Reported
	Galantamine			S				Not Reported
	Irbesartan			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14270908	EXPEDITED (15-DAY)		OT	US-OTSUKA-12487039			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Constipation;	Abilify			S	Oral	15 Mg, Qd		Otsuka

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Dyskinesia; Fear; Glucose Tolerance Impaired;	Lexapro	S	Oral	20 Mg, Qd	Not Reported
Insulin Resistance; Nightmare; Polycystic Ovaries; Sleep Disorder; Weight Increased	Lexapro	S	Oral	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14281208	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-45068		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Escitalopram 10 Mg			S	Oral	10 Mg, Daily		Aurobindo
	Escitalopram 10 Mg			S	Oral	20 Mg, Unk		Aurobindo
	Quetiapine 150mg			S	Oral	150 Mg, Daily		Aurobindo
	Quetiapine 150mg			S	Oral	50 Mg, Daily		Aurobindo
	Lorazepam			S	Oral	0.25 Mg, Daily		Not Reported
	Lorazepam			S	Oral	1.5 Mg, Daily		Not Reported
	Lorazepam			S	Oral	1 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14281673	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094387		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Flecainide			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Verapamil			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14281676	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094391		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Completed Suicide	Naproxen	S	Oral	Not Reported
	Alprazolam	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Glucophage	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14282215	EXPEDITED (15-DAY)		HO	FR-TEVA-2017-FR-831078		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol Fumarate			S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening		Duramed	
	Bisoprolol Fumarate			S	Oral	Unk		Duramed	
	Tahor			S	Oral	Unk		Not Reported	
	Tahor			S	Oral	40 Mg/Day		Not Reported	
	Diffu-K			S	Oral	Unk		Not Reported	
	Diffu-K			S	Oral	Unk		Not Reported	
	Triatec (Ramipril)			S	Oral	Unk		Not Reported	
	Triatec (Ramipril)			S	Oral	2.5 Mg 2/Day		Not Reported	
	Brilique			S	Oral	90 Mg 2/Day		Not Reported	
	Brilique			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	5 Mg/Day		Not Reported	
	Inexium			C		20 Mg/Day		Not Reported	
	Kardegic			C		75 Mg/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14282284	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030899		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death	Ibuprofen	S	Oral	Unk	Perrigo
	Amitriptyline	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Gabapentin	S	Oral	Unk	Not Reported
	Ethanol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14282995	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1771264US		40 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Face Injury; Fall; Fracture; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14283332	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00532			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram			S		Unk		Prinston Pharmaceutical	
	Fondaparinux Sodium			C	Subcutaneous	Unk, 1x/Day		Not Reported	
	Lisinopril			C				Not Reported	
	Temazepam			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14283480	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1771353US		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose	Escitalopram Oxalate Unk			S	Oral	30 Mg, Unk		Allergan	
	Clonazepam			S	Oral	22.5 Mg, Unk		Not Reported	
	Quetiapina			S	Oral	19 Mg, Unk		Not Reported	

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Valproato Sodio	S	Oral	2.6 Mg, Unk	Not Reported
Antabus	S	Oral		Not Reported
Abilify	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14283485	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45118		62 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol			S	Oral	3.25 Mg In The Morning And 2.5 Mg In The Evening		Aurobindo
	Bisoprolol			S	Oral	Unk ()		Aurobindo
	Tahor			S	Oral	Unk ()		Not Reported
	Tahor			S	Oral	40 Mg/Day ()		Not Reported
	Diffu-K			S	Oral	Unk ()		Not Reported
	Diffu-K			S	Oral	Unk ()		Not Reported
	Triatec /00116401/			S	Oral	Unk ()		Not Reported
	Triatec /00116401/			S	Oral	2.5 Mg 2/Day ()		Not Reported
	Brilique			S	Oral	90 Mg 2/Day ()		Not Reported
	Brilique			S	Oral	Unk ()		Not Reported
	Seroplex			S	Oral	Unk ()		Not Reported
	Seroplex			S	Oral	5 Mg/Day ()		Not Reported
	Kardegic			C		75 Mg/Day ()		Not Reported
	Inexium /01479302/			C		20 Mg/Day ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284189	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA006584		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Loratadine			S	Oral	Unk		Merck

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Furosemide	S	Unk	Merck
Levothyroxine Sodium	S	Unk	Not Reported
Ethylene Glycol	S	Unk	Not Reported
Escitalopram	S		Not Reported
Folic Acid	S	Unk	Not Reported
Thiamine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284475	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094307		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Venlafaxine			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284486	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094489		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Oxycodone/Apap			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	
	Ibuprofen			S	Oral			Not Reported	
	Ondansetron			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Montelukast Sodium			S				Not Reported	
	Aciclovir			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284600	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094410		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Fluoxetine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Risperidone			S	Oral			Not Reported	
	Diphenhydramine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284877	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2017AU22772			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anterograde Amnesia	Escitalopram			S	Unknown	Unk		Invagen	
	Temazepam			S	Unknown	Unk		Not Reported	
	Oxycodone			S	Oral	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285258	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094535		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Bupropion			S				Not Reported	
	Escitalopram			S				Not Reported	
	Alprazolam			S				Not Reported	
	Cocaine			S	Oral			Not Reported	
	Ethanol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285282	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-094506		21 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285468	NON-EXPEDITED			US-PFIZER INC-2017530623		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Atropine Sulfate/Diphenoxylate Hydrochloride			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Bupropion			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285561	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US030933		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Acetaminophen			S	Oral	Unk		Perrigo	
	Propranolol			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285565	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US031077		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Ibuprofen			S	Oral	Unknown, Unknown		Perrigo	
	Propranolol			S	Oral	Unknown, Unkknown		Not Reported	

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Escitalopram	S	Oral	Unknown, Unknown	Not Reported
Lamotrigine	S	Oral	Unknown, Unknown	Not Reported
Acetaminophen W/Oxycodone	S	Oral	Unknown, Unknown	Not Reported
Singulair	S	Oral	Unknown, Unknown	Not Reported
Ondansetron	S	Oral	Unknown, Unknown	Not Reported
Acyclovir /00587301/	S	Oral	Unknown, Unknown	Not Reported
Alprazolam	S	Oral	Unknown, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285803	EXPEDITED (15-DAY)		DE	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2017VAL001647		79 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Furosemide			S	Unknown	Unk		Validus
	Upravi			S	Oral	1400 Mg, Qd		Not Reported
	Inexium /01479302/			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Previscan /00789001/			S	Unknown	Unk		Not Reported
	Revatio			S	Unknown	Unk		Not Reported
	Selexipag			S	Oral	1400 Mg, Qd		Not Reported
	Aldactone /00006201/			S	Unknown	Unk		Not Reported
	Tracleer /01587701/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14288934	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA- 2017TUS025914			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Sensation In Eye; Agitation; Anxiety; Fall; Feeling Abnormal; Hypotension; Malaise;	Brintellix			S	Unknown	5 Mg, Qd		Takeda
	Seroplex			S	Oral	15 Mg, Qd		Not Reported

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Movement Disorder; Muscle Twitching; Musculoskeletal Stiffness; Panic Attack; Suicidal Ideation	Tranxene	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14289969	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033613		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Acyclovir			S	Oral			Not Reported	
	Ibuprofen			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	
	Acetaminophen/Oxycodone			S	Oral			Not Reported	
	Singulair			S	Oral			Not Reported	
	Ondansetron			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	12433729	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-JNJFOC-20160529315		28 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Odour; Confusional State; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Seizure; Shoulder Deformity; Weight Increased	Risperdal			S	Unknown			Not Reported	
	Xeplion			S	Unknown			Not Reported	
	Zyprexa			S	Unknown			Not Reported	
	Cipralex			S	Unknown			Not Reported	
	Abilify			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	13401513	EXPEDITED (15-DAY)		DE, DS, OT	CH-PFIZER INC-2017138980		51 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Assisted Suicide; Condition Aggravated; Malnutrition; Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Temesta (Lorazepam)			S	Oral	1 Mg, 3x/Day + 0.5mg 2x/Day As Needed		Pfizer	
	Temesta			S	Oral	3.5 Mg, Daily (1mg Morning-And 2.5mg In The Evening + 1mg 2x/Day Prn)		Pfizer	
	Quetiapine			S	Oral	25 Mg, 1x/Day		Not Reported	
	Quetiapine			S	Oral	25 Mg, 1x/Day + 25mg Prn		Not Reported	
	Quetiapine			S	Oral	25 Mg, 3x/Day		Not Reported	
	Quetiapine			S	Oral	12.5 Mg, 1x/Day		Not Reported	
	Depakine Chrono			S	Oral	1000 Mg, 2x/Day		Not Reported	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Lamictal			S		200 Mg, 1x/Day		Not Reported	
	Calciparine			C		Unk		Not Reported	
	Ziagen			C		Unk		Not Reported	
	Aspirin Cardio			C		Unk		Not Reported	
	Quantalan			C		Unk		Not Reported	
	Nexium /01479302/			C		Unk		Not Reported	
	Intelence			C		Unk		Not Reported	
	Zeffix			C		Unk		Not Reported	
	Imodium			C		Unk		Not Reported	
	Metamucil /00091301/			C		Unk		Not Reported	
	Isentress			C		Unk		Not Reported	
	Vi-De 3			C		Unk		Not Reported	
	Buscopan			C		Unk		Not Reported	
	Dafalgan			C		Unk		Not Reported	

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Zolpidem			C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14217440	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-104040			Male	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Death; Product Use In Unapproved Indication	Abilify				S	Unknown	Unk		Bristol Myers Squibb	
	Lexapro				S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14288109	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017006717			Unknown	ESP	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Escitalopram Oxalate				S	Oral	30 Mg, Unk, 1 Total		Macleods	
	Quetiapine				S	Oral	19 G, Single (1 Total)		Macleods	
	Abilify 15 Mg Tablets				S	Oral	15 Mg, Qd		Not Reported	
	Antabus 250 Mg Compressed				S	Oral	250 Mg, Qd		Not Reported	
	Clonazepam				S	Oral	22.5 Mg, Single (1 Total)		Not Reported	
	Valproate Sodium				S	Oral	3.6 Mg, Single (1 Total)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14288110	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD-MAC2017006718			Unknown	PRT	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram				S	Unknown	10 Mg, Qd		Macleods	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14288613	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR- 002700		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Metoclopramide Escitalopram Diazepam			S S S				Ipca Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14290743	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR- APL-2017-45390		29 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S	Unknown	10 Mg, Qd		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14293335	EXPEDITED (15-DAY)		DE, HO, OT	US-BAUSCH-BL-2017- 033118		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Venlafaxine Bupropion Escitalopram			S S S	Oral Oral Oral			Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14293533	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00004751		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide;	Lamotrigine			S	Oral			Unknown	

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Toxicity To Various Agents	Carbamazepine	S	Oral	Unknown
	Alprazolam	S	Oral	Unknown
	Escitalopram	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2017	14293734	EXPEDITED (15-DAY)		OT	US-ACCORD-061823			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coeliac Disease	Escitalopram			S		Strength: 10 Mg		Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2017	14294034	EXPEDITED (15-DAY)		DE, LT	BE-CIPLA LTD.- 2017BE25675			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation	Escitalopram			S	Transplacental	Unk		Invagen
	Levocetirizine			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental	Unk		Cipla
	Fluticasone Propionate			S	Transplacental	Unk		Not Reported
	Theophylline			S	Transplacental	Unk		Cipla
	Salbutamol Sulphate			S	Transplacental	Unk		Not Reported
	Fluticasone			S	Transplacental	Unk		Cipla
	Nucala Powder For Solution For Injection			S	Transplacental	Unk		Not Reported
	D-Cure			S	Transplacental	Unk		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	10730958	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2015- 001057		34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cardio-Respiratory Arrest; Completed Suicide	Tramadol	S	Oral	Not Reported
	Diclofenac	S	Oral	Bausch And Lomb
	Zolpidem	S	Oral	Not Reported
	Hydrocodone W/Acetaminophen	S	Oral	Not Reported
	Ondansetron	S	Oral	Not Reported
	Linaclotide	S	Oral	Not Reported
	Lubiprostone	S	Oral	Not Reported
	Liothyronine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Gabapentin	S	Oral	Not Reported
	Sertraline	S	Oral	Not Reported
	Amitriptyline	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	13036364	EXPEDITED (15-DAY)		CA, DE, HO, LT, OT	US-FERRINGPH-2016FE06514			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Human Herpesvirus 6 Infection; Multiple Organ Dysfunction Syndrome	Sertraline			S	Transplacental	Unk		Not Reported
	Ondansetron			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported
	Progesterone			S	Transplacental	Unk		Ferring

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295045	EXPEDITED (15-DAY)		OT	CZ-CIPLA LTD.-2017CZ24327			Unknown	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295057	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005083		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown	
	Citalopram			S	Oral			Unknown	
	Escitalopram			S	Oral			Unknown	
	Venlafaxine Hydrochloride			S	Oral			Unknown	
	Ethanol			S	Oral			Unknown	
	Hydroxyzine Pamoate			S	Oral			Unknown	
	Atenolol			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295158	EXPEDITED (15-DAY)		CA, DE, OT	BE-APOTEX-2017AP022599		7 DAY	Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus	Levocetirizine Apotex			S	Transplacental	5 Mg, Qd		Apotex	
	Pantomed /01263204/			S	Transplacental	Unk		Not Reported	
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk		Not Reported	
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported	
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported	
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported	
	Ventolin			S	Unknown	100 Ug, Unk		Not Reported	
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk, Qd		Not Reported	
	Sipralexa Tablet			S	Transplacental	10 Mg, Z		Not Reported	
	Avamys Nasal Spray			S	Transplacental	Unk Unk, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295218	EXPEDITED (15-DAY)		DE	US-TORRENT-		57 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown
	Diphenhydramine			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown
	Aripiprazole			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295274	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2017006908			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14295340	NON-EXPEDITED			US-PFIZER INC- 2017534086		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Sertraline Hcl			S	Oral	200 Mg, 1x/Day		Pfizer
	Celebrex			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14296003	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00004716		45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest;	Zolpidem			S	Oral			Unknown

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Completed Suicide;	Alprazolam	S	Oral	Unknown
Toxicity To Various Agents	Escitalopram	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14296008	EXPEDITED (15-DAY)		DE, HO, OT	US-TORRENT-00004828		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Bradycardia; Cardio-Respiratory Arrest; Completed Suicide; Hyperthermia;	Vilazodone Hydrochloride			S		Ingestion Plus Aspiration Vilazodone 10 Mg 21 Missing		Unknown
Hypotension; Overdose; Pulmonary Oedema; Toxicity To Various Agents; Ventricular Tachycardia	Alprazolam			S		Ingestion Plus Aspiration Alprazolam 0.5 Mg 100 Missing		Unknown
	Escitalopram			S		Ingestion Plus Aspiration		Unknown
	Duloxetine			S		Ingestion Plus Aspiration		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14296075	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201705105		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Oxycodone/Acetaminophen			S	Oral	Unk		Mallinckrodt
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Singulair			S	Oral	Unk		Not Reported
	Ondansetron			S	Oral	Unk		Not Reported
	Acyclovir			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14296719	EXPEDITED (15-DAY)		DE, HO, OT	US-BAYER-2017-238536		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral			Bayer	
	Glucophage			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14297909	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033727		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Lorazepam			S	Oral			Not Reported	
	Lithium			S	Oral			Not Reported	
	Amitriptyline			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	14297969	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2017-033753		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Primidone			S	Oral			Not Reported	
	Carvedilol			S	Oral			Not Reported	
	Valproic Acid			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Sitagliptin			S	Oral			Not Reported	
	Mirtazapine			S	Oral			Not Reported	
	Phenytoin			S	Oral			Not Reported	

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18-Dec-2017	14298567	EXPEDITED (15-DAY)		DE	US-SA-2017SA253412		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Diltiazem Hydrochloride			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Propranolol Hydrochloride			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14273878	EXPEDITED (15-DAY)		DE, HO, OT	DE-OTSUKA-14927875		55 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Abilify			S	Oral	15 Mg, Qd		Otsuka
	Abilify			S	Oral	20 Mg, Qd		Otsuka
	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Eferox			C	Oral	50 Mg, Qd		Not Reported
	Simeticone			C	Oral	1 Df= 3x40 Gtts		Not Reported
	Movicol			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14299208	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.- 2017AU22984			Unknown	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Drug Interaction; Hyponatraemia	Bupropion Hcl XI			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	
	Dothiepin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14299484	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US22975			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Pregnancy Test False Positive	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14299755	EXPEDITED (15-DAY)		HO, LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-157451		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose	Escitalopram			S	Oral	30 Mg, In Total		Not Reported	
	Clonazepam			S	Oral	22.5 Mg, In Total		Sun	
	Quetiapine			S	Oral	19 G, In Total		Sun	
	Valproic Acid			S	Oral	3.6 Mg, In Total		Sun	
	Abilify			S	Oral	30 Mg, Daily		Not Reported	
	Antabus			S	Oral	250 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14299788	EXPEDITED (15-DAY)		OT	IN-CIPLA (EU) LIMITED-2017IN23201			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Olanzapine			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14299978	EXPEDITED (15-DAY)		HO, LT	IT-CIPLA LTD.- 2017IT24393			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Abuse; Sopor; Tremor	Escitalopram			S	Oral	280 Mg, Total		Invagen	
	Bromazepam			S	Oral	40 MI, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300326	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2016IT02796			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Erythema; Pemphigoid; Pruritus	Escitalopram			S	Unknown	10 Mg Daily, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300525	EXPEDITED (15-DAY)		HO, LT	DE-CIPLA LTD.- 2017DE23830			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	15 Mg, Qd		Invagen	
	Escitalopram			S	Oral	20 Mg, Qd		Invagen	
	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Aripiprazole			S	Oral	10 Mg, Qd		Cipla	
	Aripiprazole			S	Oral	5 Mg, Qd		Cipla	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported	
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported	
	L-Thyroxin			C	Oral	100 Mg, Qd		Not Reported	
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported	
	Metformin			C	Oral	1500 Mg, Qd		Not Reported	

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	Atorvastatin		C	Oral	20 Mg, Qd			Not Reported	
	Acetylsalicylic Acid		C	Oral	100 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300736	EXPEDITED (15-DAY)		OT	TH-CIPLA LTD.- 2017TH23200			Unknown	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Invagen	
	Rasagiline			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300737	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2017- 239544		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Acetylsalicylic Acid (> 100 Mg)		Y	S	Oral			Bayer	
	Bupropion			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Losartan			S	Oral			Not Reported	
	Levothyroxine			S	Oral			Not Reported	
	Ethanol			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300893	EXPEDITED (15-DAY)		OT	TR-CIPLA LTD.- 2017TR22980			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Escitalopram			S	Unknown	10 Mg Per Day		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14301331	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.- 2017ES23126			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Unknown	Unk		Invagen	
	Citalopram			S	Unknown	Unk		Invagen	
	Olanzapine			S	Unknown	Unk		Invagen	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Haloperidol			S	Unknown	Unk		Not Reported	
	Enalapril			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14301693	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.- 2017ES23018			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Choroidal Effusion	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14301697	EXPEDITED (15-DAY)		HO, LT, OT	ES-CIPLA LTD.- 2017ES24386			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Df, Per Day		Invagen	
	Topiramate			S	Unknown	1 Df, Per Day		Invagen	
	Topiramate			S	Unknown	0.5 Df, Per Day		Invagen	
	Escitalopram			S	Unknown	1 Df, Per Day		Invagen	
	Naproxen			S	Unknown	2 Df, Per Day, 1 Df, Bid		Invagen	
	Paracetamol			S	Unknown	3 Df, Per Day, 1 Df, T Id		Cipla	
	Simvastatin			S	Unknown	1 Df, Per Day		Cipla	
	Simvastatin			S	Unknown	20 Mg, Unk		Cipla	
	Glibenclamide			S	Unknown	2 Df, Per Day, 1 Df, Bid		Not Reported	
	Omeprazole			S	Unknown	1 Df, Per Day, 1 Df, Qd		Cipla	
	Diazepam			S	Unknown	0.5 Df, Per Day		Not Reported	

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Tramadol/Paracetamol	S	Unknown	3 Df, Per Day, 1 Df, Tid	Not Reported
Amitriptyline	S	Unknown	5 Mg, Per Day	Not Reported
Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Per Day, 1 2 .5 Mg, Qd	Not Reported
Enalapril, Hydrochlorothiazide	S	Unknown	1 Df, Per Day	Not Reported
Lormetazepam	S	Unknown	1 Df Per Day, 1 Df, Qd	Not Reported
Tepazepam	S	Unknown	1, Per Day	Not Reported
Metoclopramide	C	Unknown	Unk, 1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14302405	NON-EXPEDITED			US-SUPERMUS PHARMACEUTICALS, INC.-2017SUP00281		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Emotional Disorder; Insomnia; Migraine	Trokendi Xr			S	Oral	50 Mg, 1x/Day		Supernus	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14302875	EXPEDITED (15-DAY)		DE	US-BAYER-2017-239143		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Loratadine			S	Oral	Unk		Bayer	
	Ethylene Glycol			S		Unk		Not Reported	
	Escitalopram			S				Not Reported	
	Furosemide			S		Unk		Not Reported	
	Levothyroxine			S		Unk		Not Reported	
	Folic Acid			S		Unk		Not Reported	
	Vitamin B1			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303004	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1079458		29 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S		10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303302	EXPEDITED (15-DAY)		OT	US-OTSUKA-17316720		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Fatigue; Mania	Abilify			S	Unknown	5 Mg, Unk		Otsuka	
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303403	EXPEDITED (15-DAY)		OT	JP-OTSUKA-2016_015261		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothermia; Malaise; Prescribed Underdose	Abilify 3mg			S	Oral	1.5 Mg, Qd		Otsuka	
	Abilify 3mg			S	Oral	0.75 Mg, Qd		Otsuka	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S	Oral	20 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S	Oral	20 Mg, Qd		Not Reported	
	Lendormin			C	Oral	0.25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303486	EXPEDITED (15-DAY)		OT	US-OTSUKA-2016_001315			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gestational Diabetes; Maternal Exposure During Pregnancy	Abilify			S	Unknown	20 Mg, Unk		Otsuka	
	Lexapro			S	Unknown	Unknown		Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303499	EXPEDITED (15-DAY)		CA, OT	US-OTSUKA-2016_001252			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cleft Palate; Foetal Exposure During Pregnancy	Abilify			S	Transplacental	20 Mg, Unk		Otsuka	
	Lexapro			S	Transplacental	Unk		Not Reported	
	Lexapro			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303707	EXPEDITED (15-DAY)		DE, OT	JP-OTSUKA-2017_014254		30 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Completed Suicide; Decreased Appetite; Insomnia; Refusal Of Treatment By Patient; Suicidal Ideation	Abilify 3mg			S	Oral	24 Mg, Qd		Otsuka	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	10 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	15 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported	
	Reflex			S	Oral	15 Mg, Qd		Not Reported	
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported	
	Olanzapine			S	Oral	15 Mg, Qd		Not Reported	
	Olanzapine			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303782	EXPEDITED (15-DAY)		OT	US-OTSUKA-J20040736		38 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Death; Pregnancy	Abilify			S	Oral	5 Mg, Qd		Otsuka	
	Seroquel			S	Unknown	25 Mg, Qd		Not Reported	
	Klonopin			S	Unknown	0.5 Mg, Qd		Not Reported	
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported	
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported	
	Quetiapine			S	Unknown	25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303840	EXPEDITED (15-DAY)		DE	US-OTSUKA-DJ20084241		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Abilify			S	Unknown	40 Mg, Unk		Otsuka	
	Abilify			S				Otsuka	
	Abilify			S				Otsuka	
	Abilify			S				Otsuka	
	Lexapro			S	Unknown	40 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303857	EXPEDITED (15-DAY)		DE, OT	US-OTSUKA-DJ20091428		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Abilify			S	Oral	10 Mg, Unk		Otsuka	
	Lexapro			S	Oral	20 Mg, Qd		Not Reported	
	Atenolol			C	Unknown	Unk		Not Reported	
	Prevacid			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303873	EXPEDITED (15-DAY)		LT, OT	ID-OTSUKA-JP-2012-15532		17 YR	Male	IDN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Abilify			S				Otsuka	
	Lexapro			S		10 Mg, Qd		Not Reported	
	Ciprallex			C	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303987	EXPEDITED (15-DAY)		HO, LT, OT	US-OTSUKA-KJ20120442			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Dizziness; Drug Ineffective; Dry Mouth; Headache; Major Depression; Medication Error; Overdose; Paranoia; Suicidal Ideation	Aripiprazole			S	Oral			Otsuka	
	Aripiprazole			S				Otsuka	
	Lexapro			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Wellbutrin			S				Not Reported	
	Prozac			S	Unknown			Not Reported	
	Lexapro			S		Unk		Not Reported	
	Lexapro			S				Not Reported	
	Fluoxetine Hydrochloride			S		Unk		Not Reported	
	Fluoxetine Hydrochloride			S				Not Reported	
	Seroquel			C	Unknown			Not Reported	
	Neurontin			C	Unknown			Not Reported	
	Topamax			C	Unknown			Not Reported	
	Misoprostol			C	Unknown			Not Reported	
	Actos			C	Unknown			Not Reported	
	Prilosec			C	Unknown			Not Reported	
	Diovan			C	Unknown			Not Reported	

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	Glimepiride	C	Unknown		Not Reported
	Welchol	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Vesicare	C	Unknown		Not Reported
	Singulair	C	Unknown		Not Reported
	Gabapentin	C		800 Mg, Unk	Not Reported
	Valsartan	C			Not Reported
	Glimepiride	C			Not Reported
	Quetiapine	C			Not Reported
	Omeprazole	C			Not Reported
	Misoprostol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304214	EXPEDITED (15-DAY)		DE, OT	US-OTSUKA-KJ201309353		18 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Depression; Diplopia; Disturbance In Attention; Insomnia; Mania	Abilify			S	Unknown	Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Topamax			C	Unknown	Unk		Not Reported
	Risperidone			C	Unknown	0.25 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304252	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20115996			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea; Anxiety; Menopausal Symptoms; Sjogren'S Syndrome; Swelling; Weight Increased	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304276	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20094455		44 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Gait Disturbance; Hepatic Pain; Hepatomegaly; Mood Swings; Muscle Atrophy; Restlessness	Abilify			S	Oral	2 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304548	EXPEDITED (15-DAY)		OT	FR-OTSUKA-J20127161		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Orthostatic Hypotension	Abilify			S	Oral	5 Milligram 1 Day		Otsuka
	Daflon (Diosmin/Hesperidin)			S	Unknown	Unk		Not Reported
	Haldol			S	Unknown	1 Dosage Form 1/1 Day		Not Reported
	Imovane			S	Unknown	Unk		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Lysanxia			S	Oral	10 Milligram 1 Day		Not Reported
	Seroplex			S	Oral	20 Milligram 1 Day		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Haloperidol			S	Unknown	5 Mg ½ Tab At Bed Time		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304644	EXPEDITED (15-DAY)		HO	JP-OTSUKA-JP-2015-12027		57 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage; Mania; Tooth Fracture	Aripiprazole			S	Oral	3 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	6 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	3 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	6 Mg, Qd		Otsuka
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

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Lexapro	S	Oral	5 Mg, Qd	Not Reported
Lexapro	S	Oral	15 Mg, Qd	Not Reported
Lexapro	S	Oral	10 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Cymbalta	S	Oral	40 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Cymbalta	S	Oral	40 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Cymbalta	S	Oral	40 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Cymbalta	S	Oral	40 Mg, Qd	Not Reported
Cymbalta	S	Oral	20 Mg, Qd	Not Reported
Estazolam	C	Oral	1 Mg, Qd	Not Reported
Lunesta	C	Oral	2 Mg, Qd	Not Reported
Lunesta	C	Oral	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304675	EXPEDITED (15-DAY)		OT	DK-OTSUKA-15433980		36 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Initial Insomnia; Mania	Abilify			S	Unknown	26jan09;2.5mg,Discontinued On 04nov09		Otsuka
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304680	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20115950			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Head Injury; Increased	Abilify			S	Oral	10 Mg, Unk		Otsuka

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Appetite; Logorrhoea;	Lexapro	S	Unknown	Unk	Not Reported
Loss Of Consciousness;	Lexapro	S			Not Reported
Pollakiuria; Psychomotor	Gabitril	S	Unknown	Unk	Not Reported
Hyperactivity	Gabitril	S			Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304956	EXPEDITED (15-DAY)		HO, OT	AT-OTSUKA-15812548		24 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Embolism;	Abilify			S	Oral	10 Mg, Qd		Otsuka
Suicidal Ideation	Trazodone Hydrochloride			S		150 Mg, Qd		Not Reported
	Lexapro			S		10mg		Not Reported
	Chlorprothixene			S		30mg		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Escitalopram			C	Unknown	10 Mg, Qd		Not Reported
	Chlorprothixene Hcl			C	Unknown	30 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305054	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20060414		< 1 DAY	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During	Abilify			S	Transplacental	Unk		Otsuka
Pregnancy; Foetal	Topamax			S	Transplacental	Unk		Not Reported
Exposure During	Lexapro			S	Transplacental	Unk		Not Reported
Pregnancy; Maternal	Remeron			S	Transplacental	Unk		Not Reported
Exposure During Breast	Zyprexa			S	Transplacental	Unk		Not Reported
Feeding; Neonatal	Mirtazapine			S	Transplacental	Unk		Not Reported
Disorder; Sedation;	Lexapro			S	Transplacental	Unk		Not Reported
Selective Eating Disorder	Olanzapine			S	Transplacental	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305216	EXPEDITED (15-DAY)		DE, HO, OT	US-OTSUKA-DJ20126317		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clavicle Fracture; Dysphagia; Fall; Parkinsonism; Pneumonia Aspiration	Abilify			S	Oral	10 Mg, Unk		Otsuka	
	Buspar			S	Unknown	15 Mg, Bid		Not Reported	
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Ambien			S	Unknown	10 Mg, Qd		Not Reported	
	Lipitor			C	Unknown	Unk		Not Reported	
	Allegra			C	Unknown	Unk		Not Reported	
	Vitamin C			C	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305252	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20100325		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Infertility	Abilify			S	Oral	Unk		Otsuka	
	Abilify			S	Oral	15 Mg, Unk		Otsuka	
	Abilify			S	Oral	Unk		Otsuka	
	Abilify			S	Oral	15 Mg, Unk		Otsuka	
	Seroplex			S	Oral	Unk		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S		Dose Increased To 30mg Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305437	EXPEDITED (15-DAY)		DE	FR-OTSUKA-DJ20101312		49 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Abilify			S	Oral	30 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Donormyl (Doxylamine Succinate)			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Equanil			S	Unknown	Unk		Not Reported
	Doxylamine Succinate			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305502	EXPEDITED (15-DAY)		HO, OT	AT-OTSUKA-16807471		26 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Embolism	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Lorazepam			S		6.25 Mg, Unk		Not Reported
	Trazodone Hydrochloride			S		150mg		Not Reported
	Lexapro			S		10 Mg		Not Reported
	Truxal			S		2 Tabs		Not Reported
	Ciprallex			S	Unknown	10 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305732	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1771280US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Sensation In Eye; Agitation; Anxiety; Fall; Feeling Abnormal; Hypertension; Hypotension; Malaise; Movement Disorder; Muscle Twitching;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qam		Allergan
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Tranxene			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness;
Panic Attack; Suicidal
Ideation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	13400984	EXPEDITED (15-DAY)		DE, DS	CH- GLAXOSMITHKLINE- CH2017044762		51 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Assisted Suicide; Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Quetiapine			S	Oral	25 Mg, Tid		Glaxosmithkline	
	Lamictal			S	Unknown	200 Mg, Qd		Glaxosmithkline	
	Escitalopram			S	Oral	10 Mg, Qd Starting Date Unknown		Glaxosmithkline	
	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline	
	Depakine Chrono			S	Oral	1000 Mg, Bid Start Of Administration Unkown		Not Reported	
	Depakine Chrono			S	Oral			Not Reported	
	Temesta (Lorazepam)			S	Oral	1 Mg Morning-Noon And 2.5 Mg In The Evening With A Reserve Of 1 Mg 2 X/Day		Not Reported	
	Ziagen			C	Unknown	Unk		Viiv	
	Aspirin Cardio			C	Unknown	Unk		Glaxosmithkline	
	Zeffix			C	Unknown	Unk		Glaxosmithkline	
	Metamucil			C	Unknown	Unk		Glaxosmithkline	
	Dafalgan			C	Unknown	Unk		Glaxosmithkline	
	Calciparine			C	Unknown	Unk		Not Reported	
	Nexium			C	Unknown	Unk		Not Reported	
	Intelence			C	Unknown	Unk		Not Reported	
	Imodium			C	Unknown	Unk		Not Reported	
	Isentress			C	Unknown	Unk		Not Reported	
	Vi-De 3			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Buscopan	C	Unknown	Unk		Not Reported
	Zolpidem	C	Unknown	Unk		Not Reported
	Colestyramine	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14070067	EXPEDITED (15-DAY)		HO	CA-CIPLA LTD.- 2017CA17887			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Overdose; Serotonin Syndrome; Toxicity To Various Agents	Bupropion			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	
	Olanzapine			S	Unknown	Unk		Invagen	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Phenytoin			S	Unknown	Unk		Not Reported	
	Primidone			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14306475	EXPEDITED (15-DAY)		DE	US-TORRENT- 00005537		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Zolpidem			S	Oral			Unknown	
	Cyclobenzaprine			S	Oral			Unknown	
	Escitalopram			S	Oral			Unknown	
	Alprazolam			S	Oral			Unknown	
	Desogestrel And Ethinyl Estradiol			S	Oral			Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14306881	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US23185			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Foetal Exposure During Pregnancy; Necrotising Colitis	Escitalopram	S	Transplacental	Unk	Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14307887	EXPEDITED (15-DAY)		HO, LT	FR-CIPLA LTD.- 2017FR24076			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Atorvastatin			S	Oral	Unk		Cipla
	Atorvastatin			S	Oral	40 Mg, Per Day		Cipla
	Ramipril			S	Oral	Unk		Invagen
	Ramipril			S	Oral	2.5 Mg^2/Day		Invagen
	Escitalopram			S	Oral	Unk		Invagen
	Escitalopram			S	Oral	5 Mg, Per Day		Invagen
	Diffu-K			S	Oral	Unk		Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	2, Per Day, 3.25 Mg In The Morning And 2.5 Mg In The Evening		Not Reported
	Bisoprolol Fumarate			S	Oral	Unk		Not Reported
	Brilique			S	Oral	90 Mg^2/Day		Not Reported
	Brilique			S	Oral	Unk		Not Reported
	Inexium			C	Unknown	20 Mg, Per Day		Not Reported
Kardegic			C	Unknown	75 Mg, Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14308114	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2017US23177			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Foetal Exposure During	Escitalopram			S	Transplacental	Unk		Invagen

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pregnancy; Serotonin
Syndrome; Toxicity To
Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14309019	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS- GER/GER/17/0095161		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Quetiapine			S				Not Reported	
	Quetiapine			S				Not Reported	
	Escitalopram			S				Not Reported	
	Escitalopram			S				Not Reported	
	Lorazepam			S				Not Reported	
	Lorazepam			S				Not Reported	
	Lorazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14309134	EXPEDITED (15-DAY)		DE	US-PFIZER INC- 2017540187		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Abuse; Respiratory Arrest	Alprazolam			S		Unk		Pfizer	
	Cocaine			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Bupropion			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14309345	EXPEDITED (15-DAY)		OT	PK-JNJFOC- 20171219218			Unknown	PAK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Unknown			Not Reported	
	Haloperidol			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Zuclopenthixol			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amlodipine	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14310245	EXPEDITED (15-DAY)	HO		AT-OTSUKA-2017_026748			Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased	Abilify			S	Oral	2.5 Mg, Unk		Otsuka
	Abilify			S	Unknown	2.5 Mg, Unk		Otsuka
	Abilify			S	Unknown	5 Mg, Daily		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	7.5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Trittico			S	Oral	100 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Trittico			S	Oral	250 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Sycrest			S	Unknown	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	10 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sycrest	S	Unknown	20 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	25 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Quilonium R	S	Unknown	400 Mg, Unk	Not Reported
Quilonium R	S	Unknown	900 Mg, Unk	Not Reported
Quilonium R	S	Unknown	675 Mg, Unk	Not Reported
Quilonium R	S	Unknown	450 Mg, Unk	Not Reported
Zeldox	S	Unknown	20 Mg, Unk	Not Reported
Zeldox	S	Unknown	40 Mg, Unk	Not Reported
Zeldox	S	Unknown	80 Mg, Unk	Not Reported
Zeldox	S	Unknown	120 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported

**FDA Adverse Event Reporting System
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Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	10 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Akineton	C	Unknown	4 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Risperdal	C	Unknown	2 Mg, Unk	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Neurotrop	C	Oral	300 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	90 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	60 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	20 Mg, Unk	Not Reported
Zoldem	C	Unknown	5 Mg, Unk	Not Reported

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Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	1 Mg, Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Adasuve	C	Unknown	Unk	Not Reported
Dibondrin	C	Unknown	50 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.26 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.34 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14070525	EXPEDITED (15-DAY)		OT	AT- ELI_LILLY_AND_COMP ANY-AT201709012029		57 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Food Craving; Gamma-Glutamyltransferase Increased; Increased Appetite; Neutrophil Percentage Decreased; Weight Increased	Zyprexa Velotab 15mg			S	Oral	10 Mg, Unknown		Not Reported
	Zyprexa Velotab 15mg			S	Oral	15 Mg, Unknown		Not Reported
	Zyprexa Velotab 15mg			S	Oral	5 Mg, Unknown		Not Reported
	Cymbalta 30mg			S	Unknown	30 Mg, Unknown		Eli Lilly And Co
	Seroquel			S	Oral	50 Mg, Unknown		Not Reported
	Seroquel			S	Oral	400 Mg, Unknown		Not Reported
	Seroquel			S	Oral	500 Mg, Unknown		Not Reported
	Seroquel			S	Oral	450 Mg, Unknown		Not Reported
	Seroquel			S	Oral	500 Mg, Unknown		Not Reported

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Seroquel	S	Oral	400 Mg, Unknown	Not Reported
Seroquel	S	Oral	300 Mg, Unknown	Not Reported
Seroquel	S	Oral	100 Mg, Unknown	Not Reported
Seroquel	S	Oral	50 Mg, Unknown	Not Reported
Seroquel	S	Oral	100 Mg, Unknown	Not Reported
Seroquel	S	Oral	50 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	100 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	200 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	50 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	200 Mg, Unknown	Not Reported
Quetiapine Xr	S	Oral	100 Mg, Unknown	Not Reported
Pregabalin	S	Oral	150 Mg, Unknown	Not Reported
Pregabalin	S	Oral	300 Mg, Unknown	Not Reported
Pregabalin	S	Oral	450 Mg, Unknown	Not Reported
Cipralext /01588502/	S	Oral	10 Mg, Unknown	Not Reported
Cipralext /01588502/	S	Unknown	15 Mg, Unknown	Not Reported
Cipralext /01588502/	S	Unknown	20 Mg, Unknown	Not Reported
Cipralext /01588502/	S	Unknown	30 Mg, Unknown	Not Reported
Lamotrigin	C	Oral	50 Mg, Unknown	Not Reported
Temesta /00273201/	C	Oral	5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	1.25 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	1.25 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Temesta /00273201/	C	Unknown	2.5 Mg, Unknown	Not Reported
Rivotril	C	Unknown	1 Mg, Unknown	Not Reported
Thyrex	C	Oral	50 Ug, Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Combithyrex	C	Unknown	1 Df, Unknown	Not Reported
Molaxole	C	Oral	1 Df, Unknown	Not Reported
Molaxole	C	Unknown	2 Df, Unknown	Not Reported
Molaxole	C	Unknown	3 Df, Unknown	Not Reported
Molaxole	C	Unknown	1 Df, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14312426	EXPEDITED (15-DAY)	DE		FR-CIPLA LTD.- 2017FR24395			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Escitalopram			S	Unknown	Unk		Invagen	
	Upravi			S	Oral	1400 Mg, Unk		Not Reported	
	Inexium			S	Unknown	Unk		Not Reported	
	Previscan (Fluindione)			S	Unknown	Unk		Not Reported	
	Revatio			S	Unknown	Unk		Not Reported	
	Selexipag			S	Oral	1400 Mg, Unk		Not Reported	
	Lasilix			S	Unknown	Unk		Not Reported	
	Aldactone			S	Unknown	Unk		Not Reported	
	Tracleer			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14312430	EXPEDITED (15-DAY)	DS		HU-ALLERGAN- 1772824US		22 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Emotional Poverty; Genital Hypoaesthesia; Loss Of Libido	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14313059	EXPEDITED (15-DAY)	HO, LT		FR-CIPLA LTD.- 2017FR24269			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Levofloxacin			S	Oral	2 Df, Unk		Cipla
	Irbesartan			S	Oral	300 Mg, Unk		Cipla
	Amlodipine			S	Oral	10 Mg, Unk		Invagen
	Pantoprazole			S	Oral	20 Mg, Unk		Cipla
	Metformin			S	Oral	1000 Mg, Unk		Not Reported
	Furosemide			S	Oral	30 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Nefopam Hydrochloride			S	Oral	3 Df, Unk		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, Unk		Not Reported
	Xarelto			S	Oral	1 Df, Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Valium			S	Oral	3 Df, Unk		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Unk		Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)	1 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14314745	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017544308		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Lorazepam			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Lithium			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14314747	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017544437		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Phenytoin			S	Oral	Unk		Pfizer	
	Carvedilol			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Sitagliptin			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
	Valproic Acid			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	11186090	EXPEDITED (15-DAY)		HO, OT	AT-ELI_LILLY_AND_COMP ANY-AT201506001187			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Blood Triglycerides Increased; Fatigue; Frustration Tolerance Decreased; Kidney Enlargement; Liver Injury; Neutrophil Count Decreased; Splenomegaly; Tremor; Weight Increased	Cymbalta			S	Oral	60 Mg, Unknown		Eli Lilly And Co	
	Lyrica			S	Unknown	300 Mg, Unknown		Not Reported	
	Lyrica			S	Unknown	600 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	750 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	450 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	375 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	300 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	150 Mg, Unknown		Not Reported	
	Risperdal			S	Unknown	0.5 Mg, Unknown		Not Reported	
	Risperdal			S	Unknown	1 Mg, Unknown		Not Reported	
	Risperdal			S	Unknown	2 Mg, Unknown		Not Reported	
	Cipralext /01588501/			S	Oral	10 Mg, Unknown		Not Reported	

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Ciprallex /01588501/	S	Oral	10 Mg, Unknown	Not Reported
Ciprallex /01588501/	S	Oral	15 Mg, Unknown	Not Reported
Ciprallex /01588501/	S	Oral	15 Mg, Unknown	Not Reported
Ciprallex /01588501/	S	Oral	10 Mg, Unknown	Not Reported
Topamax	S	Oral	25 Mg, Unknown	Not Reported
Topamax	S	Oral	50 Mg, Unknown	Not Reported
Topamax	S	Oral	100 Mg, Unknown	Not Reported
Topamax	S	Oral	25 Mg, Unknown	Not Reported
Rivotril	C	Unknown	0.5 Mg, Unknown	Not Reported
Wellbutrin	C	Unknown	Unk, Unknown	Not Reported
Pantoloc /01263204/	C	Unknown	40 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	13824271	EXPEDITED (15-DAY)		OT	CH- ELI_LILLY_AND_COMP ANY-CH201707011883		23 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower;	Zyprexa			S	Oral	20 Mg, Daily		Eli Lilly And Co	
Cerebral Cyst; Drug	Ciprallex /01588501/			S	Oral	15 Mg, Daily		Not Reported	
Ineffective; Maternal	Trittico			S	Oral	50 Mg, Daily		Not Reported	
Exposure During	Paliperidone			S	Oral	3 Mg, Daily		Not Reported	
Pregnancy									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14257389	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-156226		3 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour;	Citoles (Drop Form)			S	Oral	1 To 2 Mg/D		Not Reported	
Aggression; Attention	Citoles (Drop Form)			S				Not Reported	
Deficit/Hyperactivity	Risperdal Liquid			S	Oral	0.25 Mg, Daily		Not Reported	
Disorder; Condition	Abilify Liquid			S	Oral	1 To 2 Mg/D		Not Reported	
Aggravated; Disease									

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Progression; Energy Increased; Flight Of Ideas; Initial Insomnia; Insomnia; Irritability; Logorrhoea; Mania; Obsessive-Compulsive Disorder; Pressure Of Speech; Self Esteem Inflated; Weight Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14259460	EXPEDITED (15-DAY)		HO	TW-ALLERGAN-1769398US		22 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14288415	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1771267US		37 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Loss Of Consciousness; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Lendormin			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14316295	EXPEDITED (15-DAY)		HO	FR-GLENMARK PHARMACEUTICALS-2017GMK030105			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Metformin Hydrochloride			S	Oral	1000 Mg, Qd		Glenmark	
	Dafalgan			S	Oral	6 Df, Qd		Not Reported	
	Alprazolam			S	Oral	0.75 Mg, Qd		Not Reported	
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported	

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Nefopam Hydrochloride	S	Oral	3 Df, Qd	Not Reported
Diffu K	S	Oral	3 Df, Unk	Not Reported
Amlodipine	S	Oral	10 Mg, Qd	Not Reported
Colchicine Opocalcium	S	Oral	1 Df, Od	Not Reported
Xarelto	S	Oral	1 Df, Qd	Not Reported
Pantoprazole	S	Oral	20 Mg, Qd	Not Reported
Seroplex	S	Oral	1 Df, Qd	Not Reported
Tavanic	S	Oral	2 Df, Qd	Not Reported
Valium	S	Oral	3 Df, Qd	Not Reported
Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
Furosemide	S	Oral	30 Mg, Unk	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	1 Df, Unk	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14316310	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-115740		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Metformin Hydrochloride			S	Oral			Bristol Myers Squibb
	Glyburide, Metformin Hydrochloride			S	Oral			Bristol Myers Squibb
	Diltiazem			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14318974	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1079815			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Lipidil			S				Mylan	
Anxiety Disorder;	Escitalopram			S	Unknown			Not Reported	
Cardiometabolic	Amisulpride			S				Not Reported	
Syndrome; Cholelithiasis;	Entecavir			S				Not Reported	
Chronic Kidney Disease;	Clozapine			S				Not Reported	
Constipation;	Clopine			S				Mylan	
Electrocardiogram Qt	Movicol			S				Mylan	
Prolonged; Gastritis;	Norvasc /00972401/			S				Mylan	
Gastrooesophageal Reflux	Fishaphos			S				Mylan	
Disease; Hepatic	(Herbs\Minerals\Vitamins)								
Cirrhosis; Hepatic	Ostelin Vitamin D			S				Mylan	
Steatosis; Hepatitis B;	Zantac			S				Mylan	
Hypertension;									
Hypertriglyceridaemia;									
Hypoacusis; Impaired									
Fasting Glucose; Left									
Ventricular Dysfunction;									
Oesophagitis; Renal Cyst;									
Renal Impairment;									
Schizophrenia;									
Tachycardia; Varices									
Oesophageal; Vitamin D									
Deficiency									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14318991	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017544259		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Verapamil Hcl			S	Oral	Unk		Pfizer	
	Alprazolam			S	Oral	Unk		Pfizer	
	Flecainide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14319477	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017540513		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Gabapentin			S	Oral	Unk		Pfizer	
	Ibuprofen			S	Oral	Unk		Pfizer	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14319521	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2017M1080788		81 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14319740	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017540212		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Alprazolam			S	Oral	Unk		Pfizer	
	Glucophage			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Naproxen Sodium			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14274775	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE-HET2017DE00397		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg	Not Reported
	Quetiapine Fumarate	S	Oral	50 Mg, Qd	Not Reported
	Quetiapine Fumarate	S	Oral	50 Mg, Qd	Not Reported
	Quetiapine Fumarate	S	Oral	150 Mg	Not Reported
	Quetiapine Fumarate	S		50 Unk	Not Reported
	Lorazepam	S	Oral	0.25 Mg, Qd	Not Reported
	Lorazepam	S	Oral	1.5 Mg, Qd	Not Reported
	Lorazepam	S	Oral	1 Mg, Qd	Not Reported
	Lorazepam	S	Oral	0.9 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14300026	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2017-46135		81 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram 10 Mg			S	Oral	10 Mg, Unk		Aurobindo
	Escitalopram 10 Mg 28 Comprimidos			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14320903	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-MACLEODS PHARMACEUTICALS US LTD- MAC2017007131			Unknown	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication;	Escitalopram Tablet			S	Oral	Unk		Macleods
	Olanzapine Tablet			S	Oral	Unk		Macleods
	Xeplion			S	Unknown	Unk		Not Reported
	Risperidone			S	Oral	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown	Unk, Suspension For		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Shoulder Deformity; Weight Increased					Injection	
	Zyprexa	S	Unknown	Unk		Not Reported
	Abilify	S	Oral	Unk		Not Reported
	Cipralext	S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14321092	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2017007140			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Off Label Use; Respiratory Distress; Somnolence	Escitalopram Oxalate 20mg Tablet			S	Oral	20 Mg, Qd		Macleods
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg, Unk		Not Reported
	Carbamazepine			C	Oral	400 Mg, Unk		Not Reported
	Domperidone			C	Unknown	Unknown		Not Reported
	Pantoprazole			C	Unknown	Unknown		Macleods
	Tamsulosin			C	Unknown	0.4 Mg, Unk		Macleods
	Tamsulosin			C	Unknown	0.4 Mg, Unk		Macleods
	Allopurinol			C	Unknown	Unknown		Not Reported
	Avodart			C	Oral	Unknown		Not Reported
	Bisoce			C	Oral	Unknown		Not Reported
	Dafalgan			C	Oral	Unknown		Not Reported
	Flodil [Felodipine]			C	Oral	Unknown		Not Reported
	Gardenal			C	Oral	Unknown		Not Reported
	Inegy			C	Oral	Unknown		Not Reported
	Kardegic			C	Oral	Unknown		Not Reported
	Loperamide			C	Unknown	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Omexel	C	Oral	Unknown	Not Reported
	Omexel	C	Unknown	Unknown	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unknown	Not Reported
	Tegretol	C	Oral	Unknown	Not Reported
	Topalgic (Tramadol Hydrochloride)	C	Oral	Unknown	Not Reported
	Topalgic (Tramadol Hydrochloride)	C	Unknown	Unknown	Not Reported
	Uvedose	C	Oral	Unknown	Not Reported
	Ventoline	C	Unknown	Unknown	Not Reported
	Vesicare	C	Oral	Unknown	Not Reported
	Vesicare	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14321477	EXPEDITED (15-DAY)		DS, OT	HU-CIPLA LTD.- 2017HU24990			Unknown	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Apathy; Emotional Poverty; Genital Hypoaesthesia; Loss Of Libido	Escitalopram			S	Unknown	5 Mg, Unk		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2017	14321763	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS- 2015010067		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Zolpidem			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Hydrocodone W/Acetaminophen			S	Oral	Unk		Mylan	
	Ondansetron			S	Oral	Unk		Not Reported	
	Linaclotide			S	Oral	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Diclofenac	S	Oral	Unk	Not Reported
	Lubiprostone	S	Oral	Unk	Mylan
	Liothyronine	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Sertraline	S	Oral	Unk	Not Reported
	Gabapentin	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2017	14322626	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SF29132		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Inexium			S	Oral	1.0df Unknown		Astrazeneca	
	Escitalopram			S	Oral	10.0mg Unknown		Not Reported	
	Pravastatine Sodique			C	Oral			Not Reported	
	Pregabalin			C	Oral	50.0mg Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	9745762	EXPEDITED (15-DAY)		DE, LT	PHHY2013NO141077		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Intentional Self-Injury	Tramadol			S				Novartis	
	Tramadol			S	Unknown			Novartis	
	Levomepromazine Maleate			S	Unknown	Unk Ukn, Unk		Not Reported	
	Atarax			S	Unknown	Unk Ukn, Unk		Not Reported	
	Pinex Forte			S	Unknown			Not Reported	
	Pinex Forte			S				Not Reported	
	Vival			S	Unknown			Not Reported	
	Vival			S				Not Reported	
	Diazepam			S	Unknown			Not Reported	
	Truxal			S	Unknown			Not Reported	
	Truxal			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxyzine	S	Unknown	Unk Ukn, Unk	Not Reported
	Nozinan	S			Not Reported
	Imovane	S	Oral		Not Reported
	Imovane	S	Oral		Not Reported
	Sobril	S	Unknown		Not Reported
	Lamictal	S	Unknown		Not Reported
	Lamictal	S			Not Reported
	Nobligan	S	Unknown		Not Reported
	Nobligan	S			Not Reported
	Sarotex	S	Unknown		Not Reported
	Sarotex	S			Not Reported
	Orfiril	S	Unknown		Not Reported
	Orfiril	S			Not Reported
	Cipralelex	S	Unknown		Not Reported
	Cipralelex	S			Not Reported
	Catapresan	S	Unknown		Not Reported
	Catapresan	S			Not Reported
	Oxynorm	S	Unknown		Not Reported
	Oxynorm	S			Not Reported
	Seroquel	S	Unknown		Not Reported
	Seroquel	S			Not Reported
	Rivotril	S	Unknown		Not Reported
	Rivotril	S			Not Reported
	Remeron	S	Unknown		Not Reported
	Remeron	S			Not Reported
	Cipramil [Citalopram Hydrochloride]	S	Unknown	Unk Ukn, Unk	Not Reported
	Cyanocobalamin	C			Not Reported
	Diamorphine	C			Not Reported
	Forte	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14255823	EXPEDITED (15-DAY)		OT	JP-JNJFOC-20170728213		60 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Constipation; Hypoaesthesia; Parkinsonism	Tramcet	S	Oral	Dose: 2.5-5 Mg	Not Reported
	Lexapro	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported
	Toledomin	S	Oral		Not Reported
	Cymbalta	C	Oral		Not Reported
	Voltaren	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14322889	EXPEDITED (15-DAY)		DE, OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-115761		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Glucophage			S	Oral			Bristol Myers Squibb
	Alprazolam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14323093	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-157215		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Lethargy; Somnolence; Suicide Attempt	Loperamide			S	Oral	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Ranbaxy

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14323352	NON-EXPEDITED			US-TEVA-2017-US- 835719			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperhidrosis; Product Size Issue		Escitalopram		S	Unknown		Ivax		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14323564	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023026		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Diphenhydramine			S	Oral	Unk		Apotex	
	Fluoxetine			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Risperidone			S	Oral	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14325957	EXPEDITED (15-DAY)		HO, LT	PHHY2017ES190203		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose	Quetiapine			S	Oral	19 G, Unk		Novartis	
	Escitalopram			S	Oral	30 Mg, Unk		Not Reported	
	Abilify			S	Oral	30 Mg, Unk		Not Reported	
	Clonazepam			S	Oral	22.5 Mg, Unk		Not Reported	
	Antabus			S	Oral	250 Mg, Unk		Not Reported	
	Valproato De Sodio			S	Oral	3.6 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14325981	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1773510US		34 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure Timing Unspecified	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan	
	Abilify Maintena			S	Unknown	1 Df, Unknown		Not Reported	
	Abilify			S	Oral	15 Mg, Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	12412887	NON-EXPEDITED			US-PFIZER INC-2016274985		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zoloft			S	Oral	100 Mg, Unk		Pfizer	
	Lexapro			S	Oral	10 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	13407051	EXPEDITED (15-DAY)		DS	CH-ABBVIE-17P-151-1932895-00		51 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Rigidity; Psychomotor Retardation; Somnolence; Tremor	Depakine Chrono			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Temesta (Lorazepam)			S	Oral			Not Reported	
	Temesta (Lorazepam)			S	Oral			Not Reported	
	Escitalopram (Escitalopram Oxalate)			S	Oral			Not Reported	
	Lamictal (Lamotrigine)			S	Unknown			Not Reported	
	Calciparine (Heparin Calcium)			C	Unknown			Not Reported	
	Ziagen (Abacavir Sulfate)			C	Unknown			Not Reported	
	Aspirin Cardio (Acetylsalicylic Acid)			C	Unknown			Not Reported	
	Colestyramin (Colestyramine)			C	Unknown			Not Reported	
	Nexium (Esomeprazole)			C	Unknown			Not Reported	
	Intelence (Etravirine)			C	Unknown			Not Reported	
	Zeffix (Lamivudine)			C	Unknown			Not Reported	
	Imodium (Loperamide Hydrochloride)			C	Unknown			Not Reported	
	Metamucil (Plantago Ovata)			C	Unknown			Not Reported	

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Isentress (Raltegravir)	C	Unknown	Not Reported
Vi-De 3 (Colecalciferol)	C	Unknown	Not Reported
Buscopan (Hyoscine Butylbromide)	C	Unknown	Not Reported
Dafalgan (Paracetamol)	C	Unknown	Not Reported
Zolpidem (Zolpidem Tartrate)	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14223843	EXPEDITED (15-DAY)		OT	PHHY2017AT170968		36 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Maternal Exposure During Pregnancy	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Cipraxel			S	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14280292	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1712FRA003237		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Norset			S	Oral	15 Mg, 1x/Day		Merck
	Furosemide			S	Oral	30 Mg, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, 1x/Day		Not Reported
	Alprazolam			S	Oral	0.75 Mg, 1x/Day		Not Reported
	Nefopam Hydrochloride			S	Oral	3 Df, 1x/Day		Not Reported
	Diffu-K			S	Oral	3 Df, Unk		Not Reported
	Amlodipine			S	Oral	10 Mg, 1x/Day		Not Reported
	Colchicine			S	Oral	1 Df, 1x/Day		Not Reported
	Xarelto			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Not Reported
	Metformin			S	Oral	1000 Mg, 1x/Day		Not Reported

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Seroplex	S	Oral	1 Df, 1x/Day	Not Reported
Tavanic	S	Oral	30 Mg, 1x/Day	Not Reported
Valium	S	Oral	3 Df, 1x/Day	Not Reported
Bisoprolol Fumarate	S	Oral	1.25 Mg, 1x/Day	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Unk	Not Reported
Irbesartan	S	Oral	300 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14288884	EXPEDITED (15-DAY)	HO		FR-ZYDUS-018403		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Dafalgan			S	Oral	1000 Mg		Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral	15 Mg, Once Daily		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day		Not Reported
	Diffu K			S	Oral	3 Df Daily (2-1-0) 2x/Day		Not Reported
	Amlodipine			S	Oral	10 Mg, Once Daily		Zydus Pharm
	Colchicine			S	Oral	1 Mg, Once Daily		Not Reported
	Xarelto			S	Oral	20 Mg, Once Daily		Not Reported
	Pantoprazole			S	Oral	20 Mg, Once Daily		Not Reported
	Metformin			S	Oral	500 Mg, 2x/Day (Bid)		Not Reported
	Seroplex			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Valium			S	Oral	10 Mg, 3x/Day		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily		Not Reported
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day		Not Reported
	Terbutaline			S	Respiratory (inhalation)			Not Reported

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Irbesartan			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14326443	EXPEDITED (15-DAY)		DE	FR-009507513-1712FRA012281		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Mg, Qd		Merck	
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported	
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14326653	NON-EXPEDITED			US-TEVA-2017-US-830603		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Product Formulation Issue; Product Substitution Issue	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14326847	EXPEDITED (15-DAY)		OT	AU-ABBVIE-17S-008-2204138-00			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Lipidil			S	Unknown			Not Reported	
Anxiety Disorder;	Amisulpride			S	Unknown			Not Reported	
Cardiometabolic Syndrome; Cholelithiasis;	Entecavir			S	Unknown			Not Reported	
Chronic Kidney Disease; Constipation;	Clozapine			S	Unknown			Not Reported	
Electrocardiogram Qt Prolonged; Gastritis;	Clopine			S	Unknown			Not Reported	
Gastrooesophageal Reflux Disease; Hepatic	Movicol			S	Unknown			Not Reported	
	Norvask			S	Unknown			Not Reported	
Cirrhosis; Hepatic	Fishaphos			S	Unknown			Not Reported	

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Steatosis; Hepatitis B; Hypertension; Hypertriglyceridaemia; Hypoacusis; Impaired Fasting Glucose; Left Ventricular Dysfunction; Oesophagitis; Renal Cyst; Renal Impairment; Schizophrenia; Tachycardia; Varices Oesophageal; Vitamin D Deficiency	(Herbs\Minerals\Vitamins) Ostelin Vitamin D Zantac Escitalopram	S S S	Unknown Unknown Unknown	Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14328031	EXPEDITED (15-DAY)		DE, OT	US-APOTEX- 2017AP023288		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Diltiazem			S	Oral	Unk		Apotex
	Metformin			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Losartan			S	Oral	Unk		Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14328044	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2017549342		90 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis; Interstitial Lung Disease	Venlafaxine Hcl			S		37.5 Mg, Unk		Pfizer
	Duloxetine			S		15 Mg, Unk		Not Reported
	Escitalopram			S		5 Mg, Unk		Not Reported

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27-Dec-2017	14328718	NON-EXPEDITED			US-SUNOVION-2017SUN005266			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Libido; Sexual Dysfunction	Latuda			S	Oral	Unk		Sunovion	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14329417	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2017543147		26 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism	Lorazepam			S		6.25 Mg, Unk		Pfizer	
	Abilify			S	Oral	10 Mg, Unk		Not Reported	
	Abilify			S		Unk		Not Reported	
	Truxal			S		2 Tabs		Not Reported	
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported	
	Trazodone Hydrochloride			S		150 Mg		Not Reported	
	Lexapro			S		10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14329932	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017543386		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown	
	Alprazolam			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Acetaminophen			S	Oral	Unk		Not Reported	

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27-Dec-2017	14329934	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017543384		28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Propanolol Hcl			S		Unk (Aspiration)		Unknown
	Escitalopram			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk (Aspiration)		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Lamotrigine			S		Unk (Aspiration)		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Mirtazapine			S		Unk (Aspiration)		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S		Unk (Aspiration)		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Buspirone			S		Unk (Aspiration)		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Clonazepam			S		Unk (Aspiration)		Not Reported
	Activated Charcoal			S	Oral	Unk		Not Reported
	Activated Charcoal			S		Unk (Aspiration)		Not Reported
	Citalopram			S	Oral			Not Reported
	Citalopram			S		Unk (Aspiration)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14330000	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017543377		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Ibuprofen			S	Oral	Unk		Pfizer

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Ondansetron	S	Oral	Unk	Pfizer
Alprazolam	S	Oral	Unk	Pfizer
Escitalopram	S	Oral	Unk	Not Reported
Lamotrigine	S	Oral	Unk	Not Reported
Acetaminophen W/Oxycodone	S	Oral	Unk	Not Reported
Singulair	S	Oral	Unk	Not Reported
Acyclovir /00587301/	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14330253	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1773516US		68 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Burning Sensation; Drug Ineffective; Hyperhidrosis; Nausea; Nervousness; Poor Quality Sleep; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	11792123	EXPEDITED (15-DAY)		DE, HO	US-ACTELION PHARMACEUTICALS US, INC.-A-NJ2015-1254		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Ascites; Bronchitis; Cardiac Failure	Velettri			S	Intravenous (not otherwise specified)	13 Ng/Kg, Per Min		Actelion
Acute; Clostridium Difficile Infection; Diarrhoea; Disease Progression;	Velettri			S	Intravenous (not otherwise specified)	12 Ng/Kg, Per Min		Actelion
Dyspnoea; Fluid Retention; Flushing;	Tracleer			S	Oral	125 Mg, Bid		Actelion
Gallbladder Enlargement; Haemoptysis; Headache; Malaise; Muscle Spasms;	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Tyvaso			C				Not Reported
	Riociguat			C		2.5 Mg, Qd		Not Reported

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Nausea; Pain In Jaw;	Riociguat	C	2.5 Mg, Tid	Not Reported
Paracentesis; Pulmonary	Warfarin	C		Not Reported
Arterial Pressure	Escitalopram Oxalate	C	10 Mg, Qd	Not Reported
Increased; Pyrexia;	Furosemide	C	40 Mg, Qd	Not Reported
Vomiting; Weight	Potassium Chloride	C	10 Mcg, Qd	Not Reported
Fluctuation	Spirolactone	C	100 Mg, 1/2 Tablet Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14077399	EXPEDITED (15-DAY)		HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-090472		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Disinhibition; Mental Disorder	Abilify			S	Unknown	Unk		Bristol Myers Squibb	
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported	
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported	
	Cipralex /01588501/			S	Oral	1 Df, Qd		Not Reported	
	Calcium 600 Plus Vitamin D			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14330103	EXPEDITED (15-DAY)		OT	PHEH2017US041454			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Malignant Neoplasm Progression; Metastases To Central Nervous System; Metastases To Meninges; Product Use In Unapproved Indication	Tykerb			S	Oral	4 Df, Qd		Not Reported	
	Voltaren			S	Topical	1 %, Bid		Not Reported	
	Voltaren			S				Not Reported	
	Clonazepam Sandoz			S	Unknown			Not Reported	Novartis
	Anastrozole			S	Unknown	1 Mg, Qd		Not Reported	
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported	
	Potassium Chloride			S	Unknown	10 Ot, Bid		Not Reported	
	Nexium			S	Unknown	40 Mg, Bid		Not Reported	
	Hydrochlorothiazide			S	Unknown	25 Mg, Qd		Not Reported	

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Herceptin	C	Unknown		Not Reported
Zometa	C	Intravenous (not otherwise specified)	Unk Unk, Qw61d	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14330929	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP023785		90 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Venlafaxine			S	Unknown	37.5 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)			Not Reported
	Duloxetine			S	Unknown	15 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)			Apotex
	Escitalopram			S	Unknown	5 Mg, Unk, (Standardized To 10 Mg Of Citalopram Equivalent)			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14331246	EXPEDITED (15-DAY)		HO, LT	ES-ROCHE-2045252		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose	Clonazepam			S	Oral				Not Reported
	Escitalopram			S	Oral				Not Reported
	Quetiapina			S	Oral				Not Reported
	Valproato			S	Oral				Not Reported
	Antabus			S	Oral				Not Reported
	Abilify			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14331249	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US28893			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Balance Disorder; Cognitive Disorder; Memory Impairment; Psychiatric Symptom; Sleep Disorder; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14331375	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR-002693		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Furosemide Bisoprolol Tablets Escitalopram			S S S		20 Mg, Unk		Ipca Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332232	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017540385		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besilate Bupropion Escitalopram Acetylsalicylic Acid Losartan Levothyroxine Sodium			S S S S S S	Oral Oral Oral Oral Oral Oral	Unk Unk Unk Unk Unk Unk		Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332385	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017540457		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Diltiazem Hcl	S	Oral	Unk	Unknown
	Propanolol Hcl	S	Oral	Unk	Unknown
	Glibenclamide	S	Oral	Unk	Pfizer
	Levothyroxine Sodium	S	Oral	Unk	Pfizer
	Lorazepam	S	Oral	Unk	Pfizer
	Metformin	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Losartan	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332787	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-AUROBINDO-AUR-APL-2017-47465		28 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Olanzapine Tablet			S	Unknown	Unk		Aurobindo
	Xeplion			S	Unknown	Unk ()		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk ()		Not Reported
	Escitalopram			S	Unknown	()		Not Reported
	Paliperidone Palmitate			S	Unknown	()		Not Reported
	Zyprexa			S	Unknown	Unk ()		Not Reported
	Abilify			S	Unknown	Unk ()		Not Reported
	Cipralex /01588501/			S	Unknown	Unk ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332876	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017542709		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Venlafaxine Hcl			S	Oral	Unk		Pfizer
	Escitalopram			S	Oral	Unk		Not Reported
	Bupropion			S	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332916	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023216		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Bupropion			S	Oral			Apotex	
	Escitalopram			S	Oral			Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332939	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023153		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Valproic Acid			S	Oral	Unk		Apotex	
	Carvedilol			S	Oral	Unk		Apotex	
	Mirtazapine			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Phenytoin			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
	Sitagliptin			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332940	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023151		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Lamotrigine			S	Oral	Unk		Apotex	
	Acyclovir			S	Oral	Unk		Apotex	
	Alprazolam			S	Oral	Unk		Apotex	
	Ondansetron			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Propranolol			S	Oral	Unk		Not Reported	

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	Acetaminophen W/Oxycodone	S	Oral	Unk		Not Reported			
	Ibuprofen	S	Oral	Unk		Not Reported			
	Singulair	S	Oral	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333020	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023137		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Lithium Carbonate			S	Oral	Unk		Apotex	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333432	EXPEDITED (15-DAY)		OT	HR-ELI_LILLY_AND_COMP ANY-HR201712011138		17 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Somnolence; Suicide Attempt	Olanzapine			S	Oral	20 Mg, Unknown		Eli Lilly And Co	
	Aspirin /00002701/			S	Oral	2 Df, Unknown		Not Reported	
	Escitalopram			S	Oral	3 Df, Unknown		Not Reported	
	Ibuprofen			S	Oral	2 Df, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333586	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-MYLANLABS-2017M1082524		28 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal	Escitalopram			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk		Mylan	
	Risperidone			S	Unknown	Unk		Mylan	

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Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Xeplion	S	Unknown	Unk	Mylan
	Risperdal	S	Unknown	Unk	Mylan
	Paliperidone Palmitate	S	Unknown	Unk	Mylan
	Zyprexa	S	Unknown	Unk	Mylan
	Abilify	S	Unknown	Unk	Mylan
	Cipralex /01588501/	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333650	EXPEDITED (15-DAY)		OT	SI-ASTRAZENECA-2017SF30310		49 YR	Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Rosuvastatin Calcium			S	Oral			Astrazeneca
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Indapamide			S	Unknown			Not Reported
	Alprazolam			S	Unknown	Unk, Unk, As Needed		Not Reported
	Alprazolam			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333950	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1773734US		62 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Tahor			S	Oral			Not Reported
	Diffu-K			S	Oral	Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	3.25 Mg, Qam		Not Reported

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Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence	Bisoprolol Fumarate	S	Oral	2.5 Mg, Qpm	Not Reported
	Triatec (Codeine Phosphate/Paracetamol)	S	Oral		Not Reported
	Ramipril	S	Oral		Not Reported
	Brilique	S	Oral		Not Reported
	Inexium	C	Unknown	20 Mg, Qd	Not Reported
	Kardegic	C	Unknown	75 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14334769	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023439		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Bupropion			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex
	Venlafaxine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	13162567	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0086579			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy	Ondansetron			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Progesterone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	13401489	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017138586		24 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abdominal Pain Upper;	Zoloft			S	Oral	700 Mg (14 Tablets), Single		Pfizer

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Asthenia; Burning Sensation; Headache; Intentional Overdose; Somnolence; Toxicity To Various Agents	Alprazolam	S	Oral	5 Mg (20 Tablets), Single	Pfizer
	Dafalgan	S	Oral	16 G (32 Tablets), Single	Not Reported
	Seroplex	S	Oral	780 Mg (78 Tablets), Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	13841226	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1733376US		23 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Trittico			S	Oral	50 Mg, Unk		Not Reported	
	Zyprexa			S	Oral	20 Mg, Qd		Not Reported	
	Paliperidone			S	Oral	3 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14317844	EXPEDITED (15-DAY)		HO, OT	AT-ASTRAZENECA-2017SF29252		57 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	
	Seroquel			S	Oral			Zeneca	

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Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Seroquel	S	Oral		Zeneca
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Cipralex	S	Oral		Not Reported
Zyprexa	S	Unknown		Not Reported
Zyprexa	S	Unknown		Not Reported
Zyprexa	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Rivotril	C	Unknown		Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Plantago Afra	C	Unknown	Daily	Not Reported
Cymbalta	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported

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Temesta (Lorazepam)	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown		Not Reported
Molaxole	C	Unknown	Daily	Not Reported
Molaxole	C	Unknown	Daily	Not Reported
Molaxole	C	Unknown	Daily	Not Reported
Molaxole	C	Unknown	Daily	Not Reported
Combithyrex Mite	C	Unknown	Daily	Not Reported
Lamotrigine	C	Unknown		Not Reported
Thyrex	C	Unknown	50 Ug/Inhalation	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335317	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023042		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Lamotrigine			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Buspirone			S	Oral	Unk		Apotex	
	Clonazepam			S	Oral	Unk		Apotex	
	Mirtazapine			S	Oral	Unk		Apotex	
	Cyclobenzaprine			S	Parenteral	Unk		Not Reported	
	Propranolol			S	Parenteral	Unk		Not Reported	
	Activated Charcoal			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335330	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023045		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Alprazolam			S	Oral	Unk		Apotex	
	Propranolol			S	Oral	Unk		Not Reported	

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Amitriptyline	S	Oral	Unk	Not Reported
Acetaminophen	S	Oral	Unk	Not Reported
Ethanol	S	Oral	Unk	Not Reported
Cocaine	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335474	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023441		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Oral			Apotex
	Lamotrigine			S	Oral			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335485	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023275		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Verapamil			S	Oral	Unk		Apotex
	Flecainide			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335502	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP022921		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Drug Abuse	Escitalopram			S	Unknown	Unk		Apotex
	Bupropion			S	Unknown	Unk		Apotex
	Alprazolam			S	Unknown	Unk		Apotex
	Cocaine			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

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29-Dec-2017	14335539	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2017-FR- 003933		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Metformin			S	Oral	500 Mg, Bid		Ipca	
	Furosemide			S	Oral	30 Mg, Bid		Ipca	
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported	
	Bisoprolol Tablets 10mg			S	Oral	1.25 Mg, Qd		Not Reported	
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Qd		Not Reported	
	Dafalgan			S	Oral	1000 Mg, Tid		Not Reported	
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported	
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported	
	Tavanic			S	Oral	250 Mg, Bid		Not Reported	
	Xarelto			S	Oral	20 Mg, Qd		Not Reported	
	Diazepam			S	Oral	10 Mg, Tid		Not Reported	
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported	
	Seroplex			S	Oral	1 Df, Qd		Not Reported	
	Nefopam			S	Oral	1 Df, Tid		Not Reported	
	Diffu-K			S	Oral	3 Df, Bid		Not Reported	
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported	
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335567	EXPEDITED (15-DAY)		HO	ES-TEVA-2017-ES- 837863		81 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram 10 Mg 28 Comprimidos			S	Oral	10 Milligram Daily;		Ivax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335659	NON-EXPEDITED		OT	US-TEVA-2017-US-837929			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Suicidal Ideation	Provigil			S	Unknown			Cephalon	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335689	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023032		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Apotex	
	Losartan			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Amlodipine			S	Oral	Unk		Apotex	
	Salicylate Sodium			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335711	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023005		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Gabapentin			S	Oral			Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Ibuprofen			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	

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29-Dec-2017	14335715	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP022991		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Alprazolam			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Metformin			S	Oral			Apotex	
	Naproxen			S	Oral	Unk		Not Reported	
	Glucophage			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14335740	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP022953		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Other	Unk (Ingstpaspir)		Apotex	
	Escitalopram			S	Other	Unk (Aspiration)		Apotex	
	Ethanol			S	Other	Unk (Ingstpaspir)		Not Reported	
	Ethanol			S	Other	Unk (Aspiration)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14336237	EXPEDITED (15-DAY)		DE	TR-ALLERGAN-1773894US		57 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Remeron			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14336378	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2017AP023417		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Escitalopram	S	Oral	Unk	Apotex
	Loratadine	S	Oral	Unk	Apotex
	Furosemide	S	Oral	Unk	Not Reported
	Levothyroxine	S	Oral	Unk	Not Reported
	Folic Acid	S	Oral	Unk	Not Reported
	Vitamin B-1	S	Oral	Unk	Not Reported
	Ethylene Glycol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14336401	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023459		14 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide	Diphenhydramine			S	Oral			Apotex
	Escitalopram			S	Oral			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14336731	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK201226			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Malignant Neoplasm Progression; Metastases To Central Nervous System; Metastases To Meninges; Product Use In Unapproved Indication	Diclofenac			S	Topical	1 %, Bid		Glaxosmithkline
	Diclofenac			S				Glaxosmithkline
	Tykerb			S	Oral	4 Df, Qd		Not Reported
	Clonazepam			S		125 Mg, Bid		Not Reported
	Lexapro			S		10 Mg, Qd		Not Reported
	Sulfamethoxazole + Tmp			S		Unk, Z		Not Reported
	Potassium Chloride			S		10 Meq, Bid		Not Reported
	Zofran			S		8 Mg, Prn		Not Reported
	Anastrozole			S		1 Mg, Qd		Not Reported
	Nexium			S		40 Mg, Bid		Not Reported

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	Hydrochlorothiazide	S	25 Mg, Qd	Not Reported
	Zometa	C		Not Reported
	Herceptin	C		Not Reported

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29-Dec-2017	14337249	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.- 2017FR27330			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Face Oedema; Tongue Oedema	Escitalopram			S	Oral	10 Mg, Daily		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14337621	EXPEDITED (15-DAY)		OT	PHHY2017AU161414		33 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Body Mass Index Increased; Body Temperature Increased; Depressed Mood; Hypoaesthesia; Multiple Sclerosis Relapse; Muscle Spasticity; Musculoskeletal Stiffness; Optic Neuritis; Papilloma Viral Infection; Paraesthesia; Smear Cervix Abnormal; Weight Decreased; Weight Increased	Gilenya			S	Oral	Unk		Novartis
	Gilenya			S	Oral	Unk		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported
	Vitamin D2			C	Unknown	Unk		Not Reported
	Multi Vitamin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14337755	EXPEDITED (15-DAY)		OT	SI-PFIZER INC- 2017551008		49 YR	Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Kidney Disease; Left Ventricular	Alprazolam			S		Unk Unk, As Needed		Pfizer

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Hypertrophy	Escitalopram Oxalate	S	Unk	Not Reported
	Perindopril	S	Unk	Not Reported
	Rosuvastatin	S	Unk	Not Reported
	Indapamide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14338072	EXPEDITED (15-DAY)		OT	US-CELGENEUS-USA-20171207594			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Cerebral Disorder	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Lexapro			S	Unknown			Not Reported
	Ativan			S	Unknown			Not Reported
	Eliquis			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Neupogen			C	Unknown			Not Reported
	Lunesta			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Amitriptyline			C	Unknown	50 Milligram		Not Reported
	Simvastatin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14342826	DIRECT	Y					Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Level Below Therapeutic	Escitalopram			S	Oral		6 MTH	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2017	14339091	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-			Unknown	FRA

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MAC2017007680

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Interaction; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram Oxalate			S	Oral	10 Mg, Unk		Macleods
	Inexium 20 Mg, Gastro-Resistant Tablet (Esomeprazole Magnesium)			S	Oral	1 Df, Unk		Not Reported
	Pravastatin Sodium			C	Oral	20 Mg, Unk		Not Reported
	Pregabalin			C	Oral	50 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2017	14339154	EXPEDITED (15-DAY)		HO, OT	JP-ACCORD-062420			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Asphyxia	Escitalopram			S	Transplacental			Accord
	Ethyl Loflazepate			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2017	14339833	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1083080			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Mylan
	Valdoxan			S	Unknown	25 Milligram Daily;		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2017	14339865	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1083151		38 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure	Ketoprofen			S	Oral			Not Reported	
	Hydrocortancyl /00016201/			S	Intra-articular			Mylan	
	Tercian /00759301/			S	Oral			Mylan	
	Seroplex			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2018	12761904	EXPEDITED (15-DAY)		OT	PHHY2016US128699			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Human Herpesvirus 6 Infection; Hypersensitivity; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Ondansetron			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Progesterone			S	Unknown	Unk (High Dose)		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	13621179	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1704103US		29 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased; Off Label Use	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S		5 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan	
	Sycrest			S	Unknown	5 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	10 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	15 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	20 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	15 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	10 Mg, Qd		Not Reported	
	Sycrest			S	Unknown	5 Mg, Qd		Not Reported	

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Trittico Retard	S	Unknown	100, Qd	Not Reported
Trittico Retard	S	Unknown	150, Qd	Not Reported
Trittico Retard	S	Unknown	300, Qd	Not Reported
Trittico Retard	S	Unknown	250, Qd	Not Reported
Trittico Retard	S	Unknown	150, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	10 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	30 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	30 Mg, Qd	Not Reported
Zyprexa	S	Unknown	25 Mg, Qd	Not Reported
Zyprexa	S	Unknown	20 Mg, Qd	Not Reported
Zyprexa	S	Unknown	10 Mg, Qd	Not Reported
Zeldox	S	Unknown	120 Mg, Qd	Not Reported
Zeldox	S	Unknown	80 Mg, Qd	Not Reported
Zeldox	S	Unknown	40 Mg, Qd	Not Reported
Zeldox	S	Unknown	20 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	450 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	675 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	900 Mg, Qd	Not Reported
Quilonorm Retard	S	Unknown	450 Mg, Qd	Not Reported
Fluctine	S	Unknown	20 Mg, Qd	Not Reported
Abilify	S	Unknown	5 Mg, Qd	Not Reported
Abilify	S	Unknown	10 Mg, Qd	Not Reported
Abilify	S	Unknown	7.5 Mg, Qd	Not Reported
Abilify	S	Unknown	5 Mg, Qd	Not Reported
Abilify	S	Unknown	2.5 Mg, Qd	Not Reported
Topiramate	C	Unknown	250 Mg, Qd	Not Reported

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Topiramate	C	Unknown	200 Mg, Qd	Not Reported
Topiramate	C	Unknown	175 Mg, Qd	Not Reported
Topiramate	C	Unknown	125 Mg, Qd	Not Reported
Topiramate	C	Unknown	100 Mg, Qd	Not Reported
Topiramate	C	Unknown	75 Mg, Qd	Not Reported
Topiramate	C	Unknown	50 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	250 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	1000 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	750 Mg, Qd	Not Reported
Depakine Cr	C	Unknown	250 Mg, Qd	Not Reported
Lamictal	C	Unknown	300 Mg, Qd	Not Reported
Lamictal	C	Unknown	250 Mg, Qd	Not Reported
Lamictal	C	Unknown	200 Mg, Qd	Not Reported
Lamictal	C	Unknown	100 Mg, Qd	Not Reported
Lamictal	C	Unknown	75 Mg, Qd	Not Reported
Lamictal	C	Unknown	50 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	150 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	200 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Leponex	C	Unknown	100 Mg, Qd	Not Reported
Rivotril	C	Unknown	2 Mg, Qd	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported

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Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Rivotril	C		Unk	Not Reported
Dominal Forte	C	Unknown	160 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	80 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	160 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	120 Mg, Qd	Not Reported
Dominal Forte	C	Unknown	120 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	300 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	600 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	900 Mg, Qd	Not Reported
Neurotop Retard	C	Unknown	Unk	Not Reported
Neurotop Retard	C	Unknown	900 Mg, Qd	Not Reported
Risperdal	C	Unknown	1 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	10 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	7.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported

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Temesta (Lorazepam)	C	Unknown	8 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	4 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	3.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	6.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	8.75 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	7.5 Mg, Qd	Not Reported
Truxal	C	Unknown	50 Mg, Qd	Not Reported
Sterimar Nose Spray	C	Nasal	Unk	Not Reported
Gastrozepin	C	Unknown	150 Mg, Qd	Not Reported
Gastrozepin	C	Unknown	100 Mg, Qd	Not Reported
Laevolac	C	Unknown	3 Df, Qd	Not Reported
Laevolac	C	Unknown	4 Df, Qd	Not Reported
Laevolac	C	Unknown	6 Df, Qd	Not Reported
Nozinan	C	Unknown	50 Mg, Qd	Not Reported
Nozinan	C	Unknown	50 Mg, Qd	Not Reported
Nozinan	C	Unknown	100 Mg, Qd	Not Reported
Nozinan	C	Unknown	25 Mg, Qd	Not Reported
Nozinan	C	Unknown	100 Mg, Qd	Not Reported
Nozinan	C	Unknown	150 Mg, Qd	Not Reported
Zoldem	C	Unknown	5 Mg, Qd	Not Reported

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Dibondrin	C	Unknown	50 Mg, Qd	Not Reported
Praxiten	C	Unknown	25 Mg, Qd	Not Reported
Praxiten	C	Unknown	50 Mg, Qd	Not Reported
Inderal	C	Unknown	20 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Inderal	C	Unknown	40 Mg, Qd	Not Reported
Inderal	C	Unknown	50 Mg, Qd	Not Reported
Inderal	C	Unknown	90 Mg, Qd	Not Reported
Inderal	C	Unknown	40 Mg, Qd	Not Reported
Inderal	C	Unknown	60 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Inderal	C	Unknown	30 Mg, Qd	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	4 Mg, Qd	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	2 Mg, Qd	Not Reported
Akineton	C	Unknown	4 Mg, Qd	Not Reported
Adasuve	C	Unknown	1 Df, Qd	Not Reported
Adasuve	C	Unknown	1 Df, Qd	Not Reported
Nubain	C	Unknown	1 Df, Qd	Not Reported
Mucobene	C	Unknown	600 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14244466	EXPEDITED (15-DAY)		OT	PHHY2017MX176089		78 YR	Male	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Arrhythmia; Feeling	Entresto			S	Oral	2 Df (50 Mg), Bid (1 In The Morning And 1 In The		Not Reported	

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Abnormal; Intestinal Dilatation; Product Use Issue; Vomiting	Atorvastatin	S	Unknown	Afternoon)	Novartis
	Escitalopram	S	Unknown		Not Reported
	Concor	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Pentoxifilina	C	Unknown		Not Reported
	Celecoxib	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14341322	EXPEDITED (15-DAY)		HO	KR-TAKEDA- 2017TUS027572			Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Burning Sensation; Decreased Appetite; Drug Effect Faster Than Expected; Drug Ineffective; Nausea; Pain; Paraesthesia; Sedation	Brintellix			S	Unknown	5 Mg, Qd		Takeda
	Lexapro			S	Unknown	5 Mg, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Trestan /00056201/			S	Unknown	Unk		Not Reported
	Zolpiram			S	Unknown	Unk		Not Reported
	Zolpiram			S	Unknown	Unk		Not Reported
	Zolpiram			S	Oral	Unk		Not Reported
	Ganaton			C	Unknown	Unk		Not Reported
	Ganaton			C				Not Reported
	Bearse			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Xanax			C	Unknown	0.25 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14341352	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2017-ES- 839743		81 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

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02-Jan-2018	14341968	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2017AP021046		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazole			S	Unknown	10 Mg, Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported	
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14343628	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2017M1083569		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram			S	Oral	10 Mg, Unk		Not Reported	
	Inexium 20 Mg, Comprimé			S	Oral	1 Df, Unk		Mylan	
	Gastro-Résistant Pravastatine			C	Oral	20 Mg, Unk		Mylan	
	Pregabaline			C	Oral	50 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14343643	EXPEDITED (15-DAY)		HO, OT	AT-BAUSCH-BL-2017-035456		26 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism	Lorazepam			S	Unknown			Not Reported	
	Abilify			S	Oral			Not Reported	
	Abilify			S				Not Reported	
	Truxal			S	Unknown	2 Tabs		Not Reported	
	Cipralex			S	Unknown	10 Milligram		Not Reported	
	Trazodone Hydrochloride			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14344241	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014612		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remeron			S	Oral			Merck	
	Propranolol			S				Not Reported	
	Escitalopram			S				Not Reported	
	Lamotrigine			S				Not Reported	
	Cyclobenzaprine Hydrochloride			S				Not Reported	
	Buspirone Hydrochloride			S				Not Reported	
	Clonazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14347201	DIRECT					64 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Tardive Dyskinesia; Tardive Dyskinesia	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14257578	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004500		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Lamotrigine			S	Oral			Unknown	
	Escitalopram			S	Oral			Unknown	
	Meloxicam			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14318479	EXPEDITED (15-DAY)		DE, OT	TR-009507513-1712TUR010837		57 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Remeron	S	Oral	Unknown	Merck
	Cipralelex	S		Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14343756	EXPEDITED (15-DAY)	HO		AT-PFIZER INC-2017552457		30 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Alanine Amino	Zeldox			S	Oral	20 Mg, Unk		Pfizer
transferase Increased; Blood Alkaline	Zeldox			S	Oral	80 Mg, Unk		Pfizer
Phosphatase Increased; Drug Interaction; Gamma-Glutamyltransferase Increased	Zeldox			S	Oral	120 Mg, Unk		Pfizer
	Abilify			S	Oral	2.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	7.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	2.5 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Cipralelex			S	Oral	10 Mg, Unk		Not Reported
	Cipralelex			S	Oral	10 Mg, Unk		Not Reported
	Cipralelex			S	Oral	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	Unk		Not Reported
	Sycrest			S	Unknown	20 Mg, Unk		Not Reported
	Sycrest			S	Unknown	10 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported
	Sycrest			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Oral	Unk, Per Day		Not Reported
	Trittico			S	Oral	100 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported

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Trittico	S	Oral	250 Mg, Unk	Not Reported
Trittico	S	Oral	150 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Quilonium R	S		Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	4 Mg, Unk	Not Reported
Rivotril	C	Unknown	2 Mg, Unk	Not Reported
Rivotril	C	Unknown	1 Mg, Unk	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	60 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	20 Mg, Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Inderal	C	Oral	90 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	300 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported

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Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Risperdal	C	Unknown	2 Mg, Unk	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Akineton /00079502/	C	Oral	2 Mg, Unk	Not Reported
Akineton /00079502/	C	Unknown	4 Mg, Unk	Not Reported
Akineton /00079502/	C	Unknown	2 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Praxiten	C		Unk	Not Reported
Sifrol	C	Unknown	0.26 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.34 Mg, Unk	Not Reported
Temesta (Lorazepam)	C		Unk	Not Reported
Temesta (Lorazepam)	C		Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Dibondrin	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported

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03-Jan-2018	14345116	EXPEDITED (15-DAY)		OT	SI-MACLEODS PHARMACEUTICALS US LTD- MAC2017007740			Unknown	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Rosuvastatin			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Indapamide			S	Unknown	Unk		Not Reported	
	Perindopril			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345430	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2017-07602		90 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Fibrosis	Venlafaxine			S	Unknown	37.5 Mg, Qd		Not Reported	
	Duloxetine			S	Unknown	15 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	5 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345570	EXPEDITED (15-DAY)		DE, OT	US-009507513- 1712USA014579		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Cozaar			S	Oral	Unk		Merck	
	Levothyroxine Sodium			S	Oral			Not Reported	
	Bupropion Hydrochloride			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Potassium Salicylate			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345975	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014636		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Singulair			S	Oral			Merck	
	Propranolol			S				Not Reported	
	Escitalopram			S				Not Reported	
	Lamotrigine			S				Not Reported	
	Acetaminophen (+) Oxycodone			S				Not Reported	
	Hydrochloride								
	Ibuprofen			S				Not Reported	
	Ondansetron			S				Not Reported	
	Acyclovir			S				Not Reported	
	Alprazolam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14346052	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014637		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Januvia			S	Oral			Merck	
	Remeron			S				Merck	
	Carvedilol			S				Not Reported	
	Valproic Acid			S				Not Reported	
	Escitalopram			S				Not Reported	
	Phenytoin			S				Not Reported	
	Primidone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14347601	EXPEDITED (15-DAY)		OT	HR-BAYER-2017-248072		17 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Poisoning; Somnolence; Suicide Attempt	Aspirin			S	Oral			Bayer	
	Escitalopram			S		3 Df, Unk		Not Reported	

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Ibuprofen	S	Oral	Not Reported
Olanzapine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14347640	EXPEDITED (15-DAY)		DE, OT	US-009507513-1712USA014649			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Cozaar			S	Oral	Unk		Merck
	Levothyroxine Sodium			S	Oral			Not Reported
	Diltiazem			S				Not Reported
	Propranolol			S				Not Reported
	Metformin			S				Not Reported
	Glyburide			S				Not Reported
	Escitalopram			S				Not Reported
	Lorazepam			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	12468124	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-FRI-1000085324		28 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Shoulder Deformity; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Xeplion			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperdal			S	Unknown	Unk		Not Reported
	Paliperidone Palmitate			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Abilify			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14343293	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-			Male	JPN

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1774117US

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyanosis Neonatal; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Premature Baby; Respiratory Disorder Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Ethyl Loflazepate			S	Transplacental	1 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14349054	EXPEDITED (15-DAY)		DE	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2017007807			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram Oxalate			S	Oral	30 Mg, Qd		Macleods
	Mirtazapine			S	Oral	45 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14349057	EXPEDITED (15-DAY)		OT	PL-MACLEODS PHARMACEUTICALS US LTD- MAC2017007809			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure Via Breast Milk; Seizure	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Bupropion			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14349564	EXPEDITED (15-DAY)		HO, OT	AT-MACLEODS PHARMACEUTICALS			Unknown	AUT

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US LTD-
MAC2017007814

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Quetiapine			S	Unknown	200 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	400 Mg, Qd		Macleods
	Quetiapine			S	Unknown	500 Mg, Qd		Macleods
	Quetiapine			S	Unknown	400 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	200 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	500 Mg, Qd		Macleods
	Quetiapine			S	Unknown	450 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	100 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Quetiapine			S	Unknown	300 Mg, Qd		Macleods
	Quetiapine			S	Unknown	50 Mg, Qd		Macleods
	Olanzapine			S	Unknown	10 Mg, Qd		Macleods
	Olanzapine			S	Unknown	5 Mg, Qd		Macleods
	Olanzapine			S	Unknown	15 Mg, Qd		Macleods
	CipraleX			S	Oral	10 Mg, Qd		Not Reported
	CipraleX			S	Unknown	15 Mg, Qd		Not Reported
	CipraleX			S	Unknown	30 Mg, Qd		Not Reported
	CipraleX			S	Unknown	20 Mg, Qd		Not Reported
	Molaxole			C	Unknown	1 Unk, Qd		Not Reported

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Molaxole	C	Unknown	1 Unk, Qd	Not Reported
Molaxole	C	Unknown	1 Unk, Unk	Not Reported
Molaxole	C	Unknown	1 Unk, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Rivotril	C	Unknown	1 Mg, Qd	Not Reported
Pregabalin	C	Unknown	450 Mg, Qd	Not Reported
Pregabalin	C	Unknown	300 Mg, Qd	Not Reported
Pregabalin	C	Unknown	150 Mg, Qd	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Plantago Indica	C	Unknown	(1)	Not Reported
Cymbalta	C	Unknown	30 Mg, Qd	Not Reported
Combithyrex Mite	C	Unknown	1 Df, Qd	Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd	Not Reported
Thyrex	C	Unknown	50 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14349579	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2017-48575		24 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Headache; Somnolence	Alprazolam			S	Oral	5 Mg, Unk		Aurobindo

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	Dafalgan	S	Oral	Not Reported
	Zoloft	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14349597	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP023737		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Mg, Per Day		Apotex	
	Aripiprazole			S	Unknown	5 Mg, Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351093	EXPEDITED (15-DAY)		DE	JP-HERITAGE PHARMACEUTICALS-2017HTG00382			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arteriosclerosis Coronary Artery; Blister; Drug Abuse; Injury; Overdose; Rhabdomyolysis; Serotonin Syndrome; Skin Abrasion; Toxicity To Various Agents	Fluoxetine			S	Unknown			Heritage	
	Chlorpheniramine			S	Unknown			Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	S Citadep			S	Unknown			Not Reported	
	Venlor Xr			S	Unknown			Not Reported	
	Diazepam			C	Unknown			Not Reported	
	Sibutramine			C	Unknown			Not Reported	
	Thyroid Gland Powder			C	Unknown			Not Reported	
	Bisacodyl			C	Unknown			Not Reported	
	Micronase			C	Unknown			Not Reported	
	Fastin			C	Unknown			Not Reported	
	Dragon			C	Unknown			Not Reported	
	666 Xii			C	Unknown			Not Reported	
	666 Xiii			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351414	NON-EXPEDITED			US-TAKEDA-2017TUS027574			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Trintellix			S	Oral	Unk Unk, Qd		Takeda	
	Trintellix			S	Oral	10 Mg, Qd		Takeda	
	Trintellix			S	Oral	20 Mg, Qd		Takeda	
	Lexapro			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351571	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1774404US			Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Burning Sensation; Decreased Appetite; Drug Effect Faster Than Expected; Drug Ineffective; Nausea; Pain; Paraesthesia; Sedation	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Tylenol			S	Unknown			Not Reported	
	Trestan Cap (Cyanocobalamin)			S	Unknown			Not Reported	
	Zolpiram			S	Oral	Less Than Half Tablet		Not Reported	
	Ganaton			C	Unknown			Not Reported	
	Ganaton			C				Not Reported	
	Ganaton			C				Not Reported	
	Bearse			C	Unknown			Not Reported	
	Bearse			C				Not Reported	
	Ativan			C	Unknown			Not Reported	
	Xanax			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351778	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1000462		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Sedation	Alprazolam			S	Oral	0.13 Df, Unk		Not Reported	

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	Escitalopram		S	Oral	10 Mg, Unk			Not Reported	
	Risperdal		S	Oral	1.5 G, Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352299	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1800151US		16 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Major Depression; Off Label Use; Suspected Counterfeit Product	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Seroquel			C	Unknown	Unk		Not Reported	
	Lamotrigine			C	Unknown	Unk		Not Reported	
	Ou Lai Ning			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352562	NON-EXPEDITED		OT	US-JAZZ-2017-US-014968			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataplexy; Drug Ineffective; Fatigue; Feeling Abnormal; Myalgia; Night Sweats; Taste Disorder	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustment		Jazz	
	Xyrem			S	Oral	3 G, Bid		Jazz	
	Provigil /01265601/			S				Not Reported	
	Lexapro			S				Not Reported	
	Claritin /00413701/			S				Not Reported	
	Augmentin /00756801/			C		Unk		Not Reported	
	Diflucan			C		Unk		Not Reported	
	Meclizine /00072801/			C		Unk		Not Reported	
	Macrobid /00024401/			C		Unk		Not Reported	
	Hydroxyzine Hcl			C		Unk		Not Reported	
	Metoprolol Tartrate			C		Unk		Not Reported	

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Adderall	C	Unk	Not Reported
Lidocaine Hcl	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Prelief	C	Unk	Not Reported
Allegra Allergy	C	Unk	Not Reported
Phentermine Hydrochloride	C	Unk	Not Reported
Codeine Sulfate	C	Unk	Not Reported
Dilaudid	C	Unk	Not Reported
Opana	C	Unk	Not Reported
Buspirone Hcl	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Sudafed /00076302/	C	Unk	Not Reported
Tizanidine Hcl	C	Unk	Not Reported
Xanax	C	Unk	Not Reported
Marcaine /00330101/	C	Unk	Not Reported
Acyclovir /00587301/	C		Not Reported
Aspirin 81	C		Not Reported
Azo Bladder Control With Go Less	C	Unk	Not Reported
Msm	C		Not Reported
Nasalcrom	C		Not Reported
Oxytrol For Women	C	Unk	Not Reported
Zyrtec	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352914	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210518-00		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Ethylene Glycol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

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		Furosemide	S	Oral				Not Reported	
		Folic Acid	S	Oral				Not Reported	
		Vitamin B-1	S	Oral				Not Reported	
		Loratadine	S	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352960	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1000487		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Headache; Somnolence	Alprazolam			S	Oral			Not Reported	
	Dafalgan			S	Oral			Mylan	
	Zoloft 50 Mg,Gelule			S	Oral			Mylan	
	Seroplex			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14355207	DIRECT		HO, LT, OT			16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Panic Attack; Suicidal Ideation	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14324632	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2017-035823			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Incontinence; Breast Cancer; Breast Mass; Coeliac Disease; Colitis Microscopic; Diarrhoea; Irritable Bowel Syndrome; Large Intestine Polyp; Visual Impairment	Xifaxan (Rifaximin) Tablets 550mg			S	Oral			Valeant	
	Uceris (Budesonide) Extended Release Tablets			S	Unknown			Santarus	
	Budesonide Dr And Er			S	Oral			Santarus	
	Bupropion Hcl XI			S	Oral	24 Hour Extended Release Tablet		Not Reported	

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Bupropion Hcl XI	S	Oral	24 Hour Extended Release Tablet	Not Reported
Clonazepam	S	Oral	As Needed	Not Reported
Dexamethasone	S	Unknown		Bausch And Lomb
Sulfamethoxazole And Trimethoprim	S	Unknown	800/160 Mg	Not Reported
Buspirone	S	Oral		Not Reported
Methylphenidate	S	Oral	As Needed	Not Reported
Minivelle	S		24 Hour Transdermal Patch, Change Patch Twice Weekly As Directed	Not Reported
Valacyclovir	S	Oral		Not Reported
Valacyclovir	S	Oral	2 Tablets As Needed	Not Reported
Bionect	S	Topical		Not Reported
Anastrozole	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Fluvirin	S	Intramuscular	45 Mcg (15 Mcg X 3) 0.5 MI Intramuscular Suspension	Not Reported
Ondansetron Hcl	S	Unknown	2 Tablets As Needed	Not Reported
Entecort	C		Worked Well In The Past	Not Reported
Entecort	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14353407	EXPEDITED (15-DAY)	HO		FR-MACLEODS PHARMACEUTICALS US LTD- MAC2017007927			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods	
	Amlodipine Besylate			S	Oral	5 Mg, Qd		Macleods	
	Domperidone			S	Oral	Unk		Not Reported	
	Transulose			S	Unknown	Unk, (Oral Jelly In Jar)		Not Reported	

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Calcium Carbonate			S	Oral	1 Df, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354107	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.- 2017FR29904			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Impulsive Behaviour	Escitalopram			S	Oral	Unk		Invagen	
	Stresam, Gelule			S	Oral	Unk		Not Reported	
	Seresta			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354148	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.- 2017FR30110			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Testicular Pain	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Inexium			S	Oral	1 Df, Unk		Not Reported	
	Pravastatine Sodique			C	Oral	20 Mg, Unk		Not Reported	
	Pregabaline			C	Oral	50 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354243	EXPEDITED (15-DAY)		OT	FR-009507513- 1801FRA000761			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus;	Simvastatin			S		20 Mg, Qd		Merck	
	Levothyroxine Sodium			S	Oral	1 Df, Qd		Not Reported	
	Zyloric			S		1 Df, Qd		Not Reported	
	Atenolol			S		50 Microgram, Qd		Not Reported	
	Cotareg			S		1 Df, Qd		Not Reported	
	Amlor			S		1 Df, Qd		Not Reported	
	Seresta			S		12.5 Mg, Qd		Not Reported	

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Urticaria; Vertigo; Vision Blurred	Uvedose	S	1 Df, Unk	Not Reported
	Imovane	S	0.5 Df, Qd	Not Reported
	Seroplex	S	1 Df, Qd	Not Reported
	Endotelon	S	2 To 3 Tablets/Day	Not Reported
	Voltarene (Diclofenac Sodium)	S	2x / Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354247	EXPEDITED (15-DAY)		DE	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-158961		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Mg, Qd		Sun
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354333	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2017007926			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram Oxalate			S	Oral	1 Df, Qd		Macleods
	Rulid			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354855	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-000296		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	()		Aurobindo

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Valium	S	Oral	()	Not Reported
Baclofene	S	Oral	()	Not Reported
Lexomil	S	Oral	()	Not Reported
Seroplex	S	Oral	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14354987	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR- APL-2018-000105		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea;	Escitalopram			S	Oral			Aurobindo	
Hyperhidrosis;	Mirtazapine			S	Oral			Aurobindo	
Hyperthermia; Hypertonia	Tiapridal			S	Oral			Not Reported	
	Orozamudol			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355097	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC- 2018002508			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase	Lyrica			S	Oral	750 Mg, Unk		Pfizer	
Increased; Aspartate	Lyrica			S	Oral	375 Mg, Unk		Pfizer	
Aminotransferase	Lyrica			S	Oral	300 Mg, Unk		Pfizer	
Increased; Blood	Lyrica			S		150 Mg, Unk		Pfizer	
Cholesterol Increased;	Lyrica			S	Oral	300 Mg, Unk		Pfizer	
Blood Triglycerides	Lyrica			S	Oral	450 Mg, Unk		Pfizer	
Increased; Drug	Lyrica			S	Oral	600 Mg, Unk		Pfizer	
Interaction; Frustration	Lyrica			S	Oral	10 Mg, Unk		Not Reported	
Tolerance Decreased;	Lyrica			S	Oral	10 Mg, Unk		Not Reported	
Gamma-	Cipralelex			S	Oral	15 Mg, Unk		Not Reported	
Glutamyltransferase	Cipralelex			S	Oral	60 Mg, Unk		Not Reported	
Increased; Kidney	Cipralelex			S	Oral	0.5 Mg, Unk		Not Reported	
Enlargement; Liver Injury;	Cymbalta			S				Not Reported	
Neutrophil Count	Risperdal			S				Not Reported	
Decreased;									
Splenomegaly; Weight									
Increased									

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Risperdal	S		1 Mg, Unk	Not Reported
Risperdal	S		2 Mg, Unk	Not Reported
Topamax	S	Oral	25 Mg, Unk	Not Reported
Topamax	S	Oral	25 Mg, Unk	Not Reported
Topamax	S	Oral	50 Mg, Unk	Not Reported
Topamax	S	Oral	100 Mg, Unk	Not Reported
Pantoloc	C		40 Mg, Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Rivotril	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355281	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017555874		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Amlodipine			S	Oral	5 Mg, 1x/Day		Pfizer	
	Transulose			S	Oral	Unk		Not Reported	
	Domperidone			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Calcium Carbonate			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355408	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210727-00		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Levothyroxine			S	Oral			Not Reported	
	Bupropion			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Losartan			S	Oral			Not Reported	
	Ethanol			S	Oral			Not Reported	

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05-Jan-2018	14355518	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SA-2018SA003378			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Xyzall			S	Transplacental			Not Reported
	Avamys			S	Transplacental	Form: Nasal Spray		Not Reported
	Seretide			S	Transplacental			Not Reported
	Sipralexa			S	Transplacental			Not Reported
	Vilanterol Trifenatate			S	Transplacental	Form: Inhalation Powder		Not Reported
	Fluticasone Furoate			S	Transplacental	Form: Inhalation Powder		Not Reported
	Flixotide			S	Transplacental			Not Reported
	D-Cure			S	Transplacental			Not Reported
	Pantomed (Pantoprazole Sodium)			S	Transplacental			Not Reported
	Ventolin			S	Transplacental			Not Reported
	Mepolizumab			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355532	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2212383-00		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Valproic Acid			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Sitagliptin			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Phenytoin			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported

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05-Jan-2018	14355613	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-18P-163-2210729-00		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Levothyroxine			S	Oral			Not Reported
	Diltiazem			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Glyburide			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Losartan			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14356537	EXPEDITED (15-DAY)		HO, OT	TR-MYLANLABS-2017M1082641			Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Meconium Aspiration Syndrome; Newborn Persistent Pulmonary Hypertension	Escitalopram			S	Transplacental	10 Mg Per Day		Not Reported
	Passiflora Incarnata			S	Transplacental	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14356678	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2018M1000582		58 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Intention Tremor; Lethargy; Resting Tremor; Sedation; Social Avoidant Behaviour; Tremor	Pregabalin			S	Unknown	300 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	150 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	375 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	450 Mg, Qd		Not Reported

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	Pregabalin	S	Oral	750 Mg, Qd	Not Reported
	Topiramate	S	Oral	25 Mg, Qd	Not Reported
	Topiramate	S	Oral	100 Mg, Qd	Not Reported
	Cipralelex	S	Oral	10 Mg, Qd	Mylan
	Cipralelex	S	Oral	15 Mg, Qd	Mylan
	Risperidone	S	Unknown	2 Mg, Qd	Mylan
	Pantoprazol	C	Unknown	40 Mg, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14357034	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2018M1000968		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Orozamudol 50 Mg, Comprimé			S	Oral			Mylan	
	Orodispersible Escitalopram			S	Oral			Not Reported	
	Mirtazapine			S	Oral			Not Reported	
	Tiapridal			S	Oral			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14357081	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1000076		45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	Unk		Not Reported	
	Lexomil			S	Oral	Unk		Mylan	
	Seroplex			S	Oral	Unk		Mylan	
	Baclofene			S	Oral	Unk		Mylan	
	Valium			S	Oral	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14361006	DIRECT		DS, OT			22 YR	Male	USA

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Intellectual Disability; Nervousness	Lexapro			S		Quantity:1 Tablet(S);		Forest	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14363635	DIRECT		OT			33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Sickle Cell Trait; Syndactyly	Lexapro 20mg			S	Oral	20mg One Po Qam Oral		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360147	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-000503		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Unk		Aurobindo	
	Domperidone			S	Oral	()		Not Reported	
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo	
	Transulose			S	Oral	()		Not Reported	
	Calcium Carbonate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360271	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-000562		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Df, Unk		Aurobindo	
	Rulid			S	Oral	Unk		Not Reported	

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06-Jan-2018	14360425	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159233		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Daily		Sun	
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported	
	Transulose, Gelee Orale En Pot			S	Oral	()		Not Reported	
	Domperidone			S	Oral	()		Not Reported	
	Carbonate De Calcium			S	Oral	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360451	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00004172		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Atenolol			S				Unknown	
	Escitalopram Oxalate			S				Unknown	
	Primidone			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360454	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00004175		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Loperamide Hydrochloride			S	Oral			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	
	Meloxicam			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360498	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE- HET2018CA00005		90 YR	Female	CAN

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Interstitial Lung Disease	Duloxetine			S	Unknown	15 Mg		Hetero	
	Escitalopram			S	Unknown	5 Mg		Hetero	
	Venlafaxine			S	Unknown	37.5 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360640	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1001064		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Amlodipine			S	Oral	5 Mg, Qd		Not Reported	
	Domperidone			S	Oral			Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Calcium Carbonate			S	Oral	1 Df, Qd		Not Reported	
	Transulose			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14254114	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1768933US		52 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Nitrazepam			C	Unknown			Not Reported	
	Omega-3-Acid Ethyl Ester			C	Unknown			Not Reported	
	Zyloric			C				Not Reported	
	Nexium			C	Unknown			Not Reported	
	Urso /00465701/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14334306	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK200541			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anal Incontinence; Breast Cancer; Breast Mass; Coeliac Disease; Colitis Microscopic; Diarrhoea; Irritable Bowel Syndrome; Large Intestine Polyp; Visual Impairment	Bupropion Hydrochloride XI	S	Oral	300 Mg, 1d	Glaxosmithkline
	Bupropion Hydrochloride XI	S	Oral	150 Mg, 1d	Glaxosmithkline
	Valacyclovir	S	Oral	1 Gm Tablet; 2 Tablets, Prn	Glaxosmithkline
	Budesonide	S	Oral	Budesonide Dr And Er 3 Mg Capsule	Glaxosmithkline
	Dexamethasone	S	Unknown		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim	S	Unknown		Glaxosmithkline
	Buspirone Hydrochloride	S	Oral	30 Mg, 1d	Glaxosmithkline
	Methylphenidate	S	Oral	20 Mg Tablet, 2 Daily, Prn	Glaxosmithkline
	Anastrozole	S	Oral	1 Mg, 1d	Glaxosmithkline
	Escitalopram	S	Oral	10 Mg Tablet, 1d	Glaxosmithkline
	Xifaxan	S	Oral	Three 550 Mg Tablets Daily	Not Reported
	Uceris	S	Unknown	9 Mg Extended Release Tablets	Not Reported
	Fluvirin	S	Intramuscular	45 Mcg (15 Mcg X 3) (15 Mcg/0.5ml Im Suspension)	Not Reported
	Ondansetron Hydrochloride	S	Unknown	Two 8mg Tablets (16 Mg), Prn	Not Reported
	Clonazepam	S	Oral	0.5 Mg Tablet, 3 Daily	Not Reported
	Minivelle	S	Transdermal	24 Hour Patch, Change Twice Weekly	Not Reported
	Bionect	S	Topical	0.2 Percent Cream	Not Reported
	Entocort	C		1 Df, We	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14344162	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1774405US		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14362253	NON-EXPEDITED			US-TEVA-2017-US-838628		16 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash; Rash	Escitalopram Escitalopram			S S				Ivax Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14362333	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.-2017IT30563			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atrioventricular Block First Degree	Escitalopram Abilify			S C	Oral Oral	10 Mg, Unk 10 Mg, Unk		Invagen Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14363624	EXPEDITED (15-DAY)		HO, LT	ES-OTSUKA-2017_028769		47 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depressed Level Of Consciousness; Intentional Overdose	Abilify			S	Oral	30 Mg, Qd		Otsuka	
	Clonazepam			S	Oral	22.5 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported	
	Quetiapina			S	Oral	19 G, Qd		Not Reported	
	Valproate Sodium			S	Oral	3.6 Mg, Qd		Not Reported	
	Antabus			S	Oral	250 Mg, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14364176	EXPEDITED (15-DAY)		HO	FR-SA-2017SA269133		74 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cholestasis;	Irbesartan			S	Oral	1-0-0		Not Reported	

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Hepatocellular Injury	Pantoprazole	S	Oral	0-0-1	Not Reported
	Escitalopram	S	Oral	1-0-0	Not Reported
	Furosemide	S	Oral	1-0-0	Not Reported
	Seresta	C	Oral		Not Reported
	Duphalac	C	Oral		Not Reported
	Havlane	C	Oral	0-0-1 Si Besoin	Not Reported
	Kardegic	C	Oral	0-1-0	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14367580	DIRECT	Y	HO			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Ulcer	Ocrevus			S				Genentech
	Atorvastatin			C				Not Reported
	Baclofen			C				Not Reported
	Carbamazepine Er			C				Not Reported
	Escitalopram Oxalate			S				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Spironolactone			C				Not Reported
	Tizanidine			C				Not Reported
	Tramadol			C				Not Reported
	Multivitamin			C				Not Reported
	Dexilant			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	13854198	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2017GSK121129		19 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Overdose; Sopor	Lamictal			S	Oral	In Total		Glaxosmithkline
	Lamictal			S	Oral	350 Mg, Single		Glaxosmithkline
	Cipralelex			S	Oral	In Total		Glaxosmithkline
	Cipralelex			S		120 Mg, Single		Glaxosmithkline

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14311899	NON-EXPEDITED			US-009507513-1712USA010434		76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Fatigue; Hypotension; Overdose; Presyncope	Olmesartan Medoxomil			S	Unknown	Daily Dose Unknown		Not Reported
	Aspirin			S	Unknown	Daily Dose Unknown		Not Reported
	Finasteride			S	Unknown	Daily Dose Unknown		Merck
	Mirtazapine			S	Unknown	Daily Dose Unknown		Merck
	Simvastatin			S	Unknown	Daily Dose Unknown		Merck
	Nitroglycerin			S	Unknown	Unk Unk,As Needed		Merck
	Tylenol With Codeine			S	Unknown	Unk, As Needed		Not Reported
	Amlodipine			S	Unknown	Daily Dose Unknown		Not Reported
	Carvedilol			S	Unknown	Daily Dose Unknown		Not Reported
	Hydralazine			S	Unknown	Daily Dose Unknown		Not Reported
	Losartan Potassium Tablets			S	Unknown	Daily Dose Unknown		Merck
	Niacin			S	Unknown	Daily Dose Unknown		Not Reported
	Escitalopram			S	Unknown	Daily Dose Unknown		Not Reported
	Pantoprazole			S	Unknown	Daily Dose Unknown		Not Reported
	Clopidogrel			S	Unknown	Daily Dose Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14366028	EXPEDITED (15-DAY)		LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2017008183			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Neuroleptic Malignant Syndrome	Escitalopram 10mg Tablet			S	Oral	Unk, Escitalopram Cinfa 10 Mg Film-Coated Compresses Efg, 56 Tablets		Macleods
	Haloperidol			S	Oral	Unk		Not Reported

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Deprax (Fluoxetine Hydrochloride)	S	Unknown	100 Mg, Qd	Not Reported
Distraneurine Capsules	S	Oral	Unk	Not Reported
Lormetazepam Cinfa 1 Mg Comprimides Efg, 30 Tablets	S	Unknown	Unk	Not Reported
Omeprazole	C	Oral	Unk, Omeprazol Cinfamed 20 Mg Gastroresistant Hard Capsules Efg, 56 Capsules	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14366039	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2017IT30945			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematuria; Melaena; Rectal Haemorrhage	Escitalopram			S	Oral	4 Gtt, Per Day		Invagen
	Cadrioaspirin			S	Oral	100 Mg, Per Day		Not Reported
	Plavix			S	Oral	75 Mg, Per Day		Not Reported
	Lasix Fiale			C	Oral	125 Mg, Unk		Not Reported
	Cacit Vitamina D3			C	Oral	Unk		Not Reported
	Fluxum			C	Unknown	Unk		Not Reported
	Kcl Retard			C	Oral	Unk		Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Mg, Unk		Not Reported
	Lansox			C	Oral	75 Mg, Unk		Not Reported
	Tavor [Lorazepam]			C	Oral	1 Mg, Unk		Not Reported
	Lanoxin			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14366420	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2016NO185921		28 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Odour; Facial Asymmetry; Gait Disturbance; Head	Olanzapine			S	Unknown			Novartis
	Risperidone			S	Unknown			Not Reported

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Discomfort; Muscle	Xeplion	S	Unknown	Unk	Not Reported
Spasms; Musculoskeletal	Risperdal	S	Unknown	Unk	Not Reported
Stiffness; Parkinson'S	Escitalopram	S	Unknown		Not Reported
Disease; Personality	Paliperidone Palmitate	S	Unknown		Not Reported
Change; Product Use In	Zyprexa	S	Unknown	Unk	Not Reported
Unapproved Indication;	Abilify	S	Unknown	Unk	Not Reported
Shoulder Deformity;	Cipralex	S	Unknown	Unk	Not Reported
Weight Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14367689	NON-EXPEDITED			US-STI PHARMA LLC-2039726			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Tinnitus	Escitalopram			S				Sti Pharma	
	Fondaparinux Sodium			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14367987	DIRECT					44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Loss Of Libido; Male Orgasmic Disorder	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14368011	DIRECT	Y	OT			17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Tremor	Lexapro			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14368242	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-		74 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Furosemide			S	Oral	40 Mg, Qd		Validus
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Seresta			C				Not Reported
	Duphalac /00163401/			C				Not Reported
	Havlane			C				Not Reported
	Kardegic			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14368355	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2018M1001386		17 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Somnolence; Suicide Attempt	Ibuprofen			S	Oral	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14369203	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1800369US		78 YR	Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Ulcer; Gastrointestinal Haemorrhage; Off Label Use; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Celecoxib			C	Unknown	Unk		Not Reported
	Aricept			C	Unknown			Not Reported

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Lipidil Supra	C	Unknown	Not Reported
Ultracet Semi	C	Unknown	Not Reported
Stilnox	C	Unknown	Not Reported
Seroquel	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14371740	DIRECT		OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Alopecia Areata; Androgenetic Alopecia	Escitalopram (Lexapro 20mg Cut Y In Half For 10 Mg			S	Oral	Quantity:1 Tablet(S);		Forest
	Metformin Xr			C				Not Reported
	Multivitamin With Biotic			C				Not Reported
	Lysine Spirulina Ginger Lime			C				Not Reported
	Apple Cider Vinegar			C				Not Reported
	Onion Garlic			C				Not Reported
	Coffee			C				Not Reported
	Fish Oil			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14208555	EXPEDITED (15-DAY)		DS, HO	GXKR2017DE005827		57 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Unknown	900 Mg, Twice Daily		Novartis
	Ciprallex			S	Unknown	5 Mg, Once Daily		Not Reported
	Novaminsulfon			C	Unknown	500 Mg, Tid (On A Regular Basis)		Not Reported
	Ibuprofen			C	Unknown	600 Mg, Qid		Not Reported
	Xarelto			C	Unknown	10 Mg, Qd		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Ass			C	Unknown			Not Reported

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10-Jan-2018	14274044	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-2016_015925		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Abilify			S	Oral	5 Mg, Qd		Otsuka	
	Zopiclone			S	Oral	210 Mg, Qd; (Zopiclone 7.5 Mg Before Sleep)		Not Reported	
	Zyprexa			S	Oral	1 Df, Unk; (1df=1050 To 1350mg,Zyprexa)		Not Reported	
	Lysanxia			S	Oral	1440 Mg, Unk; (Lysanxia (Prazepam) 10 Mg))		Not Reported	
	Seroplex			S	Oral	140 Mg, Unk;(Seroplex (Escitalopram))		Not Reported	
	Lexapro			S	Oral	140 Mg, Unk		Not Reported	
	Olanzapin			S	Oral	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370190	EXPEDITED (15-DAY)		HO, LT	ES-CIPLA LTD.-2017ES31002			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Escitalopram			S	Oral	30 Mg, In Total		Invagen	
	Quetiapine			S	Oral	19 G, In Total		Not Reported	
	Valproato Sodio (3194so)			S	Oral	3.6 Mg, In Total		Not Reported	
	Abilify 15 Mg Comprimidos, 28 Comprimidos			S	Oral	30 Mg, Daily		Not Reported	
	Clonazepam (635a)			S	Oral	22.5 Mg, In Total		Not Reported	
	Antabus 250 Mg Comprimidos , 40 Comprimidos			S	Oral	250 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370191	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2017ES31183			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Daily		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370886	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159423		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Mg, Qd (Zopiclone 7.5 Mg Before Sleep)		Not Reported	
	Olanzapine			S	Oral	1 Df, Unk		Sun	
	Seroplex			S	Oral	140 Mg, Unk		Not Reported	
	Abilify			S	Oral	5 Mg, Qd		Not Reported	
	Lysanxia			S	Oral	1440 Mg, Unk		Not Reported	
	Zopiclone			S	Oral	210 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	1 Df, Unk		Not Reported	
	Lexapro			S	Oral	140 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371327	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2018-001225		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Mg, Qd		Not Reported	
	Olanzapine			S	Oral	1 Df, Unk		Aurobindo	
	Seroplex			S	Oral	140 Mg, Unk		Not Reported	
	Abilify			S	Oral	5 Mg, Qd		Not Reported	
	Lysanxia			S	Oral	1440 Mg, Unk		Not Reported	
	Zyprexa			S	Oral	1 Df, Unk		Not Reported	
	Lexapro			S	Oral	140 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371813	EXPEDITED (15-DAY)		OT	SI-GLENMARK PHARMACEUTICALS- 2017GMK030499			Unknown	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin Calcium			S	Unknown	Unk		Glenmark	
	Perindopril			S	Unknown	Unk		Not Reported	
	Indapamide			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14372170	EXPEDITED (15-DAY)		OT	SG-MYLANLABS- 2017M1083829		65 YR	Female	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg/Day		Not Reported	
	Metformin			C	Unknown	500 Mg; Three Times Daily		Mylan	
	Atenolol			C	Unknown	25 Mg/Day		Mylan	
	Hydrochlorothiazide			C	Unknown	12.5 Mg/Day		Mylan	
	Lovastatin			C	Unknown	20 Mg/Day		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14372191	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA- 844114		90 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Venlafaxine			S	Unknown			Teva	
	Duloxetine			S	Unknown			Teva	
	Escitalopram			S	Unknown			Ivax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14373263	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-TEVA-2017-NO-841743		28 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S Disease; Personality Change; Product Use In Unapproved Indication; Shoulder Deformity; Weight Increased	Escitalopram			S	Unknown			Ivax	
	Olanzapine			S	Unknown			Teva	
	Risperidone			S	Unknown			Not Reported	
	Risperdal			S	Unknown	Unk		Not Reported	
	Zyprexa			S	Unknown	Unk		Not Reported	
	Abilify			S	Unknown	Unk		Not Reported	
	Ciprallex			S	Unknown	Unk		Not Reported	
	Xeplion			S	Unknown	Unk		Not Reported	
	Paliperidone Palmitate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14373509	EXPEDITED (15-DAY)		OT	BE-SA-2017SA259553			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Congenital Anomaly In Offspring; Exposure During Pregnancy	Levocetirizine			S	Unknown			Not Reported	
	D-Cure			S	Unknown			Not Reported	
	Seretide			S	Unknown			Not Reported	
	Siprallexa			S	Unknown			Not Reported	
	Vilanterol Trifenatate			S	Unknown	The Dosage Form Was Inhalation Powder		Not Reported	
	Fluticasone Furoate			S	Unknown	The Dosage Form Was Inhalation Powder		Not Reported	
	Flixotide			S	Unknown			Not Reported	
	Xanthium (Theophylline)			S	Unknown			Not Reported	
	Pantomed (Pantoprazole Sodium)			S	Unknown			Not Reported	

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Ventolin	S	Unknown		Not Reported
Avamys	S	Unknown	The Dosage Form Was Nasal Spray And The Dose Was 2 (Unit Unknown)	Not Reported
Mepolizumab	S	Subcutaneous	The Dosage Form Was Powder For Solution For Injection	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14375326	DIRECT		DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Mood Altered	Lexapro 10 Mg			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14168247	NON-EXPEDITED		OT	US-AMGEN-USASL2017167837		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Fatigue; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Zolpidem			C	Unknown	10 Mg, Unk		Not Reported
	Metoprolol			C	Unknown	50 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14278470	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2016_008020		85 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Off Label Use; Respiratory Distress; Somnolence	Abilify			S	Oral	5 Mg, Qd		Otsuka
	Temesta (Lorazepam)			S	Unknown	2.5 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S				Not Reported

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Seroplex	S	Oral	20 Mg, Qd	Not Reported
Lexapro	S	Oral	20 Mg, Qd	Not Reported
Kardegic	C	Unknown	Unk	Not Reported
Flodil [Buflomedil Hydrochloride]	C	Unknown	Unk	Not Reported
Tegretol	C	Unknown	400 Mg, Unk	Not Reported
Gardenal	C	Unknown	Unk	Not Reported
Inegy	C	Unknown	Unk	Not Reported
Bisoce	C	Unknown	Unk	Not Reported
Omexel	C	Unknown	Unk	Not Reported
Uvedose	C	Unknown	Unk	Not Reported
Dafalgan	C	Unknown	Unk	Not Reported
Avodart	C	Unknown	Unk	Not Reported
Vesicare	C	Unknown	Unk	Not Reported
Topalgic (Tramadol Hydrochloride)	C	Unknown	Unk	Not Reported
Allopurinol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unk	Not Reported
Ventoline	C	Unknown	Unk	Not Reported
Tamsulosin Hydrochloride	C	Unknown	0.4 Mg, Unk	Not Reported
Felodipine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14307284	EXPEDITED (15-DAY)		HO, OT	PHHY2017SI155904		48 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Sclerosis;	Fty 720			S	Unknown	0.5 Mg, Qd		Novartis	
Palpitations; Product Use	Escitalopram			S	Unknown	10 Mg, Qd (1 Tablet In		Not Reported	

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In Unapproved Indication

Pregabalin	S	Unknown	Morning)	150 Mg, Bid	Not Reported
Fampridine	S	Unknown		10 Mg, Bid	Not Reported
Tolterodine	S	Unknown		4 Mg, Qd (1 Tablet In Morning)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14355684	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1082655		90 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Interstitial Lung Disease	Venlafaxine			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14373888	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017008202			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, Qd		Macleods
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Irbesartan			S	Oral	75 Mg, Qd		Macleods
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Seresta 10 Mg			C	Oral	1 Df, Qd		Not Reported
	Duphalac			C	Oral	3 Df, Qd		Not Reported
	Havlane			C	Oral	1 Df, Qd		Not Reported
	Kardegic 160 Mg			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14374050	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2017FR31020			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Escitalopram			S	Oral	Unk		Invagen
	Fenofibrate			S	Oral	Unk		Invagen
	Pantoprazole			S	Oral	Unk		Cipla
	Xeloda			S	Oral	Unk		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Primperan			S	Oral	Unk		Not Reported
	Movicol			S	Oral	Unk		Not Reported
	Abasaglar			S	Subcutaneous	Unk		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14374696	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159678		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Sun
	Furosemide			S	Oral	40 Mg, Qd		Not Reported
	Duphalac			C	Oral	3 Df, Tid		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C	Oral	1 Df, Qd		Not Reported
	Seresta 10 Mg, Comprime			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14374879	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159846		65 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria	Esomeprazole			S	Oral	Unk		Sun	
	Venlafaxine			S	Oral	1 Df, Daily		Sun	
	Nordazepam			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14375128	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001290		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	10 Mg, Daily		Aurobindo	
	Furosemide			S	Oral	40 Mg, Daily		Not Reported	
	Irbesartan			S	Oral	75 Mg, Daily		Aurobindo	
	Pantoprazole			S	Oral	40 Mg, Daily		Aurobindo	
	Seresta			C	Oral	0-0-1		Not Reported	
	Duphalac /00163401/			C	Oral	1-1-1		Not Reported	
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported	
	Kardegic			C	Oral	0-1-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14376002	EXPEDITED (15-DAY)		HO	FR-UCBSA-2018001230		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Raynaud'S Phenomenon	Methylphenidate Hydrochloride			S	Oral	80 Mg In Am 20 Mg In Pm		Ucb	
	Methylphenidate Hydrochloride			S	Oral	110 Mg, Once Daily (Qd)		Ucb	
	Methylphenidate Hydrochloride			S				Ucb	
	Laroxyl			S		Unk		Not Reported	
	Laroxyl			S				Not Reported	
	Laroxyl			S				Not Reported	
	Lexapro			S	Oral	10 Mg, Once Daily (Qd)		Not Reported	

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Lexapro	S				Not Reported
Lexapro	S				Not Reported
Quetiapine	S	Oral	400 Mg, Once Daily (Qd)		Not Reported
Quetiapine	S				Not Reported
Quetiapine	S				Not Reported
Abilify	S	Oral	15 Mg, Once Daily (Qd)		Not Reported
Abilify	S				Not Reported
Abilify	S				Not Reported
Lepticur	S		15 Mg, Unk		Not Reported
Lepticur	S				Not Reported
Lepticur	S				Not Reported
Ritaline	S	Oral	100 Mg, Unk		Not Reported
Ritaline	S	Oral	110 Mg, Once Daily (Qd)		Not Reported
Ritaline	S				Not Reported
Seroplex	S	Oral	10 Mg, Once Daily (Qd)		Not Reported
Seroplex	S				Not Reported
Seroplex	S				Not Reported
Quetiapine Fumarate	S	Oral	400 Mg, Once Daily (Qd)		Not Reported
Quetiapine Fumarate	S				Not Reported
Quetiapine Fumarate	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14376416	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-GLENMARK PHARMACEUTICALS- 2017GMK030467			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Mg, Qd		Glenmark
	Avamys Nasal Spray			S	Transplacental	Unk, Bid		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Sipralexa Tablet			S	Transplacental	10 Mg		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	Unk, Od		Not Reported
	Flixotide			S	Transplacental	500 Mg, Od		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported

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	Ventolin	S	Transplacental	100 Mg, Unk		Not Reported			
	Nucala Powder For Solution For Injection	S	Transplacental	100 Mg, Unk		Not Reported			
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14376504	EXPEDITED (15-DAY)		OT	CA-LANNETT COMPANY, INC.-CA-2017LAN001304		90 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Duloxetine			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14377531	EXPEDITED (15-DAY)		HO, OT	SI-ALLERGAN-1801183US		49 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Rosuvastatin			S	Unknown			Not Reported	
	Perindopril			S	Unknown			Not Reported	
	Indapamide			S	Unknown			Not Reported	
	Alprazolam			S	Unknown	Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14377755	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1002476		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Irbesartan			S	Oral	75 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	S	Oral	40 Mg, Qd	Not Reported
Seresta	C	Oral	1 Df, Qd	Mylan
Duphalac /00163401/	C	Oral	3 Df, Qd	Mylan
Havlane	C	Oral	1 Df, Qd	Mylan
Kardegic	C	Oral	0-1-0	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14380203	DIRECT					27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Decreased Appetite; Influenza; Migraine; Nausea; Product Substitution Issue; Vomiting	Escitalopram Omperazole Cetirizine Fluticazone One A Day Women'S Supplement		Y	S C C C C	Oral	Quantity:1 Tablet(S);		Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14177965	EXPEDITED (15-DAY)		DE, HO, LT	AT-ALLERGAN- 1764439US		73 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Cardiac Disorder; Condition Aggravated; Coronary Artery Disease; Dehydration; Fatigue; Oedema Peripheral; Pneumonia; Renal Impairment; Weight Decreased	Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Azilect Trittico Seroquel Madopar 62.5 Stalevo Stalevo Stalevo			S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	2 Df, Qam 1 Df, Qam 1 Df, Qam Half At Night As Needed 1 Df, Tid 1 Df, Qam 1 Df, Bid (One In The Morning, One At Noon) Unk		Allergan Allergan Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lovenox	C	Unknown	1 Daily	Not Reported
Elomel	C	Unknown	1 Daily	Not Reported
Optinem	C	Unknown	Unk	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Thrombo Ass	C	Unknown	1 At Noon	Not Reported
Spirobene	C	Unknown	Half At Noon	Not Reported
Sedacoron	C	Unknown	Half In The Morning	Not Reported
Eporatio	C	Unknown	1 Weekly	Not Reported
Ceftriaxone Sodium	C	Unknown	2 G In 200 MI, 1 Daily	Not Reported
Dancor	C	Unknown	One In The Morning, One In The Evening	Not Reported
Aquaphoril	C	Unknown	Half In The Morning	Not Reported
Torasemide	C	Unknown	One In The Morning	Not Reported
Pantoloc	C	Unknown	Two In The Morning	Not Reported
Insulatard	C	Unknown	6ie-0-0 (International Unit)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14183967	EXPEDITED (15-DAY)		OT	DE-TEVA-825403GER		32 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Dyskinesia;	Escitalopram			S	Oral			Not Reported
Extrapyramidal Disorder;	Trimipramine			S	Oral			Not Reported
Muscle Twitching; Muscle Twitching; Restlessness	Trimipramine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14334674	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2017M1082534		85 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Off Label Use;	Lorazepam			S	Unknown	2.5 Mg, Unk		Not Reported
Respiratory Distress; Somnolence	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aripiprazole	S	Oral	5 Mg, Qd	Not Reported
Lorazepam	S	Unknown	2.5 Mg, Unk	Not Reported
Escitalopram Oxalate	S	Oral	20 Mg, Qd	Not Reported
Flodil /00641902/	C	Unknown	Unk	Mylan
Ventoline /00139501/	C	Unknown	Unk	Mylan
Spasfon /00765801/	C	Unknown	Unk	Mylan
Pantoprazole	C	Unknown	Unk	Mylan
Allopurinol	C	Unknown	Unk	Mylan
Tamsulosin Hydrochloride	C	Unknown	0.4 Mg, Unk	Mylan
Gardenal /00023201/	C	Unknown	Unk	Mylan
Topalgic /00599202/	C	Unknown	Unk	Mylan
Kardegic	C	Unknown	Unk	Mylan
Vesicare	C	Unknown	Unk	Mylan
Dafalgan	C	Unknown	Unk	Mylan
Inegy	C	Unknown	Unk	Mylan
Uvedose	C	Unknown	Unk	Mylan
Carbamazepine	C	Unknown	400 Mg, Unk	Mylan
Omexel	C	Unknown	Unk	Mylan
Loperamide	C	Unknown	Unk	Mylan
Domperidone	C	Unknown	Unk	Mylan
Tegretol	C	Unknown	Unk	Mylan
Bisoce	C	Unknown	Unk	Mylan
Avodart	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379017	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013072		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Furosemide Tablets			S	Oral	Unk Unk, Unknown		Dava	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levothyroxine Sodium	S	Oral	Unk Unk, Unknown	Par
Folic Acid Tablets	S	Oral	Unk Unk, Unknown	Vintage
Ethylene Glycol	S	Oral	Unk Unk, Unknown	Not Reported
Escitalopram	S	Oral	Unk, Unknown	Not Reported
Loratadine	S	Oral	Unk Unk, Unknown	Not Reported
Vitamin B-1	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379029	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR00560			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Coma; Fall; Rib Fracture	Escitalopram			S	Oral	Unk		Invagen	
	Zolpidem Tartarate			S	Oral	Unk		Invagen	
	Lexomil Roche			S	Oral	Unk		Not Reported	
	Baclofene			S	Oral	Unk		Not Reported	
	Valium			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379137	EXPEDITED (15-DAY)		DE	FR-CIPLA LTD.- 2018FR00029			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram			S	Oral	30 Mg, Per Day		Invagen	
	Tramadol			S	Oral	150 Mg, Per Day		Not Reported	
	Chlorhydrate Detiapri De, Tiapri De (Chlorhydrate De)Tiapri De (Chlor			S	Oral	100 Mg, Per Day		Not Reported	
	Mirtazapine			S	Oral	45 Mg, Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379230	EXPEDITED (15-DAY)		OT	BE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	BEL

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

MAC2017008241

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Congenital Anomaly In Offspring; Exposure During Pregnancy	Pantoprazole			S	Unknown	20 Mg, Qd		Macleods
	Ventolin			S	Unknown	100 Mg, Unk		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Qd		Not Reported
	Avamys Nasal Spray Suspension			S	Nasal	2 Unk, Bid		Not Reported
	Mepolizumab			S	Subcutaneous	100 Mg, Powder For Solution For Injection		Not Reported
	Vilanterol Trifenatate			S	Unknown	1 Df, Qd, Inhalation Powder		Not Reported
	Seretide			S	Unknown	Unk		Not Reported
	Fluticasone Furoate			S	Unknown	1 Df, Qd, Inhalation Powder		Not Reported
	Xyzall			S	Oral	5 Mg, Qd		Not Reported
	Flixotide			S	Unknown	500 Mg, Qd, 250 Mg, 2x/Day (Bid)		Not Reported
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Sipralexa			S	Oral	10 Mg, Z, Tablet		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379307	EXPEDITED (15-DAY)		OT	FR-ALVOGEN-2018- ALVOGEN-094818			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Amnesia; Arthralgia; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness;	Atenolol			S	Respiratory (inhalation)	50		Not Reported
	Zyloric			S	Unknown			Not Reported
	Cotareg			S	Unknown	Nonaz		Not Reported
	Seroplex			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paraesthesia; Pruritus;	Amlor	S	Unknown		Not Reported
Thyroid Function Test	Levothyroxine Sodium	S	Oral		Not Reported
Abnormal; Urticaria;	Simvastatin	S	Unknown		Not Reported
Vertigo; Vision Blurred	Oxazepam	S	Unknown		Not Reported
	Uvedose	S	Unknown	1.0df Unknown	Not Reported
	Zopiclone	S	Unknown		Not Reported
	Endotelon	S	Unknown		Not Reported
	Voltarene Sr	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379555	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2017FR31159			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis;	Escitalopram			S	Oral	10 Mg, Daily, 1-0-0		Invagen
Hepatocellular Injury	Irbesartan			S	Oral	75 Mg, Daily, 1-0-0		Cipla
	Pantoprazole			S	Oral	40 Mg, Daily, 0-0-1		Cipla
	Furosemide			S	Oral	40 Mg, Daily, 1-0-0		Not Reported
	Seresta			C	Oral	1 Df, Daily, 0-0-1		Not Reported
	Duphalac			C	Oral	3 Df, Daily, 1-1-1		Not Reported
	Havlane			C	Oral	1 Df, Daily, 0-0-1 Si Besoin		Not Reported
	Kardegic			C	Oral	1 Df, Daily, 0-1-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379906	EXPEDITED (15-DAY)		HO, OT	AT-GLENMARK PHARMACEUTICALS- 2017GMK030460			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Intention Tremor;	Topiramate			S	Oral	100 Mg, Unk		Glenmark
Lethargy; Resting Tremor;	Topiramate			S	Oral	25 Mg, Unk		Glenmark
Sedation; Social Avoidant Behaviour; Tremor								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregabalin	S	Unknown	450 Mg, Unk	Not Reported
Pregabalin	S	Unknown	375 Mg, Unk	Not Reported
Pregabalin	S	Unknown	300 Mg, Unk	Not Reported
Pregabalin	S	Unknown	150 Mg, Unk	Not Reported
Risperidone	S	Unknown	2 Mg, Unk	Not Reported
Cipralex /01588501/	S	Oral	15 Mg, Unk	Not Reported
Cipralex /01588501/	S	Oral	10 Mg, Unk	Not Reported
Pantoprazol	C	Unknown	40 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379914	EXPEDITED (15-DAY)		DS	BE-GLENMARK PHARMACEUTICALS- 2017GMK030583			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Exposure During Pregnancy	Levocetirizine			S	Unknown	5 Mg, Qd		Glenmark
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Seretide			S	Unknown	Unk		Not Reported
	Sipralaxa			S	Unknown	10 Mg, Z, Tablet, Unk		Not Reported
	Relvar Ellipta			S	Unknown	Unk Unk, Qd		Not Reported
	Flixotide			S	Unknown	500 Mg Qd (250 Mg, Bid)		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Qd		Not Reported
	Pantomed /01263204/			S	Unknown	20 Mg, Qd		Not Reported
	Ventolin /00139502/			S	Unknown	100 Mg, Unk		Not Reported
	Avamys			S	Unknown	Unk, Qd (Bid)		Not Reported
	Mepolizumab			S	Subcutaneous	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14380137	EXPEDITED (15-DAY)		DS, OT	CH-AMGEN- CHESP2018003177		63 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bone Density Decreased; Lumbar Vertebral Fracture; Rebound Effect	Prolia	S	Subcutaneous	60 Mg, Q6mo	Amgen
	Cipraxel	S	Oral	20 Mg, Qd	Not Reported
	Pantozol	S	Oral		Not Reported
	Dafalgan	C	Oral	1 G, Qid	Not Reported
	Kalcipos D3	C	Oral	1 Df, Qd	Not Reported
	Novalgine (Metamizole Sodium)	C	Oral	500 Mg, Q6h (2 Tab)	Not Reported
	Requip	C	Oral	4 Mg, Qd	Not Reported
	Temesta (Lorazepam)	C	Oral	1 Df, As Necessary	Not Reported
	Vitamin D3 Streuli	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14380211	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-001533			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Atenolol			S		50 Mg, Once A Day		Aurobindo
	Zyloric			S		1 Df, Once A Day		Not Reported
	Levothyrox			S	Oral	1 Df, Once A Day		Not Reported
	Simvastatine			S		20 Mg, Once A Day		Not Reported
	Cotareg			S				Not Reported
	Amlor			S				Not Reported
	Seresta			S		12.5 Mg, Once A Day		Not Reported
	Uvedose			S				Not Reported
	Imovane			S		0.5 Df, Once A Day		Not Reported
	Seroplex			S		1 Df, Once A Day		Not Reported
	Endotelon			S		2 À 3 Cp/J ()		Not Reported
	Voltarene /00372302/			S		2x/Semaine ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14380846	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS- 2018M1002622		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Olanzapine	S	Oral	1 Df, Unk	Not Reported
	Zopiclone	S	Oral	210 Mg, Qd	Not Reported
	Zopiclone	S	Oral	210 Mg, Qd	Not Reported
	Seroplex	S	Oral	140 Mg, Unk	Mylan
	Abilify	S	Oral	5 Mg, Qd	Mylan
	Lysanxia	S	Oral	1440 Mg, Unk	Mylan
	Zyprexa	S	Oral	1 Df, Unk	Mylan
	Lexapro	S	Oral	140 Mg, Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381110	EXPEDITED (15-DAY)		HO	PHHY2018CO001274		86 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Renal Disorder; Syncope	Entresto			S	Oral	100 Mg, Q12h		Novartis
	Atorvastatin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Apixaban			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Methimazole			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381711	EXPEDITED (15-DAY)		DE	US- GENUS_LIFESCIENCE S-USA- POI0580201800056		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences
	Ethylene Glycol			S				Not Reported
	Escitalopram			S				Not Reported
	Loratadine			S				Not Reported

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		Furosemide		S					Not Reported
		Folic Acid		S					Not Reported
		Vitamin B1		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381716	EXPEDITED (15-DAY)		DE	US- GENUS_LIFESCIENCE S-USA- POI0580201800060		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences	
	Bupropion			S				Not Reported	
	Amlodipine			S				Not Reported	
	Escitalopram			S				Not Reported	
	Salicylate			S				Not Reported	
	Losartan			S				Not Reported	
	Ethanol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381720	EXPEDITED (15-DAY)		DE	US- GENUS_LIFESCIENCE S-USA- POI0580201800064		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Levolet (Levothyroxine)			S				Genus Lifesciences	
	Diltiazem			S				Not Reported	
	Propranolol			S				Not Reported	
	Metformin			S				Not Reported	
	Glyburide			S				Not Reported	
	Escitalopram			S				Not Reported	
	Losartan			S				Not Reported	
	Lorazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14382161	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN- 1801432US		75 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Halo Vision; Metamorphopsia; Vision Blurred	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
	Euthyrox	C	Unknown		Not Reported
	Rosucard	C	Unknown	20 Mg, Unk	Not Reported
	Stacyl	C	Unknown	100 Mg, Unk	Not Reported
	Triplixam	C	Unknown	10/2.5/10	Not Reported
	Rivocor	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14382422	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1801838US		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Tercian			S	Oral	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14343663	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-035455		85 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Off Label Use; Respiratory Distress; Somnolence	Lorazepam			S	Unknown			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Abilify			S	Oral			Not Reported	
	Temesta (Lorazepam)			S	Unknown			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Flodil L.P.			C	Unknown	Sustained Release Coated Tablet		Not Reported	
	Ventoline			C	Unknown			Not Reported	
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Allopurinol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tamsulosin Hydrochloride	C	Unknown	Not Reported
Gardenal	C	Unknown	Not Reported
Topalgic (Tramadol Hydrochloride)	C	Unknown	Not Reported
Kardegic	C	Unknown	Powder For Oral Solution In Sachet-Dose
Vesicare	C	Unknown	Not Reported
Dafalgan	C	Unknown	Not Reported
Inegy	C	Unknown	Not Reported
Uvedose	C	Unknown	Not Reported
Carbamazepine	C	Unknown	Not Reported
Omexel	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Domperidone	C	Unknown	Not Reported
Tegretol	C	Unknown	Not Reported
Bisoce	C	Unknown	Not Reported
Avodart	C	Unknown	Not Reported
Flodil [Buflomedil Hydrochloride]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14383197	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR00290			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Invagen	
	Amlodipine			S	Oral	5 Mg, Daily		Invagen	
	Domperidone			S	Oral	Unk		Not Reported	
	Carbonate De Calcium			S	Oral	1 Df, Daily		Not Reported	
	Transulose, Gelee Oraleen Pot			S	Oral	Unk		Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14383279	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR00042			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Df, Daily		Invagen	
	Rulid			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14383285	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.- 2018IT00476			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Sopor	Lamotrigine			S	Oral	350 Mg, In Total		Cipla	
	Escitalopram			S	Oral	120 Mg, In Total		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14334903	EXPEDITED (15-DAY)		OT	SG-MACLEODS PHARMACEUTICALS US LTD- MAC2017007442			Unknown	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Withdrawal Syndrome	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods	
	Escitalopram Oxalate			S				Macleods	
	Venlafaxine			S	Unknown	Unk		Macleods	
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported	
	Metformin Hydrochloride			C	Unknown	500 Mg, Unk, 8 Hour		Macleods	
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported	
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14389806	EXPEDITED (15-DAY)		OT	PHHY2018FR005006			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Cotareg			S	Unknown	1 Df, Qd		Not Reported
	Voltarene Lp			S	Unknown	2 Df, Qw		Not Reported
	Atenolol			S	Unknown	50 Ug, Qd		Novartis
	Simvastatin			S	Unknown	20 Mg, Qd		Not Reported
	Seroplex			S	Unknown	1 Df, Qd		Not Reported
	Endotelon			S	Unknown	2-3 Tablets, Qd		Not Reported
	Imovane			S	Unknown	0.5 Df, Qd		Not Reported
	Uvedose			S	Unknown	1 Df, Q3mo		Not Reported
	Seresta			S	Unknown	12.5 Mg, Qd		Not Reported
	Amlor			S	Unknown	1 Df, Qd		Not Reported
	Zyloric			S	Unknown	1 Df, Qd		Not Reported
	Levothyrox			S	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14390414	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013295		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Lamotrigine			S	Oral	Unk Unk, Unknown		Par	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
	Drug, Unknown			S	Oral	Unk Unk, Unknown		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390421	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013290		56 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Completed Suicide	Valproic Acid			S	Oral	Unk Unk, Unknown		Vintage	
	Primidone Tablets			S	Oral	Unk Unk, Unknown		Vintage	

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Carvedilol	S	Oral	Unk Unk, Unknown	Not Reported
Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
Sitagliptin	S	Oral	Unk Unk, Unknown	Not Reported
Mirtazapine	S	Oral	Unk Unk, Unknown	Not Reported
Phenytoin	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14390559	EXPEDITED (15-DAY)		OT	AT-MACLEODS PHARMACEUTICALS US LTD- MAC2018008478			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erectile Dysfunction; Headache; Pneumonia	Venlafaxine			S	Unknown	Unk		Macleods
	Duloxetine			S	Unknown	Unk		Macleods
	Brintellix			S	Oral	5 Mg, Qd		Not Reported
	Brintellix			S		10 Unk, Unk		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Brintellix			S	Oral	20 Mg, Qd		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Zoldem			C	Oral	10 Mg, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Curocef			C	Unknown	9 Gm, Qd		Not Reported
	Curocef			C	Unknown	Unk Unk, Qd		Not Reported
	Trittico Ret			C	Oral	200 Mg, Qd		Not Reported
	Trittico Ret			C	Oral	150 Mg, Qd, Since Months		Not Reported
	Trittico Ret			C	Oral	250 Mg, Unk		Not Reported
	Trittico Ret			C	Oral	300 Mg, Qd		Not Reported
	Cal-D-Vita			C	Oral	1 Df, Qd, Since Years		Not Reported

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Oleovit D3	C	Oral	40 [Drp], 1 Week, Since Years	Not Reported
Aprednisolon	C	Oral	5 Mg, Qd, Since Years	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14390936	EXPEDITED (15-DAY)	CA		DE-AUROBINDO-AUR-APL-2018-001998		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 [Mg/D (Mutter)]		Aurobindo
	Ebrantil /00631801/			C	Unknown	()		Not Reported
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet ()		Not Reported
	Valsartan			C	Unknown	160 [Mg/D (Vater)] ()		Not Reported
	Folsan			C	Transplacental	0.4 [Mg/D (Mutter)]		Not Reported
	Ramilich			C	Unknown	10 [Mg/D (Vater)] ()		Not Reported
	Dekristol			C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)] ()		Not Reported
	Paracetamol			C	Transplacental	()		Not Reported
	Bicanorm			C	Unknown	()		Not Reported
	Atozet			C	Unknown	40 [Mg/D] / 10 [Mg/D (Vater)]/ Probably Either Atozet Or Simvastatin ()		Not Reported
	Ass			C	Unknown	100 [Mg/D (Vater)] ()		Not Reported
	Amlodipine			C	Unknown	10 [Mg/D (Vater)] ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391031	NON-EXPEDITED			US-PFIZER INC-2018014634			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Migraine	Desvenlafaxine Succinate Monohydrate			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer

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Escitalopram Oxalate			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391192	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-002047		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazol			S	Unknown	10 Mg, Unk		Aurobindo	
	Escitalopram			S	Unknown	Unk ()		Aurobindo	
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported	
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391216	NON-EXPEDITED			US-PFIZER INC- 2018018358		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Bactrim Ds			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	
	Nubain			S		Unk		Not Reported	
	Paxil			S		Unk		Not Reported	
	Prozac			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391603	NON-EXPEDITED			US-APOTEX- 2017AP021516		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Libido Disorder; Male Sexual Dysfunction; Marital Problem; Therapeutic	Paxil Tablets			S	Unknown	Unk		Apotex	
	Cymbalta			S	Unknown	60 Mg, Unk		Not Reported	
	Cymbalta			S	Unknown	90 Mg, Unk		Not Reported	

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Response Decreased	Lexapro			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14392442	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018015723		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg, 1x/Day		Pfizer	
	Irbesartan			S	Oral	75 Mg, 1x/Day		Not Reported	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Furosemide			S	Oral	40 Mg, 1x/Day		Not Reported	
	Duphalac			C	Oral	1x/Day		Not Reported	
	Havlane			C	Oral	1x/Day		Not Reported	
	Kardegic			C	Oral	1x/Day		Not Reported	
	Seresta			C	Oral	1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14292962	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1770976US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chondrocalcinosis Pyrophosphate; Diarrhoea; Fatigue; Rheumatoid Arthritis	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Enbrel			S	Unknown	50 Mg, Q Week		Not Reported	
	Zolpidem			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14338904	EXPEDITED (15-DAY)		OT	SG-CIPLA LTD.-2017SG30512			Unknown	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg Per Day		Invagen	
	Escitalopram			S	Unknown	10 Mg Per Day		Invagen	

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Hydrochlorothiazide	C		12.5 Mg Per Day	Not Reported
Atenolol	C	Unknown	25 Mg Per Day	Not Reported
Lovastatin	C	Unknown	20 Mg Per Day	Not Reported
Metformin	C	Unknown	500 Mg, Every 8 Hours	Not Reported
Venlafaxine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14401544	EXPEDITED (15-DAY)		DS, HO	DE-ABBVIE-18P-062-2221944-00		57 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Oral			Not Reported
	Ciprallex			S	Oral			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Novaminsulfon			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14401663	EXPEDITED (15-DAY)		DE, OT	JP-MYLANLABS-2018M1003647		57 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drowning; Toxicity To Various Agents	Escitalopram			S	Unknown	Drug Toxicology: 0.4microg/MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14403052	DIRECT		OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Diarrhoea; Hallucination, Visual; Headache;	Escitalopram Lexapro			S	Oral	5mg Tab Aur 1@Bedtime Tablet 1 Mouth		Not Reported
	Clopidogrel			C				Not Reported

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Nightmare	Estradiol	C	Not Reported
	Montelukast	C	Not Reported
	Armour Thyroid	C	Not Reported
	Losartin	C	Not Reported
	Metoprolol Er	C	Not Reported
	Atorvastatin	C	Not Reported
	D3	C	Not Reported
	Probiotic	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14403895	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-843397		38 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Generalised Tonic-Clonic Seizure	Ketoprofene			S	Oral			Not Reported	
	Hydrocortancyl 2,5 Pour Cent, Suspension Injectable			S	Intra-articular			Not Reported	
	Tercian 40 Mg/Ml, Solution Buvable En Gouttes			S	Oral			Not Reported	
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14403908	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1801705US			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Blood Triglycerides Increased;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
Fatigue; Frustration	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
Tolerance Decreased;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan	
Kidney Enlargement; Liver Injury; Neutrophil Count Decreased;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan	
Splenomegaly; Tremor; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
	Cymbalta			S	Oral	60 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	450 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	150 Mg, Unknown		Not Reported	
	Lyrica			S	Oral	375 Mg, Unknown		Not Reported	

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Lyrica	S	Oral	300 Mg, Unknown	Not Reported
Lyrica	S	Oral	750 Mg, Unknown	Not Reported
Lyrica	S	Oral	300 Mg, Unknown	Not Reported
Lyrica	S	Oral	600 Mg, Unknown	Not Reported
Risperdal	S	Unknown	0.5 Mg, Unknown	Not Reported
Risperdal	S	Unknown	2 Mg, Unknown	Not Reported
Risperdal	S	Unknown	1 Mg, Unknown	Not Reported
Topamax	S	Oral	25 Mg, Unknown	Not Reported
Topamax	S	Oral	100 Mg, Unknown	Not Reported
Topamax	S	Oral	50 Mg, Unknown	Not Reported
Topamax	S	Oral	25 Mg, Unknown	Not Reported
Pantoloc	C	Unknown	40 Mg, Unknown	Not Reported
Wellbutrin	C	Unknown	Unk, Unknown	Not Reported
Rivotril	C	Unknown	0.5 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14403970	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1802505US		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Rulid			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14404063	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1003939		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Mg, Qd		Not Reported
	Ebrantil			C	Unknown			Mylan
	Simvastatin			C	Unknown	Unk		Mylan

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Valsartan	C	Unknown	Unk	Mylan
Folsan	C	Transplacental	0.4 Mg, Qd	Mylan
Ramilich	C	Unknown	10 Mg, Qd	Mylan
Dekristol	C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)]	Mylan
Paracetamol	C	Transplacental		Mylan
Bicanorm	C	Unknown		Mylan
Atozet	C	Unknown	40 Mg, Qd	Mylan
Atozet	C		10 Mg, Qd	Mylan
Ass	C	Unknown	100 Mg, Unk	Mylan
Amlodipine	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	13701821	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1727072US		86 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematuria; Melaena; Rectal Haemorrhage	Escitalopram Oxalate Unk			S				Allergan
	Cardioaspirin			S	Oral	100 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Bisoprolol Fumarate			C	Oral			Not Reported
	Lanoxin			C	Oral			Not Reported
	Kcl Retard			C	Oral			Not Reported
	Lasix Fiale			C	Oral			Not Reported
	Lansox			C	Oral			Not Reported
	Tavor [Lorazepam]			C	Oral			Not Reported
	Fluxum			C	Unknown			Not Reported
	Cacit Vitamina D3			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14404601	EXPEDITED (15-DAY)		HO	KR-JNJFOC-20180105040		58 YR	Female	KOR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Pressure Increased; Coma; Drug Dependence; Liver Injury; Mental Impairment; Overdose	Acetaminophen		Y	S	Oral			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14406164	NON-EXPEDITED			US-PFIZER INC-2018020904			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14406905	EXPEDITED (15-DAY)		DS, HO, OT	NO-ALLERGAN-1802734US		51 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Cold Sweat; Dyspnoea; Dysstasia; Limb Discomfort; Loss Of Consciousness; Muscular Weakness; Paraesthesia; Presyncope; Seizure; Syncope	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Citalopram Orion			S	Oral	20 Mg, Qd		Not Reported
	Citalopram Orion			S	Unknown	Unk		Not Reported
	Calcigran Forte			C	Unknown			Not Reported
	Telfast			C	Unknown			Not Reported
	Vitamin B12 Depot			C	Unknown			Not Reported
	Cetirizin Bluefish			C	Unknown			Not Reported
	Prolia			C	Unknown			Not Reported
	Marevan			C	Unknown			Not Reported

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Klexane			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14406911	EXPEDITED (15-DAY)		DS, OT	CH-ALLERGAN-1802748US		63 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Density Decreased; Lumbar Vertebral Fracture; Rebound Effect	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Prolia			S	Subcutaneous	60 Mg, Q6moths		Not Reported	
	Pantozol			S	Oral			Not Reported	
	Dafalgan			C	Unknown			Not Reported	
	Kalpikos D3			C	Unknown			Not Reported	
	Novalgine			C	Unknown			Not Reported	
	Requip			C	Unknown			Not Reported	
	Temesta (Lorazepam)			C	Unknown			Not Reported	
	Vitamin D3			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14407032	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1802512US		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Formication; Hyperkalaemia; Myalgia; Off Label Use; Testicular Pain	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Inexium			S	Oral	1 Df, Qd		Not Reported	
	Pravastatin			C	Oral	20 Mg, Qd		Not Reported	
	Pregabalin			C	Oral	50 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14407041	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1802635US		36 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	

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Maternal Exposure During Pregnancy	Gilenya	S	Oral	0.5 Mg, Qd	Not Reported
	Gilenya	S	Oral	0.5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14408529	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013305		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Fluoxetine			S	Oral	Unk Unk, Unknown		Par	
	Risperidone			S	Oral	Unk Unk, Unknown		Par	
	Diphenhydramine			S	Oral	Unk Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14408546	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013338		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Metformin Hydrochloride Tablets			S	Oral	Unk Unk, Unknown		Provident Pharmaceutical Vintage	
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
	Naproxen			S	Oral	Unk Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	13344568	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2017004460			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Salivary Duct Obstruction; Salivary Gland Calculus; Sialoadenitis	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Ondansetron			S	Unknown	Unk		Not Reported	
	Temozolomide			C	Unknown	Unk, Cyclical		Not Reported	

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Levetiracetam	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14312856	EXPEDITED (15-DAY)		OT	PHHY2017GT188105		84 YR	Female	GTM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arterial Occlusive Disease; Choking; Malaise; Product Use In Unapproved Indication; Wrong Technique In Product Usage Process	Vymada			S	Unknown	0.5 Df (100 Mg) (Sacubitril 49 Mg/ Valsartan 51 Mg), Bid		Novartis
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Bisoblock			C	Oral	10 Mg, Qd		Not Reported
	Anaflat			C	Oral	One After Meals		Not Reported
	Esomeprazole			C	Oral	Unk Unk, Qd		Not Reported
	Ecotrin			C	Oral	Unk Unk, Qd		Not Reported
	Hydrapress			C	Oral	50 Mg, Every 8 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14409583	EXPEDITED (15-DAY)		HO	FR-ROCHE-2056486		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Coma; Fall; Rib Fracture	Lexomil			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Baclofene			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14411462	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018001525		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash Generalised	Tums Ultra Tablets, Mint Chewable Tablet	S				Glaxosmithkline
	Ranitidine Hydrochloride	S	Unk			Glaxosmithkline
	Furosemide	S	Unk			Glaxosmithkline
	Losartan	S	Unk			Glaxosmithkline
	Escitalopram Tablet	S	Unk			Glaxosmithkline
	Atenolol	S	Unk			Glaxosmithkline
	Warfarin Tablet	S	Unk			Glaxosmithkline
	Vitamin B12 Tablet	S	Unk			Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14413212	EXPEDITED (15-DAY)		HO, LT	PHHY2017ES190639		47 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Intentional Overdose	Clonazepam			S	Oral	22.5 Mg, Unk		Novartis
	Escitalopram			S	Oral	30 Mg, Unk		Not Reported
	Quetiapine			S	Oral	19 G, Unk		Not Reported
	Valproato De Sodio			S	Oral	3.6 Mg, Unk		Not Reported
	Antabus			S	Oral	250 Mg, Unk		Not Reported
	Abilify			S	Oral	30 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14417815	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Heart Rate Increased; Hypersensitivity	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla
	Adderall			C				Not Reported
	Tenex			C				Not Reported
	Escitalopram			C				Not Reported
	Xanax			C				Not Reported
	Ambien			C				Not Reported
	Advil			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2018	14419316	DIRECT		DS			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Economic Problem; Product Substitution Issue	Lexapro Generic			S				Unknown	
	Wellbutrin Generic			C				Not Reported	
	Verapimal			C				Not Reported	
	Lopressor			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin C			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2018	14415200	EXPEDITED (15-DAY)		HO	FR-GLENMARK PHARMACEUTICALS- 2017GMK030843			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Metformin Hydrochloride			S	Oral	1000 Mg, Unk		Glenmark	
	Terbutaline			S	Respiratory (inhalation)	1 Df, Unk		Not Reported	
	Pantoprazole			S	Oral			Not Reported	
	Irbesartan			S	Oral	300 Mg, Unk		Not Reported	
	Diffu K			S	Oral			Not Reported	
	Furosemide			S	Oral	30 Mg, Unk		Not Reported	
	Furosemide			S	Oral	Unk		Not Reported	
	Diazepam			S	Oral	30 Mg, Unk		Not Reported	
	Xarelto			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Dafalgan			S	Oral	3000 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported	
	Colchicine Opocalcium			S	Oral			Not Reported	
	Nefopam			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tavanic	S	Oral		Not Reported
Bisoprolol	S	Oral	1.25 Mg, Unk	Not Reported
Mirtazapine	S	Oral	15 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14360619	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1000982		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt	Escitalopram			S	Oral			Not Reported	
Prolonged; Malaise; Potentiating Drug Interaction	Rulid			S	Oral			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14375928	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018011166			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone	Atenolol			S	Respiratory (inhalation)	50 Ug, 1x/Day		Pfizer	
Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Amlor			S	Unknown	1 Df, 1x/Day		Pfizer	
	Simvastatin			S	Unknown	20 Mg, 1x/Day		Not Reported	
	Zyloric			S	Unknown	1 Df, 1x/Day		Not Reported	
	Cotareg			S	Unknown	Nonaz (Hydrochlorothiazide: 160.0mg Valsartan: 25.0mg)		Not Reported	
	Seroplex			S	Unknown	1 Df, 1x/Day		Not Reported	
	Levothyrox			S	Oral	1 Df, 1x/Day		Not Reported	
	Seresta			S	Unknown	12.5 Mg, 1x/Day		Not Reported	
	Uvedose			S	Unknown	1 Df, Unk		Not Reported	
	Imovane			S	Unknown	0.5 Df, 1x/Day		Not Reported	
	Endotelon			S	Unknown	Unk		Not Reported	

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Voltaren Sr			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Jan-2018	14416063	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013640		43 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage		
	Lorazepam Tablets			S	Oral	Unk Unk, Unknown		Vintage		
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported		
	Lithium			S	Oral	Unk Unk, Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Jan-2018	14416066	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013634		36 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage		
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par		
	Escitaopram			S	Oral	Unk Unk, Unknown		Not Reported		
	Gabapentin			S	Oral	Unk Unk, Unknown		Not Reported		
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Jan-2018	14416191	EXPEDITED (15-DAY)		OT	NO-AUROBINDO-AUR- APL-2018-003210			Unknown	NOR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour;	Olanzapine			S	Unknown			Aurobindo		
	Valproat			S	Unknown			Not Reported		
	Seroxat			S	Unknown			Not Reported		
	Efexor			S	Unknown			Not Reported		

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Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Cipramil /00582602/ Lamictal Seroquel Cipralex /01588501/ Orfiril Zyprexa	S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14416365	EXPEDITED (15-DAY)		HO	EE-LUPIN PHARMACEUTICALS INC.-2018-00162		46 YR	Female	EST

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Drug Resistance; Somnolence	Fluoxetine			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Qd		Not Reported
	Bupropion			S	Unknown	150 Mg, Qd		Not Reported
	Bupropion			S	Unknown	300 Mg, Unk		Not Reported
	Agomelatin			S	Unknown	25 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	12296112	EXPEDITED (15-DAY)		HO	FR-FRI-1000084060		85 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Off Label Use; Respiratory Distress; Somnolence	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan
	Temesta (Lorazepam)			S	Oral	3.75 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Flodil [Felodipine]			C	Unknown	Unk		Not Reported

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Tegretol	C	Unknown	Unk	Not Reported
Gardenal	C	Unknown	Unk	Not Reported
Inegy	C	Unknown	10 Mg/40 Mg	Not Reported
Bisoce	C		Unk	Not Reported
Omexel L.P.	C	Unknown	Unk	Not Reported
Allopurinol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Uvedose	C	Unknown	Unk	Not Reported
Dafalgan	C	Unknown	Unk	Not Reported
Avodart	C	Unknown	Unk	Not Reported
Vesicare	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Topalgic Lp	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Unk	Not Reported
Ventolin	C	Unknown	Unk	Not Reported
Kardegic	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14319529	EXPEDITED (15-DAY)		DE, LT	NO-BAUSCH-BL-2017-035165		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Tramadol Hydrochloride			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Orfiril			S	Unknown	Strength: 600 Mg-1200 Mg		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Pinex Forte			S	Unknown	Strength 500/30 Mg And		Not Reported

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Truxal	S	Unknown	Pandeine	Not Reported
Nobligan	S	Unknown	Strength: 50 Mg-200 Mg	Not Reported
Sobril	S	Unknown		Not Reported
Oxynorm	S	Unknown	Strength: 5 Mg-10 Mg	Not Reported
Rivotril	S	Unknown		Not Reported
Imovane	S	Oral		Not Reported
Lamictal	S	Unknown	Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
Vival	S	Unknown		Not Reported
Remeron	S	Unknown		Not Reported
Cipralex	S	Unknown		Not Reported
Catapresan	S	Unknown	Strength 25 Mg, 50 Mg	Not Reported
Levomepromazine Maleate	S	Unknown		Not Reported
Hydroxyzine Hydrochloride	S	Unknown		Not Reported
Atarax	S	Unknown		Not Reported
Nozinan	S	Unknown		Not Reported
Cyanocobalamin	C			Not Reported
Nozinan	C			Not Reported
Diamorphine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14422070	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013960		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Verapamil			S	Oral	Unk Unk, Unknown		Par
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Flecainide			S	Oral	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14422327	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-160595		70 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Quetiapine			S	Unknown	Unk		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Lithium			S	Unknown	Unk		Sun	
	Valproic Acid			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14422372	NON-EXPEDITED		HO	PHEH2018US002166			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness	Tafinlar			S	Unknown			Novartis	
	Mekinist			S	Unknown			Not Reported	
	Spironolactone			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Not Reported	
	Furosemide			S	Unknown			Not Reported	
	Gabapentin			S	Unknown			Not Reported	
	Hydromorphone			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Buspirone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14424794	NON-EXPEDITED			US-OTSUKA- 2017_025825			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Rexulti			S	Unknown	Unk		Otsuka	

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Lexapro			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2018	14425075	EXPEDITED (15-DAY)		HO	TR-ALLERGAN-1803055US		2 YR	Female	TUR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Accidental Exposure To Product By Child	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Single		Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2018	14426963	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1803416US		74 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qam		Allergan		
	Pantoprazole			S	Oral	40 Mg, Qpm		Not Reported		
	Irbesartan			S	Oral	75 Mg, Qam		Not Reported		
	Furosemide			S	Oral	40 Mg, Qam		Not Reported		
	Seresta			C	Oral	Unk, Qd		Not Reported		
	Duphalac			C	Oral	Unk, Tid		Not Reported		
	Havlane			C	Oral	Unk, Qpm		Not Reported		
	Kardegic			C	Oral	Unk, Qpm		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Jan-2018	14256890	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1769294US		68 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Depression; Diabetes Mellitus; Drug Ineffective; Mental Disorder; Product Dose Omission; Suicidal Ideation	Lexapro			S	Oral	20 Mg, Qd		Allergan		
	Lexapro			S	Oral	20 Mg, Qd		Allergan		
	Losartan Potassium			C	Oral	100 Mg, Qd		Not Reported		
	Hydrochlorothiazide			C	Oral	50 Mg, Unk		Not Reported		

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	Simvastatin	C	Oral	40 Mg, Qd	Not Reported
	Gabapentin	C	Oral	300 Mg, Qd	Not Reported
	Metformin	C	Oral	1000 Mg, Qd	Not Reported
	Tizanidine	C	Oral	4 Mg, Tid	Not Reported
	Aspercreme	C	Topical		Not Reported
	Loratadine	C	Oral	10 Mg, Unk	Not Reported
	Fluticasone	C	Unknown	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2018	14434589	EXPEDITED (15-DAY)		OT	ES-009507513-1801ESP008415		28 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sialoadenitis	Dexamethasone			S	Unknown			Merck	
	Temozolomide			S	Unknown	Unk		Merck	
	Cipralex			S	Oral	10 Mg, Unk		Not Reported	
	Ondansetron			S	Unknown	Unk		Not Reported	
	Levetiracetam			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	13928657	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2017IN15120			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myxoedema Coma	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	
	Quetiapine			S	Unknown	50 Mg, Unk		Not Reported	
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14432427	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018023226		59 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Agranulocytosis; Condition Aggravated;	Ibrance	S	Oral	125 Mg, Once Daily	Pfizer
Craniocerebral Injury; Electrocardiogram Qt Prolonged; Fall; General Physical Health Deterioration;	Risperidone	S	Oral	2.5 Mg, Twice Daily With Additional 1mg As Needed	Not Reported
Musculoskeletal Pain; Neoplasm Progression; Vertigo	Escitalopram	S	Oral	10 Mg, Once Daily	Not Reported
	Escitalopram	S	Oral	20 Mg, Once Daily	Not Reported
	Motilium /00498201/	S	Oral	10 Mg, Thrice A Day	Not Reported
	Ondansetron	S	Oral	Unk, As Needed	Not Reported
	Nexium /01479302/	S	Oral	20 Mg, Once Daily	Not Reported
	Imodium	S	Oral	Unk, As Needed	Not Reported
	Faslodex	S	Intramuscular	500 Mg, Once A Month	Not Reported
	Imovane	C		Unk	Not Reported
	Calcimagon D3	C		Unk	Not Reported
	Condrosulf	C		Unk	Not Reported
	Euthyrox	C		Unk	Not Reported
	Dafalgan	C		Unk, As Needed	Not Reported
	Irfen	C		Unk, As Needed	Not Reported
	Flector Ep	C		Unk	Not Reported
	Flector Ep	C		Unk	Not Reported
	Temgesic	C		Unk	Not Reported
	Targin	C		Unk	Not Reported
	Oxynorm	C		Unk, As Needed	Not Reported
	Movicol	C		Unk	Not Reported
	Laxoberon	C		Unk, As Needed	Not Reported
	Clexane	C		Unk	Not Reported
	Mycostatine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14434839	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-002509		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram	S	Oral	5 Mg, Once A Day	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14435174	EXPEDITED (15-DAY)	CA		DE-CIPLA LTD.- 2018DE01662			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Invagen
	Folsan			C	Transplacental	Unk		Not Reported
	Paracetamol			C	Transplacental	Unk		Not Reported
	Ebrantil /00631801/			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Ramilich			C	Unknown	Unk		Not Reported
	Dekristol			C	Unknown	Unk		Not Reported
	Bicanorm			C	Unknown	Unk		Not Reported
	Atozet			C	Unknown	Unk		Not Reported
	Ass			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14435220	EXPEDITED (15-DAY)	OT		FR-CIPLA LTD.- 2018FR01315			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability;	Amlodipine			S	Unknown	1 Df, Daily		Invagen
	Escitalopram			S	Unknown	1 Df, Daily		Invagen
	Atenolol			S	Unknown	50 Mg, Daily		Not Reported
	Simvastatin			S	Unknown	20 Mg, Daily		Not Reported
	Zyloric			S	Unknown	1 Df, Daily		Not Reported

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Muscle Spasms; Myalgia;	Levothyrox	S	Oral	1 Df, Daily	Not Reported
Nasal Dryness;	Cotareg	S	Unknown	1 Df, Qd	Not Reported
Paraesthesia; Pruritus;	Seresta	S	Unknown	12.5 Mg, Daily	Not Reported
Urticaria; Vertigo; Vision	Uvedose	S	Unknown	1 Df, Unk	Not Reported
Blurred	Imovane	S	Unknown	0.5 Df, Daily	Not Reported
	Endotelon	S	Unknown	2 À 3 Cp/J	Not Reported
	Voltarene /00372302/	S	Unknown	2x/Semaine	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14436399	EXPEDITED (15-DAY)		DS, OT	AU-TAKEDA-2018TUS002086		31 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Brintellix			S	Unknown	10 Mg, Qd		Takeda	
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14437079	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US01324			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk; Necrotising Colitis	Escitalopram			S	Transmammary	Unk		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14440991	EXPEDITED (15-DAY)		OT	PHHY2018FR009186		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Alprazolam			S	Oral	5 Mg, Unk		Novartis	
Headache; Somnolence	Dafalgan			S	Oral	16 G, Unk		Not Reported	
	Zolof			S	Oral	700 Mg, Unk		Not Reported	
	Seroplex			S	Oral	780 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14444119	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1803794US		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan	
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported	
	Orozamudol			S	Oral	150 Mg, Qd		Not Reported	
	Mirtazapine			S	Oral	45 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14308028	EXPEDITED (15-DAY)		OT	ES-009507513-1712ESP006251			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Simvastatin			S	Unknown	Unk		Merck	
	Simvastatin			S	Unknown	1 Df, Qd		Merck	
	Enalapril Maleate (+) Hydrochlorothiazide			S	Unknown	1 Df, Qd		Merck	
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported	
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported	
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Glyburide			S	Unknown	2 Df, Qd		Not Reported	
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported	
	Diazepam (+) Sulpiride			S	Unknown	1 Df, Qd		Not Reported	
	Topiramate			S	Unknown	1 Df, Qd		Not Reported	
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported	
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported	
	Acetaminophen			S	Unknown	3 Df, Qd		Not Reported	
	Diazepam			S	Unknown	0.5 Df, Qd		Not Reported	

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Acetaminophen (+) Tramadol Hydrochloride	S	Unknown	3 Df, Qd	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
Escitalopram	S	Unknown	1 Df, Qd	Not Reported
Metoclopramide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14446545	NON-EXPEDITED			US-TELIGENT, INC-IGIL20180038		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Generalised	Ranitidine Hydrochloride			S	Unknown			Not Reported
	Tums Ultra, Mint Flavor			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Vitamin B12			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14447848	EXPEDITED (15-DAY)		DE	FR-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2018-12-00		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Pradaxa			S	Oral			Boehringer Ingelheim
	Seroplex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14457944	DIRECT					24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Asthenia; Balance Disorder; Dizziness; Flushing; Heart Rate Increased; Hyperhidrosis; Joint Stiffness; Loss Of Consciousness; Nausea; Somnolence; Vomiting	Escitalopram Pro Air Caprylic Acid Vitamin D Nos Vitamin E B12	S C C C C C	Oral	Quantity:1 Tablet(S);	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	13275469	EXPEDITED (15-DAY)		OT	ES-GLENMARK PHARMACEUTICALS- 2017GMK026519		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Ondansetron			S	Unknown	Unk		Glenmark
	Cipraxel /01588501/			S	Oral	10 Mg, Qd		Not Reported
	Temozolomide			C	Unknown	Cyclical		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449318	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013967		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Poisoning Deliberate	Propranolol Hydrochloride Tablets 80mg			S	Oral	Unk Unk, Unknown		Vintage
	Amitriptyline Hcl			S	Oral	Unk Unk, Unknown		Vintage
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Acetaminophen			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported
	Cocaine			S	Oral	Unk Unk, Unknown		Not Reported

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27-Jan-2018	14449326	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013975		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Exposure Via Ingestion; Poisoning	Propranolol Hydrochloride Tablets 80mg			S	Oral	Unk Unk, Unknown		Vintage	
	Lamotrigine			S	Oral	Unk Unk, Unknown		Par	
	Percocet			S	Oral	Unk Unk, Unknown		Vintage	
	Ibuprofen			S	Oral	Unk Unk, Unknown		Par	
	Montelukast Sodium Tablets 10mg			S	Oral	Unk Unk, Unknown		Vintage	
	Acyclovir Capsules			S	Oral	Unk Unk, Unknown		Dava	
	Alprazolam Tablets			S	Oral	Unk Unk, Unknown		Vintage	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
	Ondansetron			S	Oral	Unk Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449329	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013965		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Exposure Via Ingestion; Exposure Via Inhalation; Poisoning	Propranolol Hydrochloride Tablets 80mg			S		Unk Unk, Unknown, Ingst + Aspir		Vintage	
	Lamotrigine			S		Unk Unk, Unknown, Ingst + Aspir		Par	
	Clonazepam			S		Unk Unk, Unknown, Ingst + Aspir		Par	
	Escitalopram			S		Unk Unk, Unknown, Ingst + Aspir		Not Reported	
	Mirtazapine			S		Unk Unk, Unknown, Ingst + Aspir		Not Reported	
	Cyclobenzaprine			S		Unk Unk, Unknown, Ingst		Not Reported	

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Buspirone	S	+ Aspir	Not Reported
Activated Charcoal	S	Unk Unk, Unknown, Ingst + Aspir	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449340	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014027		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide	Bupropion Hcl XI			S	Oral	Unk Unk, Unknown		Par
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449355	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014045		39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Bupropion Hcl XI			S	Oral	Unk Unk, Unknown		Par
	Bupropion Hcl XI			S		Unk		Par
	Amlodipine Besylate Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported
	Salicylates Nos			S	Oral	Unk Unk, Unknown		Not Reported
	Losartan			S	Oral	Unk Unk, Unknown		Not Reported
	Levothyroxine			S	Oral	Unk Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449364	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014052		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Completed Suicide	Bupropion Hcl XI	S	Oral	Unk Unk, Unknown		Par
	Venlafaxine Hydrochloride	S	Oral	Unk Unk, Unknown		Par
	Escitalopram	S	Oral	Unk Unk, Unknown		Not Reported
	Alpha Blocker	S	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2018	14449384	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-014064		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Drug Abuse	Bupropion Hcl XI			S	Unknown	Unk Unk, Unknown		Par
	Alprazolam Tablets			S	Unknown	Unk Unk, Unknown		Vintage
	Cocaine			S	Unknown	Unk Unk, Unknown		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported
	Ethanol			S	Unknown	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	13260660	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1706547US		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Ondansetron			S	Unknown	Unk, Unknown		Not Reported
	Ondansetron			S	Unknown			Not Reported
	Temozolomide			S	Unknown	Unk, Unknown		Not Reported
	Dexamethasone			S	Unknown	Unk, Unknown		Not Reported
	Levetiracetam			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14450666	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013869		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Completed Suicide	Diltiazem Hcl	S	Oral	Unk Unk, Unknown	Par
	Propranolol Hcl Tablets 80mg	S	Oral	Unk Unk, Unknown	Vintage
	Metformin Hydrochloride Tablets	S	Oral	Unk Unk, Unknown	Provident Pharmaceutical Dava
	Glyburide (Micronized) Tablets	S	Oral	Unk Unk, Unknown	Vintage
	Lorazepam Tablets	S	Oral	Unk Unk, Unknown	Not Reported
	Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
	Losartan	S	Oral	Unk Unk, Unknown	Not Reported
	Levothyroxine	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14452734	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE10003		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Xeroquel			S	Oral	2500.0mg Unknown		Astrazeneca
	Escitalopram			S	Oral	880.0mg Unknown		Not Reported
	Prazepam			S	Oral	1200.0mg Unknown		Not Reported
	Valsartan			S	Oral	14400.0mg Unknown		Not Reported
	Bromazepam			S	Oral	144.0mg Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14453800	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-850313		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Sedation	Alprazolam			S	Oral	Alprazolam 0,25 1/2 Cp/D		Actavis
	Escitalopram			S	Oral			Ivax
	Risperdal 0,50 Mg, Coated Tablet			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14455259	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1804424US		68 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Olanzapine			C	Oral	2.5 Mg, Unk		Not Reported	
	Etizolam			C	Oral	0.5 Mg, Unk		Not Reported	
	Triazolam			C	Oral	0.2 Mg, Unk		Not Reported	
	Fluvoxamine Maleate			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	13020625	NON-EXPEDITED			US-ALLERGAN-1671209US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Muscle Tightness	Escitalopram Oxalate Unk			S		Unk		Allergan	
	Escitalopram Oxalate Unk			S				Allergan	
	Effexor			C				Not Reported	
	Effexor			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	13020636	NON-EXPEDITED			US-ALLERGAN-1676643US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Muscle Twitching; Tremor	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	13301802	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-30750		28 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Salivary Duct Obstruction; Sialoadenitis	Ciprallex /01588501/			S	Oral			Not Reported	
	Ondansetron			S	Unknown			Not Reported	
	Ondansetron			S		()		Not Reported	
	Temozolomide			C	Unknown			Not Reported	

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Temozolomide	C	()Cyclical	Not Reported
Levetiracetam	C	Unknown	Not Reported
Levetiracetam	C	()	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dexamethasone	C	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14425099	EXPEDITED (15-DAY)		DS, HO	DE-ALLERGAN-1802880US		57 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Valproic Acid			S	Unknown	900 Mg, Bid		Not Reported
	Ibuprofen			C	Unknown	600 Mg, Qid		Not Reported
	Xarelto			C	Unknown	10 Mg, Qd		Not Reported
	Novaminsulfon			C	Unknown	500 Mg, Tid (On A Regular Basis)		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14456098	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR01916			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram			S	Oral	14 Df, In Total		Invagen
	Tramadol			C	Oral	20 Df, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14457036	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00371		46 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hospitalisation	Zytomil Tablets	S	Oral	20 Mg, Unk	Lupin
	Dyna Lamotrigine Tablets	S	Oral	100 Mg, Unk	Not Reported
	Urbanol	S	Oral	10 Mg, Unk	Not Reported
	Fluanxol /00109702/	S	Oral	0.5 Mg, Unk	Not Reported
	Dopaquel	S	Oral	200 Mg, Unk	Not Reported
	Euthyrox	S	Oral	75 Mg, Unk	Not Reported
	Metformin Sandoz	S	Oral	850 Mg, Unk	Not Reported
	Diagluclide	S	Oral	30 Mg, Unk	Not Reported
	Levemir	S	Unknown	100 Iu, Unk	Not Reported
	Novorapid	S	Unknown	100 Iu, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14458842	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1804428US		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	14 Df, Single		Allergan
	Tramadol Base			S	Oral	; In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14458843	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1804404US		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Exposure Via Father; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram Oxalate - Bp			S	Transplacental	7.5 Mg, Qd		Allergan
	Folsan			C	Transplacental	0.4 Mg, Qd		Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Ebrantil			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Ramilich			C	Unknown	10 Mg, Qd		Not Reported

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	Dekristol	C	Unknown	20000 Iu, Q2weeks	Not Reported
	Bicanorm	C	Unknown		Not Reported
	Ass 100	C	Unknown	100 Mg, Unk	Not Reported
	Amlodipine	C	Unknown	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14459339	EXPEDITED (15-DAY)		HO	MY-IMPAX LABORATORIES, INC- 2018-IPXL-00221		48 YR	Female	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cerebellar Ataxia; Ophthalmoplegia	Divalproex Sodium Er			S	Unknown	Unk		Impax	
	Phenytoin			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461501	NON-EXPEDITED			US-ALLERGAN- 1768445US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Injection Site Pain; Tinnitus	Escitalopram Oxalate Unk			S	Unknown	5 Mg, Unk		Allergan	
	Fondaparinux			S	Subcutaneous	Unk Unk, Qd		Not Reported	
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported	
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported	
	Iron			C	Unknown	Unk Unk, Prn		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461502	NON-EXPEDITED			US-ALLERGAN- 1767157US		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Product Physical Issue	Escitalopram Oxalate - Bp			S	Oral			Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461503	NON-EXPEDITED			US-ALLERGAN-1754068US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Citalopram Hydrobromide - Bp Escitalopram Oxalate - Bp			S S				Allergan Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461505	NON-EXPEDITED			US-ALLERGAN-1774049US		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Headache; Nausea; Photophobia; Product Dose Omission; Vomiting	Escitalopram Oxalate - Bp Buspirone Hydrochloride Lorazepam			S S S	Oral Oral Oral			Allergan Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461506	NON-EXPEDITED			US-ALLERGAN-1756013US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective	Escitalopram Oxalate - Bp			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461507	NON-EXPEDITED			US-ALLERGAN-1749181US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Panic Attack	Escitalopram Oxalate Unk			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461512	NON-EXPEDITED			US-ALLERGAN-1763108US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Vomiting	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461513	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1774020US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Depressed Mood; Product Dose Omission; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461514	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1747517US		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Colitis Ulcerative; Crying; Depression; Headache; Herpes Zoster; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Humira			S	Subcutaneous	40 Mg, Q Week		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q Week		Not Reported	
	Allopurinol			C	Unknown			Not Reported	
	Imuran			C	Unknown			Not Reported	
	Tramadol			C	Unknown			Not Reported	
	Calcium			C	Unknown			Not Reported	
	Vitamin D2			C	Unknown			Not Reported	
	Risaquad			C	Unknown			Not Reported	
	Combivent			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461515	NON-EXPEDITED			US-ALLERGAN-1765347US			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus Generalised	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461516	NON-EXPEDITED			US-ALLERGAN-1766210US		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Stelara			S	Subcutaneous	90 Mg, Q3months		Not Reported	
	Losartan			C		50 Mg, Qd		Not Reported	
	Fish Oil			C				Not Reported	
	Multivitamin			C				Not Reported	
	Hyaluronic Acid			C				Not Reported	
	Aspirin			C		81 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461517	NON-EXPEDITED			US-ALLERGAN-1756926US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Plavix			C	Oral	Unk, Qd		Not Reported	
	Colace			C	Oral	Unk, Qd		Not Reported	
	Crestor			C	Oral	Unk, Qd		Not Reported	
	Miralax			C	Oral			Not Reported	
	Sucrose			C	Oral	Unk, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461518	NON-EXPEDITED			US-ALLERGAN-1774013US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Decreased Appetite; Dizziness; Drug Ineffective	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461519	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1768085US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Disturbance In Attention; Nausea; Panic Reaction; Self-Injurious Ideation	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Escitalopram Mylan			S	Unknown	15 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461520	NON-EXPEDITED			US-ALLERGAN-1768518US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461822	EXPEDITED (15-DAY)		OT	SI-TEVA-2018-SI-850286		49 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Kidney Disease; Left Ventricular Hypertrophy	Rosuvastatin			S	Unknown			Teva	
	Perindopril			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Ivax	
	Indapamide			S	Unknown			Not Reported	
	Alprazolam			S	Unknown	Unk Unk, Prn		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14463551	NON-EXPEDITED		HO, OT	US-ACORDA- ACO_133421_2017		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Therapy Cessation; Transurethral Prostatectomy; Withdrawal Syndrome	Ampyra			S	Oral	10 Mg, Bid		Acorda	
	Lexapro			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	Unk		Not Reported	
	Baclofen			C	Unknown	Unk		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	1000 lu, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14464361	NON-EXPEDITED			US-ACORDA- ACO_134485_2017			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Insomnia; Weight Increased	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda	
	Avonex			S	Intramuscular	30 Microgram, 1 For 1 Week		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Cymbalta			S	Unknown	Unk		Not Reported	
	Celexa			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	11650889	EXPEDITED (15-DAY)		DS, HO, OT	NO-ASTRAZENECA- 2015SE99390		24 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acinetobacter Bacteraemia; Alopecia; Anxiety; Atrophy Of Globe; Blister; Cataract;	Seroquel			S	Oral	Unk		Zeneca	
	Lamictal			S	Oral	Unk		Not Reported	

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Confusional State; Dacryostenosis Acquired; Drug Ineffective; Dry Eye; Entropion; Eye Injury; Eye Oedema; Eye Pain; Eyelid Oedema; Face Oedema; Generalised Erythema; Headache; Inappropriate Affect; Injury Corneal; Keratopathy; Lacrimation Increased; Lens Disorder; Migraine; Mucosal Disorder; Obstructive Airways Disorder; Ocular Hyperaemia; Oral Mucosal Blistering; Oral Pain; Photophobia; Pyrexia; Rash; Sepsis; Skin Exfoliation; Staphylococcal Bacteraemia; Stevens- Johnson Syndrome; Symblepharon; Tachycardia; Toxic Epidermal Necrolysis; Trichiasis; Ulcer; Visual Impairment; Vulvovaginal Erythema; Wound Healing Normal; Wound Infection Staphylococcal	Ciprallex	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	13599635	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1032256		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease;	Clozapine			S		450 Mg, Qd		Not Reported	
Hypotension; Labelled Drug-Drug Interaction	Clozapine			S		200 Mg, Qd		Not Reported	
Medication Error; Mental Status Changes; Toxicity	Escitalopram			S				Not Reported	

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To Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	13599639	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2017M1032255		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hip Arthroplasty; Labelled Drug-Drug Interaction Medication Error; Somnolence; Toxicity To Various Agents	Clozapine			S		400 Mg, Qd		Not Reported	
	Clozapine			S		200 Mg, Qd		Not Reported	
	Valproic Acid			S		Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Aripiprazole			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	13815646	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1047163		79 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antipsychotic Drug Level Above Therapeutic; Coma; Hallucination, Visual; Hyperhidrosis; Hypertension; Musculoskeletal Stiffness; Mutism; Neuroleptic Malignant Syndrome; Pyrexia; Renal Impairment; Rhabdomyolysis; Urinary Tract Infection	Clozapine			S		Unk		Not Reported	
	Clozapine			S		Unk		Not Reported	
	Carbidopa/Levodopa			S				Not Reported	
	Escitalopram			S				Not Reported	
	Memantine			S				Not Reported	
	Lithium			S				Not Reported	
	Pregabalin			S				Not Reported	
	Amantadine			S				Mylan	
	Zotepine			S				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	13818420	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1731982US		97 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	

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Pneumonia Aspiration	Tercian	S	Oral	5 Gtt, Tid	Not Reported
	Levothyrox	C	Oral	75 Mg, Qd	Not Reported
	Levothyrox	C	Oral	12.5 Mg, Qd	Not Reported
	Sectral	C	Oral	200 Mg, Qd	Not Reported
	Orocal D3	C	Oral	1 Df, Qd	Not Reported
	Kardegic	C	Oral	75 Mg, Qd	Not Reported
	Ogast	C	Oral	30 Mg, Qd	Not Reported
	Aldactazine	C	Oral	15 Mg, Qd	Not Reported
	Imovane	C	Oral	0.5 Df, Qd	Not Reported
	Bromazepam	C	Oral	1.5 Mg, Bid	Not Reported
	Forlax	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14466209	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-161861			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressive Symptom; Hallucination, Visual; Hypotonia; Rapid Eye Movement Sleep Behaviour Disorder; Therapeutic Product Effect Incomplete	Mirtazapine			S	Unknown			Sun
	Escitalopram			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Sun
	Clomipramine			S	Unknown			Taro
	Nortriptyline			S	Unknown			Ranbaxy
	Imipramine			S	Unknown			Mutual
	Solifenacin			S	Unknown			Not Reported
	Donepezil			S	Unknown	10 Mg, Daily		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14466310	EXPEDITED (15-DAY)		DE, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-161899		57 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Escitalopram			S	Unknown			Not Reported	
	Paracetamol		Y	S	Unknown			Ohm Lab	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14466492	EXPEDITED (15-DAY)		HO, LT	ES-APOTEX-2018AP005533		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose	Quetiapine			S	Oral	19 G, Qd, Intotal		Apotex	
	Escitalopram			S	Oral	30 Mg, Qd, In Total		Apotex	
	Clonazepam			S	Oral	22.5 Mg, Qd, Intotal		Not Reported	
	Valproato			S	Oral	3.6 Mg, Qd, Intotal		Not Reported	
	Antabus			S	Oral	250 Mg, Qd		Not Reported	
	Abilify			S	Oral	30 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14467373	EXPEDITED (15-DAY)		DE, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00363			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure	Zartan (Losartan Potassium)			S	Oral	100 Mg, Unk		Lupin	
	Aspavor			S	Oral	10 Mg, Unk		Not Reported	
	Lomanor			S	Oral	5 Mg, Unk		Not Reported	
	Calciferol /00107901/			S	Oral	50000 Iu, Unk		Not Reported	
	Onbrez Breezhaler			S	Oral	150 Mcg, Unk		Not Reported	
	Cipla-Simvastatin			S	Oral	40 Mg, Unk		Not Reported	
	Alvesco			S	Oral	80 Mcg, Unk		Not Reported	
	Forvent			S	Oral	18 Mcg, Unk		Not Reported	
	Venteze /00139501/			S	Oral	100 Mcg, Unk		Not Reported	
Lexamil			S				Not Reported		

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Ecotrin			S		Oral		81 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14467515	NON-EXPEDITED			US-ALLERGAN-1755351US				Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Savella				S	Unknown	Unk		Allergan	
	Lexapro				S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14470069	NON-EXPEDITED			US-ACORDA-ACO_142393_2017			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration; Insomnia	Ampyra				S	Oral	10 Mg, Qd		Acorda	
	Lexapro				S	Unknown	Unk, In The Morning		Not Reported	
	Gilenya				C	Unknown	Unk, 6-6:30 Pm		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14470488	EXPEDITED (15-DAY)		HO	PHHY2018FR011999			45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem				S	Oral	Unk		Novartis	
	Lexomil				S	Oral	Unk		Not Reported	
	Seroplex				S	Oral	Unk		Not Reported	
	Baclofene				S	Oral	Unk		Not Reported	
	Valium				S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14471179	EXPEDITED (15-DAY)		OT	TR-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00021			34 YR	Female	TUR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Sinus Bradycardia	Cetirizine			S	Oral	10 Mg, 1x/Day		Jubilant	
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant	
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, 6x/Day (Every 4 H)		Not Reported	
	Enoxaparin			C	Unknown	60 Mg, 1x/Day		Not Reported	
	Pantoprazole			C	Unknown	40 Mg, 1x/Day		Not Reported	
	Aspirin			C	Unknown	100 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14471785	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1804716US		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Lip Oedema; Urticaria	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14471830	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN- 1804710US		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Laryngospasm; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Xenazine			S	Oral	Unk, Unknown		Not Reported	
	Lasilix			C	Unknown			Not Reported	
	Plavix			C	Unknown			Not Reported	
	Lysanxia			C	Unknown			Not Reported	
	Dafalgan			C	Unknown			Not Reported	
	Symbicort			C	Unknown			Not Reported	
	Chondrosulf			C	Unknown			Not Reported	
	Spasmine			C	Unknown			Not Reported	
	Hydrea			C	Unknown			Not Reported	

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Zyloric	C	Unknown	Not Reported
Tareg	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14471841	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK201801181		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Ondansetron (Manufacturer Unknown)			S	Unknown			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Ciprallex			S	Oral			Not Reported
	Temozolomide			S	Unknown			Not Reported
	Levetiracetam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14472061	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1804839US		79 YR	Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Ischaemia; Migraine; Photophobia; Vomiting; Vomiting	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unk		Allergan
	Binocrit			S	Subcutaneous	1 Df, Unk		Not Reported
	Symbicort			C	Unknown			Not Reported
	Losartan Actavis			C	Unknown			Not Reported
	Norvasc			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported
	Rocaltrol			C	Unknown			Not Reported
	Seacor			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Dilatrend			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14472310	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1005861		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor; Suicide Attempt	Escitalopram			S	Oral	30 ML, Total		Not Reported	
	Alprazolam			S	Oral	16 Mg, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	11624794	EXPEDITED (15-DAY)		DS, HO, OT	NO-GLAXOSMITHKLINE-NO2015GSK142742		24 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acinetobacter	Lamictal			S	Unknown	Unk		Glaxosmithkline	
Bacteraemia; Alopecia;	Ciprallex			S	Unknown	Unk		Glaxosmithkline	
Anxiety; Atrophy Of Globe;	Seroquel			S	Unknown	Unk		Glaxosmithkline	
Blister; Cataract;									
Confusional State;									
Dacryostenosis Acquired;									
Drug Ineffective; Dry Eye;									
Entropion; Eye Injury; Eye									
Oedema; Eye Pain; Eyelid									
Oedema; Face Oedema;									
Generalised Erythema;									
Headache; Inappropriate									
Affect; Injury Corneal;									
Keratopathy; Lacrimation									
Increased; Lens Disorder;									
Migraine; Mucosal									
Disorder; Obstructive									
Airways Disorder; Ocular									
Hyperaemia; Oral Mucosal									
Blistering; Oral Pain;									
Photophobia;									
Photophobia; Pyrexia;									
Rash; Sepsis; Skin									
Exfoliation; Staphylococcal									
Bacteraemia; Stevens-									

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Johnson Syndrome;
Symblepharon;
Tachycardia; Toxic
Epidermal Necrolysis;
Trichiasis; Ulcer; Visual
Impairment; Vulvovaginal
Erythema; Wound Healing
Normal; Wound Infection
Staphylococcal

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01-Feb-2018	13949129	EXPEDITED (15-DAY)		HO, OT	NO- GLAXOSMITHKLINE- NO2017001990		17 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Aggression;	Ciprallex			S	Unknown	Unk Unk, Qd		Glaxosmithkline	
Agitation; Alcohol Abuse;	Efexor Depot			S	Unknown	Unk		Glaxosmithkline	
Bipolar Disorder;	Efexor Depot			S	Unknown	Unk		Glaxosmithkline	
Depression; Derealisation;	Efexor Depot			S	Unknown	Unk		Glaxosmithkline	
Disturbance In Attention;	Efexor Depot			S	Unknown	Unk		Glaxosmithkline	
Disturbance In Social	Efexor Depot			S	Unknown	Unk		Glaxosmithkline	
Behaviour; Dizziness;	Efexor			S	Unknown	Unk		Glaxosmithkline	
Drug Abuse; Drug	Olanzapine			S	Unknown	Unk		Glaxosmithkline	
Ineffective; Hypomania;	Lamictal			S	Unknown	Unk		Glaxosmithkline	
Impaired Work Ability;	Lamictal			S	Unknown	Unk		Glaxosmithkline	
Irritability; Judgement	Seroxat			S	Unknown	20 Mg, Qd		Glaxosmithkline	
Impaired; Logorrhoea;	Seroxat			S	Unknown	Unk		Glaxosmithkline	
Malaise; Mania; Memory	Seroquel			S	Oral	Unk		Glaxosmithkline	
Impairment; Memory	Seroquel			S	Oral	Unk		Glaxosmithkline	
Impairment; Personality	Seroquel			S	Oral	Unk		Glaxosmithkline	
Disorder; Quality Of Life	Zyprexa			S	Unknown	Unk		Glaxosmithkline	
Decreased; Restlessness;	Orfiril			S	Unknown	Unk		Not Reported	
Substance Use	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd Daily		Not Reported	

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Cipramil	S	Unknown	60 Mg, Qd	Not Reported
Sobril	C	Unknown	Unk, Prn	Glaxosmithkline
Valproat	S	Unknown	Increasing Dose	Not Reported
Lithionit	C	Unknown	Unk	Not Reported
Lithionit	C	Unknown	Unk	Not Reported

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01-Feb-2018	14474309	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1804919US		68 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Eutirox			S	Oral	1 Df, Cyclical		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14474825	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1006110			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Amnesia;	Atenolol			S		50 G, Unk		Not Reported	
Arthralgia; Blood Thyroid	Simvastatin			S		20 Mg, Unk		Not Reported	
Stimulating Hormone;	Zyloric			S		1 Df, Unk		Mylan	
Diarrhoea; Dry Skin; Eye	Levothyrox			S	Oral	1 Df, Unk		Mylan	
Burns; Fatigue; Feeling	Cotareg			S		1 Df, Unk		Mylan	
Hot; Feeling Jittery;	Amlor			S		1 Df, Unk		Mylan	
Insomnia; Irritability;	Seresta			S		12.5 Mg, Unk		Mylan	
Muscle Spasms; Myalgia;	Uvedose			S		1 Df, Unk		Mylan	
Nasal Dryness;	Imovane			S		0.5 Df, Unk		Mylan	
Paraesthesia; Pruritus;	Seroplex			S		1 Df, Unk		Mylan	
Urticaria; Vertigo; Vision	Endotelon			S		2 À 3 Cp/J		Mylan	
Blurred	Voltarene /00372302/			S		2x/Semaine		Mylan	

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01-Feb-2018	14475599	EXPEDITED (15-DAY)		OT	PHHY2018AU014267			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetic Ketoacidosis	Clozapine			S	Unknown			Not Reported	
	Atorvastatin			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Esomeprazole			S	Unknown			Not Reported	
	Gliclazide			S	Unknown			Not Reported	
	Dapagliflozin			S	Unknown			Not Reported	
	Sitagliptin Metformin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14480549	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	13551649	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1719890US		13 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Fear Of Injection; Hereditary Angioedema; Infusion Site Pain; Off Label Use; Pharyngitis Streptococcal; Selective Mutism; Vaginal Infection; Vascular Access Site Occlusion	Escitalopram Oxalate Unk			S	Unknown			Allergan	
	Beriner			S	Subcutaneous	Unk		Not Reported	
	Beriner			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Beriner			S	Subcutaneous	1500 lu, Unk		Not Reported	
	Beriner			S	Intravenous (not otherwise specified)	3000 lu (1500 ltx2)		Not Reported	
	Beriner			S	Subcutaneous	1500 lu, Three Times A		Not Reported	

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Berinert	S	Intravenous (not otherwise specified)	3000 Iu, Unk	Week	Not Reported
Berinert	S	Intravenous (not otherwise specified)	3000 Iu, Unk		Not Reported
Berinert	S	Intravenous (not otherwise specified)	Unk		Not Reported
Berinert	S	Intravenous (not otherwise specified)	1500 Iu, Unk		Not Reported
Berinert	S	Subcutaneous	1500 Iu, Unk		Not Reported
Berinert	S	Intravenous (not otherwise specified)	1500 Iu, Three Times A Week		Not Reported
Firazyr Pre-Filled Syringe	C	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14303391	EXPEDITED (15-DAY)			IE-OTSUKA-2017_025246		34 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Abilify			S	Oral	Unk		Otsuka
	Abilify Maintena			S	Unknown	1 Df, Unk		Otsuka
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14473887	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-003727		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Type 2 Diabetes Mellitus	Escitalopram			S	Oral	Unk		Aurobindo
	Laroxyl			S	Oral	Unk		Not Reported
	Oxycontin			S	Oral	2 Df, Once A Day		Not Reported
	Triumeq			S	Oral	1 Df, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14478271	EXPEDITED (15-DAY)		HO, OT	AT-TEVA-2018-AT-849637		58 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Intention Tremor; Lethargy; Resting Tremor; Sedation; Social Avoidant Behaviour; Tremor	Risperidone			S	Unknown			Pliva	
	Pregabalin			S	Unknown			Not Reported	
	Pregabalin			S	Unknown			Not Reported	
	Pregabalin			S	Unknown			Not Reported	
	Pregabalin			S	Unknown			Not Reported	
	Pregabalin			S	Oral			Not Reported	
	Topiramate			S	Oral			Not Reported	
	Topiramate			S	Oral			Not Reported	
	Cipralelex			S	Oral			Not Reported	
	Cipralelex			S	Oral			Not Reported	
	Pantoprazol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14479082	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018009087			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram Oxalate			S	Oral	880 Mg, Unk		Macleods	
	Valsartan			S	Oral	14400 Mg, Unk		Macleods	
	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported	
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported	
	Bromazepam			S	Oral	144 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14479310	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005691		50 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Extended Release		Unknown
	Escitalopram Oxalate			S	Oral			Unknown
	Lorazepam			S	Oral			Unknown
	Oxcarbazepine			S	Oral			Unknown
	Quetiapine Fumarate			S	Oral			Unknown
	Zolpidem			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14480635	EXPEDITED (15-DAY)		OT	PHHY2018AU014247			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Electrocardiogram Qt Prolonged; Pulmonary Embolism; Tricuspid Valve Incompetence	Clozapine			S	Unknown			Not Reported
	Metformin			S	Unknown			Novartis
	Escitalopram			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Clopine			S	Unknown			Not Reported
	Paliperidone			S	Unknown			Not Reported
	Cholecalciferol			S	Unknown			Not Reported
	Desmopressin			S	Unknown			Not Reported
	Fluticone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2018	14482714	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-850982		17 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypotension; Somnolence; Suicide Attempt	Escitalopram	S	Oral	3 Tablets	Not Reported
	Ibuprofen	S	Oral	A Couple Of Tablets	Actavis
	Olanzapine	S	Oral		Not Reported
	Aspirin	S	Oral	A Couple Of Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2018	14482900	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-162230		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral	880 Mg, Unk		Not Reported
	Valsartan			S	Oral			Ranbaxy
	Xeroquel			S	Oral			Not Reported
	Prazepam			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2018	14483005	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-004567		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Bromazepam			S	Oral	144 Mg, Unk		Not Reported
	Escitalopram			S	Oral	880 Mg, Unk		Aurobindo
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported
	Valsartan			S	Oral	14400 Mg, Unk		Aurobindo
	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	11676813	EXPEDITED (15-DAY)		DS, HO, OT	NO-FRI-1000080382		24 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acinetobacter	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
Bacteraemia; Alopecia;	Lamictal Dispersible Tablet	S		Unk	Not Reported
Anxiety; Atrophy Of Globe;	Seroquel	S	Unknown	Unk	Not Reported
Blister; Body Temperature					
Increased; Cataract;					
Confusional State;					
Dacryostenosis Acquired;					
Drug Ineffective; Dry Eye;					
Entropion; Eye Injury; Eye					
Oedema; Eye Pain; Eyelid					
Oedema; Face Oedema;					
Generalised Erythema;					
Headache; Inappropriate					
Affect; Injury Corneal;					
Keratopathy; Lacrimation					
Increased; Lens Disorder;					
Migraine; Mucosal					
Disorder; Obstructive					
Airways Disorder; Ocular					
Hyperaemia; Oral Mucosal					
Blistering; Oral Pain;					
Photophobia; Rash;					
Sepsis; Skin Exfoliation;					
Staphylococcal					
Bacteraemia; Stevens-					
Johnson Syndrome;					
Symblepharon;					
Tachycardia; Toxic					
Epidermal Necrolysis;					
Trichiasis; Ulcer; Visual					
Impairment; Vulvovaginal					
Erythema; Wound Healing					
Normal; Wound Infection					
Staphylococcal					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	13926975	EXPEDITED (15-DAY)		HO, LT	CH-ALLERGAN-1748462US		55 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

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Phosphokinase Increased; Consciousness	Escitalopram Oxalate - Bp	S		Unk	Allergan
Fluctuating; Dysphagia;	Abilify	S	Intramuscular		Not Reported
Hyperreflexia; Muscle	Abilify	S			Not Reported
Rigidity; Mutism;	Aripiprazole	S	Oral	15 Mg, Qd	Not Reported
Neuroleptic Malignant	Aripiprazole	S	Oral	5 Mg, Qd	Not Reported
Syndrome; Serotonin	Quetiapin Actavis Xr (Quetiapine	C	Oral		Not Reported
Syndrome; Tremor	Fumarate)				
	Temesta (Lorazepam)	C	Oral		Not Reported
	Amlodipin (Amlodipine)	C	Oral		Not Reported
	Sandoz	C	Oral	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14325861	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1773529US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Daily		Allergan
Depression;	Zoely			S	Oral	One Tablet (2.5mg		Not Reported
Dysmenorrhoea;						Nomegestrol Acetate And		
Hypomenorrhoea;						1.5 Mg Estradiol), Daily		
Menorrhagia	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14407893	EXPEDITED (15-DAY)		DS, OT	CH-PFIZER INC-2018020850		63 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Density Decreased;	Pantozol			S	Oral	20 Mg, 1x/Day		Pfizer
Lumbar Vertebral	Prolia			S	Subcutaneous	60 Mg, Cyclic (Every Six		Not Reported
Fracture; Rebound Effect						Months)		
	Cipralext			S	Oral	Unk		Not Reported
	Dafalgan			C	Oral	1 G, 4x/Day		Not Reported
	Kalcipos D3			C	Oral	Unk, 1x/Day		Not Reported

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Metamizole Sodium	C	Oral	Unk	Not Reported
Requip	C	Oral	4 Mg, 1x/Day	Not Reported
Temesta (Lorazepam)	C	Oral	Unk	Not Reported
Vitamin D3 Streuli	C	Oral	2 Ml, Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14452831	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1804318US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Thyroid Stimulating Hormone	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan
	Zyloric			S	Unknown	1 Df, Qd		Not Reported
	Levothyrox			S	Oral	1 Df, Qd		Not Reported
	Atenolol			S	Unknown	50 Mg, Qd		Not Reported
	Simvastatine			S	Unknown	20 Mg, Qd		Not Reported
	Cotareg			S	Unknown	1 Df, Qd		Not Reported
	Amlor			S	Unknown	1 Df, Qd		Not Reported
	Seresta			S	Unknown	12.5 Mg, Qd		Not Reported
	Uvedose			S	Unknown	Time Interval:1		Not Reported
	Imovane			S	Unknown	0.5 Df, Qd		Not Reported
	Endotelon			S	Unknown	Unk		Not Reported
	Voltarene (Diclofenac Sodium)			S	Unknown	Unk, Bi-Weekly		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14488227	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2018-002364		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Dexamethasone			S	Unknown			Bausch And Lomb
	Cipralext			S	Oral			Not Reported
	Temozolomide			S	Unknown			Not Reported

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Ondansetron	S	Unknown	Not Reported
Levetiracetam	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14488356	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1805719US		24 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Oracilline			C	Oral	Unk		Not Reported
	Speciafoldine			C	Oral	15 Mg, Q Week		Not Reported
	Doliprane			C	Oral	Unk		Not Reported
	Atarax			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14488357	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1805745US		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia;	Escitalopram Oxalate - Bp			S	Oral	880 Mg, Single		Allergan
Hypotension; Poisoning	Xeroquel			S	Oral	2500 Mg, Single		Not Reported
Deliberate; Somnolence	Prazepam			S	Oral	1200 Mg, Single		Not Reported
	Valsartan			S	Oral	14400 Mg, Single		Not Reported
	Bromazepam			S	Oral	144 Mg, Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14376856	EXPEDITED (15-DAY)	HO		US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006955			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delusion; Hallucination;	Nuplazid			S	Unknown	17 Mg, Qd		Acadia Pharmaceuticals
Prescribed Underdose;	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals
Product Dose Omission;								
Somnolence								

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Nuplazid	S	Unknown	17 Mg, Qd	Acadia Pharmaceuticals
Lexapro	S	Unknown	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14401061	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2018008493			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Aripiprazole 10mg Tablet			S	Oral	10 Mg, Unk		Macleods	
	Escitalopram Tablet			S	Oral	Unk		Macleods	
	Clomipramine			S	Unknown	150 Mg/ 24 Hour (Qd)		Not Reported	
	Fluvoxamine			S	Unknown	200 Mg/ 24 Hour (Qd)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14490215	NON-EXPEDITED		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-00362		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Ethylene Glycol			S	Oral	Unk		Not Reported	
	Loratadine			S	Oral	Unk		Not Reported	
	Furosemide			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
	Folic Acid			S	Oral	Unk		Not Reported	
	Vitamin B-1			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14490796	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR- APL-2018-004571		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Paracetamol Tablet	S	Unknown	()	Aurobindo
	Escitalopram	S	Unknown		Aurobindo
	Baclofen	S	Unknown		Not Reported
	Dextropropoxyphene	S	Unknown		Not Reported
	Valpromide	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14491254	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1009818			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetic Ketoacidosis	Atorvastatin			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazole			S		Unk		Not Reported
	Gliclazide			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported
	Dapagliflozin			S		Unk		Mylan
	Sitagliptin Metformin			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14491946	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805653US		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Type 2 Diabetes Mellitus	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Laroxyl			S	Oral	Unk		Not Reported
	Oxycontin Lp			S	Oral	2 Dosage Forms Daily		Not Reported
	Triumeq			S	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14494732	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1007823		44 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Type 2 Diabetes Mellitus	Escitalopram			S	Oral			Not Reported	
	Laroxyl			S	Oral			Mylan	
	Oxycontin Lp			S	Oral	2 Df, Unk		Mylan	
	Triumeq			S	Oral	1 Df, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14497866	DIRECT					16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission; Sleep Disorder	Escitalopram Tab 10mg			S	Oral	Quantity:1 Tablet(S); At Bedtime		Not Reported	
	Vitamin C			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Multivitamin			C				Not Reported	
	Folic Acid			C				Not Reported	
	Biotin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	13115203	EXPEDITED (15-DAY)		HO, OT	NO-ALLERGAN-1701429US		21 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise;	Citalopram Hydrobromide - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Citalopram Hydrobromide - Bp			S	Unknown	60 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Seroxat			S	Unknown	Unk		Not Reported	
	Seroxat			S	Unknown	20 Mg, Daily		Not Reported	
	Seroxat			S	Unknown	Unk		Not Reported	
	Valproat			S	Unknown	Increasing Dose		Not Reported	
	Orfiril			S	Unknown	Unk, Qd		Not Reported	
	Zyprexa			S	Unknown	Unk, Qd		Not Reported	

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Mania; Memory	Olanzapine	S	Unknown	Unk, Qd	Not Reported
Impairment; Personality	Efexor Depot	S	Unknown	Unk, Qd	Not Reported
Disorder; Quality Of Life	Efexor Depot	S	Unknown	Unk, Qd	Not Reported
Decreased; Restlessness	Efexor Depot	S	Unknown	Unk, Qd	Not Reported
	Lamictal	S	Unknown	Unk, Qd	Not Reported
	Seroquel	S	Unknown	Unk, Qd	Not Reported
	Seroquel	S	Unknown	Unk, Qd	Not Reported
	Seroquel	S	Unknown	Unk, Qd	Not Reported
	Lithium	C	Unknown	Unk	Not Reported
	Lithionit	C	Unknown	Unk	Not Reported
	Lithionit	C	Unknown	Unk	Not Reported
	Sobril	C	Unknown	Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14322389	EXPEDITED (15-DAY)	HO		AT-OTSUKA-2017_027875		30 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Alanine	Abilify			S	Oral	2.5 Mg, Qd		Otsuka
Aminotransferase	Abilify			S	Oral	5 Mg, Qd		Otsuka
Increased; Blood Alkaline	Abilify			S	Oral	7.5 Mg, Qd		Otsuka
Phosphatase Increased;	Abilify			S	Oral	5 Mg, Qd		Otsuka
Drug Interaction; Gamma-	Abilify			S	Oral	2.5 Mg, Qd		Otsuka
Glutamyltransferase	Abilify			S	Oral	5 Mg, Qd		Otsuka
Increased	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	10 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Cipralex			S	Oral	5 Mg, Unk		Not Reported
	Sycrest			S	Unknown	5 Mg, Unk		Not Reported

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Sycrest	S	Unknown	20 Mg, Unk	Not Reported
Sycrest	S	Unknown	10 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Sycrest	S	Unknown	15 Mg, Unk	Not Reported
Zeldox	S	Oral	20 Mg, Unk	Not Reported
Zeldox	S	Unknown	80 Mg, Unk	Not Reported
Zeldox	S	Unknown	120 Mg, Unk	Not Reported
Zeldox	S	Unknown	40 Mg, Unk	Not Reported
Zeldox	S	Unknown	Unk, Unknown	Not Reported
Zyprexa	S	Oral	1 Mg, Qd (Mg Per Day1)	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	30 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	10 Mg, Unk	Not Reported
Zyprexa	S	Oral	20 Mg, Unk	Not Reported
Zyprexa	S	Oral	25 Mg, Unk	Not Reported
Trittico	S	Oral	100 Mg, Unk	Not Reported
Trittico	S	Oral	150 Mg, Unknown	Not Reported
Trittico	S	Oral	300 Mg, Unknown	Not Reported
Trittico	S	Oral	250 Mg, Unknown	Not Reported
Trittico	S	Oral	150 Mg, Unk	Not Reported
Trittico	S	Oral	100 Mg, Unk	Not Reported
Fluctine	S	Unknown	20 Mg, Unk	Not Reported
Quilonium R	S	Unknown	900 Mg, Unk	Not Reported
Quilonium R	S	Unknown	450 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quilonium R	S	Unknown	400 Mg, Unk	Not Reported
Quilonium R	S	Unknown	675 Mg, Unk	Not Reported
Rivotril	C	Unknown	2mg, Unknown	Not Reported
Rivotril	C	Unknown	4 Mg, Unknown	Not Reported
Rivotril	C	Unknown	4 Mg, Unknown	Not Reported
Rivotril	C	Unknown	2 Mg, Unknown	Not Reported
Rivotril	C	Unknown	1 Mg, Unknown	Not Reported
Inderal	C	Oral	50 Mg, Unk	Not Reported
Inderal	C	Oral	30 Mg, Unknown	Not Reported
Inderal	C	Oral	60 Mg, Unknown	Not Reported
Inderal	C	Oral	30 Mg, Unknown	Not Reported
Inderal	C	Oral	40 Mg, Unknown	Not Reported
Inderal	C	Oral	20 Mg, Unknown	Not Reported
Inderal	C	Oral	40 Mg, Unknown	Not Reported
Inderal	C	Oral	90 Mg, Unknown	Not Reported
Inderal	C	Oral	30 Mg, Unk	Not Reported
Inderal	C	Oral	Unk	Not Reported
Inderal	C	Oral	40 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	300 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	900 Mg, Unk	Not Reported
Neurotropic Caplets	C	Oral	600 Mg, Unk	Not Reported
Nozinan	C	Unknown	150 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	100 Mg, Unk	Not Reported
Nozinan	C	Unknown	25 Mg, Unk	Not Reported
Nozinan	C	Unknown	50 Mg, Unk	Not Reported

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Nozinan	C	Unknown	Unk	Not Reported
Lamictal	C	Oral	250 Mg, Unk	Not Reported
Lamictal	C	Oral	200 Mg, Unk	Not Reported
Lamictal	C	Oral	75 Mg, Unk	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Lamictal	C	Oral	50 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unk	Not Reported
Lamictal	C	Oral	300 Mg, Unknown	Not Reported
Lamictal	C	Oral	100 Mg, Unk	Not Reported
Nubain	C	Unknown	1 Unk, 1df In 100ml Nacl	Not Reported
Risperdal	C	Unknown	2 Mg, Unknown	Not Reported
Risperdal	C	Unknown	1 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	4 Mg, Unk	Not Reported
Akineton	C	Unknown	2 Mg, Unk	Not Reported
Akineton	C	Unknown	Unk, Unknown	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	160 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	80 Mg, Unk	Not Reported
Dominal (Prothipendyl Hydrochloride)	C	Oral	120 Mg, Unk	Not Reported
Praxiten	C	Unknown	25 Mg, Unk	Not Reported
Praxiten	C	Unknown	50 Mg, Unk	Not Reported
Sifrol	C	Unknown	0.26 Mg, Unknown	Not Reported
Sifrol	C	Unknown	0.34 Mg, Unknown	Not Reported
Temesta (Lorazepam)	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported

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Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	10 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	5.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	4 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	8.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	6.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	7.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Oral	3.75 Mg, Unk	Not Reported
Zoldem	C	Unknown	5 Mg, Unk	Not Reported
Dibondrin	C	Unknown	50 Mg, Unk	Not Reported
Gastrozepin	C	Unknown	100 Mg, Unk	Not Reported
Truxal	C	Unknown	50 Mg, Unk	Not Reported

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Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Neurotrop	C	Oral	300 Mg, Unk	Not Reported
Neurotrop	C	Oral	600 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Neurotrop	C	Oral	900 Mg, Unk	Not Reported
Adasuve	C	Unknown	Unk, Unknown	Not Reported
Quilonorm	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14355553	NON-EXPEDITED			US-PFIZER INC-2018003646		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer	
	Dilantin Kapseal			S		Unk		Pfizer	
	Arava			S		Unk		Not Reported	
	Etodolac			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Lamictal			S		Unk		Not Reported	
	Leflunomide			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Naprosyn			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14496414	EXPEDITED (15-DAY)		OT	IE-MACLEODS PHARMACEUTICALS US LTD-MAC2018009320			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Discomfort;	Escitalopram Oxalate 10mg			S	Oral	10 Mg, Unk		Macleods	

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Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia		Tablet Escitalopram Oxalate 10mg Tablet	S		Macleods				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14496419	EXPEDITED (15-DAY)		DS, HO, OT	NO-MACLEODS PHARMACEUTICALS US LTD- MAC2018009322			Unknown	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation;	Olanzapine Tablet			S	Oral	Unk		Macleods	
Alcohol Abuse; Bipolar	Cipralext			S	Oral	Unk, Qd		Not Reported	
Disorder; Depression;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Derealisation; Disturbance	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
In Attention; Disturbance	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
In Social Behaviour;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Dizziness; Drug Abuse;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Drug Ineffective;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Hypomania; Impaired	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Work Ability; Irritability;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Judgement Impaired;	Efexor Depot			S	Oral	Unk, Prolonged-Release Capsule		Not Reported	
Logorrhoea; Malaise;	Efexor Depot			S	Unknown	Unk		Not Reported	
Mania; Memory	Lamictal			S	Unknown	Unk		Not Reported	
Impairment; Personality	Seroquel			S	Oral	Unk, Film-Coated Tablet		Not Reported	
Disorder; Quality Of Life	Seroquel			S	Oral	Unk, Film-Coated Tablet		Not Reported	
Decreased; Restlessness	Seroxat			S	Oral	Unk		Not Reported	
	Seroxat			S	Oral	20 Mg, Qd		Not Reported	
	Zyprexa			S	Unknown	Unk		Not Reported	
	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd		Not Reported	
	Cipramil			S	Unknown	60 Mg, Qd		Not Reported	
	Sodium Valproate			S	Unknown	Unk, Increasing Dose		Not Reported	
	Sobril			C	Oral	Unk, As Needed		Not Reported	
	Lithionit			C	Unknown	Unk		Not Reported	

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Lithionit	C	Unknown	Unk	Not Reported
Orfiril	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14501794	EXPEDITED (15-DAY)	HO		PHHY2018FR017687		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	40 Mg (0-0-1), Qd		Novartis
	Escitalopram			S	Oral	10 Mg (1-0-0), Qd		Not Reported
	Irbesartan			S	Oral	75 Mg (1-0-0), Qd		Not Reported
	Furosemide			S	Oral	40 Mg (1-0-0), Qd		Not Reported
	Duphalac			C	Oral	1 Df, Tid (1-1-1)		Not Reported
	Havlane			C	Oral	1 Df (0-0-1), Qd		Not Reported
	Kardegic			C	Oral	1 Df (0-1-0), Qd		Not Reported
	Seresta			C	Oral	1 Df (0-0-1), Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	11242199	NON-EXPEDITED		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2015-01662		20 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Escitalopram			S	Unknown	Unk (Dose Progressively Titrated From 5 Mg To 20 Mg)		Lupin
	Escitalopram			S	Unknown	30 Mg, Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	13093527	EXPEDITED (15-DAY)		HO, OT	NO-PFIZER INC- 2017005122		21 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Aggression; Agitation; Alcohol Abuse;	Efexor Depot			S		Unk		Pfizer

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Bipolar Disorder;	Efexor Depot	S	Unk	Pfizer
Depression; Derealisation;	Efexor Depot	S	Unk	Pfizer
Disturbance In Attention;	Efexor Depot	S	Unk	Pfizer
Disturbance In Social Behaviour; Dizziness;	Olanzapine	S	Unk	Not Reported
Drug Abuse; Drug Abuse;	Seroxat	S	Unk	Not Reported
Drug Ineffective;	Seroxat	S	20 Mg, Daily	Not Reported
Hypomania; Impaired Work Ability; Irritability;	Cipramil /00582602/	S	10 Mg, Daily	Not Reported
Judgement Impaired;	Cipramil /00582602/	S	60 Mg, Daily	Not Reported
Logorrhoea; Malaise;	Ciprallex /01588501/	S	Unk Unk, Daily	Not Reported
Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Valproat	S	Increasing Dose	Not Reported
	Seroquel	S	Unk	Not Reported
	Seroquel	S	Unk	Not Reported
	Seroquel	S	Unk	Not Reported
	Zyprexa	S	Unk	Not Reported
	Orfiril	S	Unk	Not Reported
	Lamictal	S	Unk	Not Reported
	Lithionit	C	Unk	Not Reported
	Lithionit	C	Unk	Not Reported
	Sobril	C	Unk Unk, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	13746883	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1729015US		46 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction;	Escitalopram Oxalate Unk			S	Oral			Allergan	
Headache; Pneumonia	Brintellix			S	Oral	15 Mg, Qd		Not Reported	
	Brintellix			S	Oral	20 Mg, Qd		Not Reported	
	Brintellix			S	Oral	15 Mg, Qd		Not Reported	
	Brintellix			S	Oral	10 Mg, Qd		Not Reported	

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Brintellix	S	Oral	5 Mg, Qd	Not Reported
Cymbalta	S			Not Reported
Efectin	S			Not Reported
Trittico Ret.	C	Unknown	Unk	Not Reported
Trittico Ret.	C	Unknown	Unk	Not Reported
Trittico Ret.	C	Unknown	Unk	Not Reported
Trittico Ret.	C	Unknown	Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Aprednisolon	C	Unknown	Unk	Not Reported
Cal-D-Vita	C	Unknown		Not Reported
Oleovit D3	C	Unknown	N/A	Not Reported
Curocef	C	Unknown	Unk	Not Reported
Curocef	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063071	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04781		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin
	Bisoprol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063083	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04778		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063085	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04780		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063089	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04777		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin	
	Bisoprolol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063091	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04774		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
	Cyamemazine			S	Unknown	Unk		Not Reported	
	Dextropropoxyphene			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063093	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04775		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin	
	Bisoprolol			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063095	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04776		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
	Bilastine			S	Unknown	Unk		Not Reported	
	Hydroxyzine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14063107	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04779		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067233	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04788		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067234	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04796		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
	Amiodarone			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067236	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04783		71 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067238	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04791		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
	Pramipexole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067241	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04787		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067243	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04790		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
	Furosemide			S	Unknown	Unk		Not Reported	
	Bisoprolol			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067245	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04794		94 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067247	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04789		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Lupin	
	Candesartan			S	Unknown	Unk		Not Reported	
	Ivabradine			S	Unknown	Unk		Not Reported	
	Spironolactone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067251	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04792		82 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
	Amiodarone			S	Unknown	Unk		Not Reported	
	Flecainide			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067252	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04785		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	10 Mg, Unk		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067253	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04782		38 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	5 Mg, Unk			Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067254	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04786		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	Unk			Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067256	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04784		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	Unk			Lupin	
	Amiodarone		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067257	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04793		86 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram		S	Unknown	Unk			Lupin	
	Digoxine		S	Unknown	Unk			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14067263	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04795		87 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram Alimemazine			S S	Unknown Unknown	5 Mg, Unk Unk		Lupin Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14132883	NON-EXPEDITED		OT	CH-LUPIN PHARMACEUTICALS INC.-2017-03532			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema; Suicidal Ideation	Escitalopram Venlafaxine Mirtazapine Sertraline Fluoxetine Trazodone			S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk Unk Unk		Lupin Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14189507	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06097			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Irritability; Wrong Technique In Product Usage Process	Escitalopram Oxalate Tablets Usp, 20 Mg Atenolol Valsartan			S C C	Oral Oral Oral	20 Mg, Qd 25 Mg, Qd 160 Mg, Qd, Hs		Lupin Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14197865	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS		58 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety; Decreased Appetite; Insomnia; Sexual Dysfunction; Weight Increased	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	100 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14200676	NON-EXPEDITED		OT	GR-LUPIN PHARMACEUTICALS INC.-2017-06039		63 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urinary Retention	Escitalopram			S	Unknown	10 Mg, Qd		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14339367	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2017-47973			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S	Unknown	20 Milligram Daily;		Aurobindo
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Not Reported
	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14374572	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-001266		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Escitalopram Film-Coated Tablets			S	Oral	Non Renseignée ()		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S		Unk ()		Aurobindo
	Xeloda			S	Oral	Non Renseignée ()		Not Reported
	Xeloda			S	Oral	Unk ()		Not Reported
	Xeloda			S	Oral	Unk ()		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignée ()		Not Reported
	Novorapid			S		Unk ()		Not Reported
	Novorapid			S		Unk ()		Not Reported
	Primperan			S	Oral	Non Renseignée ()		Not Reported
	Primperan			S	Oral	Unk ()		Not Reported
	Primperan			S	Oral	Unk ()		Not Reported
	Lipanthyl			S	Oral	Non Renseignée ()		Not Reported
	Lipanthyl			S	Oral	Unk ()		Not Reported
	Lipanthyl			S	Oral	Unk ()		Not Reported
	Movicol /01749801/			S	Oral	Non Renseignée ()		Not Reported
	Movicol /01749801/			S		Unk ()		Not Reported
	Abasaglar			S	Subcutaneous	Non Renseignée ()		Not Reported
	Abasaglar			S		Unk ()		Not Reported
	Abasaglar			S		Unk ()		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Non Renseignée ()		Not Reported

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08-Feb-2018	14501945	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2017-01271		25 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Tract Irritation	Escitalopram			S	Unknown	10 Mg, Daily		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14501951	NON-EXPEDITED			TW-LUPIN PHARMACEUTICALS INC.-2017-03196		70 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Somnolence	Mirtazapine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Lupin	
	Fenofibrate			C	Unknown	200 Mg, Qod		Not Reported	
	Clopidogrel			C	Unknown	Unk		Not Reported	
	Carvedilol			C	Unknown	Unk		Not Reported	
	Famotidine			C	Unknown	Unk		Not Reported	
	Sennoside /00571901/			C	Unknown	Unk		Not Reported	
	Levocetirizine			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502525	NON-EXPEDITED		OT	AU-LUPIN (EUROPE) LIMITED-2017-02379			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Suicidal Ideation	Escitalopram			S	Unknown	2 Df, Qd (2 Tablets Each Morning)		Lupin	

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08-Feb-2018	14502526	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-03560			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zytomil			S	Oral	20 Mg, Qd		Lupin	
	Aspen Trazodone			C	Oral	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502527	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02285		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Drug Ineffective; Dry Mouth; Hyperhidrosis; Menstruation Irregular; Rash; Sleep Disorder; Tremor; Vision Blurred	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin	
	Alprazolam			C	Oral	Unk Unk, Bid		Not Reported	
	Complex B /00653501/			C	Oral	1, Qd		Not Reported	
	Melatonin			C	Oral	3 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502532	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2017-02140		25 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event; Prescription Drug Used Without A Prescription	Stalopam			S	Oral	1 Df, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502533	NON-EXPEDITED		OT	ZA-LUPIN PHARMACEUTICALS INC.-2017-05515		49 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebrovascular Accident;	Fedaloc Sr 30 Mg	S	Oral	30 Mg, Qd	Not Reported
Drug Ineffective;	Zytomil 10 Mg	S	Oral	10 Mg, Qd	Lupin
Hypertension	Stilnox	S	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502534	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02514			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502535	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-04639		67 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Insomnia	Zytomil 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Zytomil 20 Mg			S	Oral	0.5 Df, Unk		Lupin
	Zytomil 20 Mg			S	Oral	Unk		Lupin
	Euthyrox			C	Oral	100 Mcg, Qd		Not Reported
	Aspavor			C	Oral	40 Mg, Qd		Not Reported
	Premarin			C	Oral	0.3 Mg, Qd		Not Reported
	Plenish-K			C	Oral	1200 Mg, Qd		Not Reported
	Bilocor			C	Oral	5 Mg, Qd		Not Reported
	Co Pritor			C	Oral	40/12.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502574	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06828			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Diarrhoea	Escitalopram	S	Unknown	Unk	Lupin
	Lisinopril	C	Unknown	Unk	Not Reported
	Temazepam	C	Unknown	Unk	Not Reported
	Iron	C	Unknown	Unk Unk, Prn	Not Reported
	Fondaparinux Sodium	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502576	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03637			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal	Escitalopram			S	Unknown	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502577	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00007427		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Epistaxis; Headache; Hypersomnia; Oxygen Saturation Decreased; Pruritus; Sinusitis	Escitalopram Oxalate Tablets Usp, 20 Mg Albuterol /00139501/			S	Oral	20 Mg, Qd		Lupin	
				S	Respiratory (inhalation)	Nebulization, Once In 4 Hours		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502579	NON-EXPEDITED			ZA-LUPIN PHARMACEUTICALS INC.-2017-06375			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza	Zytomil Tablets			S	Oral	20 Mg, Qd		Lupin	
	Puricos			S	Oral	100 Mg, Qd		Not Reported	
	Carloc			S	Oral	6.25 Mg, Qd		Not Reported	
	Ultimag			S	Oral	Unk		Not Reported	

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08-Feb-2018	14502580	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-05676		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Memory Impairment	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502581	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06822		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea; Therapeutic Product Effect Incomplete	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Oral	5 Mg, Qd, In Morning		Lupin	
	Escitalopram Oxalate Tablets Usp, 5 Mg			S				Lupin	
	Estradiol-Norethindrone Acetate 1/0.2 (Grandmark Pharma)			C	Oral	1 Df, Qd, At Night,		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14502597	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-05801			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Restless Legs Syndrome	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Unknown	10 Mg,Unk,Unknown		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505128	NON-EXPEDITED		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2016-05747		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Methylene Blue			S	Unknown	7.5 Mg/Kg,Unk,Unknown		Not Reported	
	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Lupin	

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08-Feb-2018	14505129	NON-EXPEDITED		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2017-00841		49 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin	
	Enrelax			C	Unknown	Unk Unk,Unk,Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505138	NON-EXPEDITED		HO, OT	IT-LUPIN PHARMACEUTICALS INC.-2017-01650		89 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S		Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505139	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-E2B_00006938			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Weight Increased	Escitalopram			S	Unknown	20 Mg,Qd,		Lupin	
	Escitalopram			S	Unknown	20 Mg,Qd,		Lupin	
	Citalopram			S	Unknown	30 Mg,Qd,		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505141	NON-EXPEDITED		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2017-07129		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Lorazepam			S	Oral	1.5 Mg, Unk		Not Reported	
	Lorazepam			S	Oral	1 Mg, Unk		Not Reported	

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Lorazepam	S	Oral	0.25 Mg, Unk	Not Reported
Escitalopram	S	Oral	20 Mg, Unk	Lupin
Escitalopram	S	Oral	10 Mg, Unk	Lupin
Quetiapine	S	Oral	50 Mg, Unk	Not Reported
Quetiapine	S	Oral	150 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505142	NON-EXPEDITED		OT	JP-LUPIN PHARMACEUTICALS INC.-2017-00705		30 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathy	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Escitalopram			S	Unknown	Unk Unk,Unk,		Lupin
	Flunitrazepam			C	Unknown	Unk Unk,Unk,		Not Reported
	Trazodone			C	Unknown	Unk Unk,Unk,		Not Reported
	Trazodone			C	Unknown	Unk Unk,Unk,		Not Reported
	Duloxetine			C	Unknown	Unk Unk,Unk,		Not Reported
	Duloxetine			C	Unknown	Unk Unk,Unk,		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505143	NON-EXPEDITED		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2016-05743		19 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia; Overdose; Suicide Attempt	Venlafaxine			S	Oral	37.5 Mg,Qd,		Not Reported
	Venlafaxine			S	Oral	10-15 Tablets		Not Reported
	Escitalopram			S	Oral	Unk Unk,Qd,		Lupin
	Escitalopram			S	Oral	10-15 Tablets		Lupin
	Clonazepam			S	Oral	Unk Unk,Qd,		Not Reported
	Clonazepam			S	Oral	10-15 Tablets		Not Reported

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08-Feb-2018	14505144	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-02231		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence	Escitalopram			S	Unknown	5 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505145	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03160		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14505656	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-005212		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	()		Aurobindo	
	Aripiprazol			S	Unknown	10 Milligram Daily; ()		Aurobindo	
	Clomipramine			S	Unknown	150 Milligram Daily;		Not Reported	
	Fluvoxamine			S	Unknown	200 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14506073	EXPEDITED (15-DAY)		OT	AU-MYLANLABS- 2018M1010751			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest;	Metformin			S		Unk		Not Reported	
Electrocardiogram Qt	Escitalopram			S		Unk		Not Reported	
Prolonged; Pulmonary	Paracetamol			S		Unk		Not Reported	
Embolism; Tricuspid Valve	Zopiclone			S		Unk		Not Reported	
Incompetence									

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Pantoprazole	S	Unk	Not Reported
Clozapine	S	Unk	Not Reported
Clopine	S	Unk	Mylan
Paliperidone	S	Unk	Mylan
Cholecalciferol	S	Unk	Mylan
Desmopressin	S	Unk	Mylan
Fluticone	S	Unk	Mylan
Lorazepam	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14507048	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1806413US		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Pradaxa			S	Oral			Not Reported
	Furosemide			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Anastrozole			C	Unknown			Not Reported
	Repaglinide			C	Unknown			Not Reported
	Fumafer			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	13885057	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-GLENMARK PHARMACEUTICALS-2017GMK028495			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder;	Escitalopram			S	Oral	10 Mg, Hs		Not Reported
Condition Aggravated;	Escitalopram			S	Unknown	Unk		Not Reported
Impaired Work Ability;	Escitalopram			S				Not Reported
Insomnia; Intentional	Escitalopram			S				Not Reported
Overdose; Intentional	Escitalopram			S				Not Reported
Product Misuse; Loss Of	Atorvastatin			S	Oral	Unk (Bedtime)		Not Reported

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Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Meloxicam	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago	Glenmark
	Meloxicam	S			Glenmark
	Perindopril	S	Oral	Unk	Not Reported
	Tramadol	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol	S			Not Reported
	Clarithromycin	S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses	Not Reported
	Sertraline	S	Oral	50 Mg, Od, (In The Morning)	Not Reported
	Sertraline	S			Not Reported
	Zolpidem	S	Oral	10 Mg, Od	Not Reported
	Zolpidem	S			Not Reported
	Doxepin	S	Oral	25 Mg, Od, At Bed Time	Not Reported
	Doxepin	S			Not Reported
	Doxepin	S			Not Reported
	Doxepin	S			Not Reported
	Bisoprolol	S	Oral	Unk	Not Reported
	Atoris	S	Unknown	Unk	Not Reported
	Atoris	S			Not Reported
	Polisen	S	Unknown	10 Mg, Od, At Bed Time	Not Reported
	Concor	S	Unknown	Unk	Not Reported
	Trosicam	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14063087	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-04773		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Electrocardiogram Qt Prolonged	Escitalopram	S	Unknown	10 Mg, Unk	Lupin
	Aliskiren	S	Unknown	Unk	Not Reported
	Amiodaron /00133101/	S	Unknown	Unk	Not Reported
	Domperidone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14334021	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1773695US		1 DAY	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Neonatal Respiratory Depression	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan	
	Wypax			S	Transplacental	Unk		Not Reported	
	Zolpidem Tartrate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14506252	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2017-00837		37 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania	Escitalopram Oxalate			S	Unknown	Unk Unk,Unk,Unknown		Lupin	
	Escitalopram Oxalate			S				Lupin	
	Escitalopram Oxalate			S				Lupin	
	Risperidone			S	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Risperidone			S				Not Reported	
	Risperidone			S				Not Reported	
	Sertraline			S	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Sertraline			S				Not Reported	
	Sertraline			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14506253	NON-EXPEDITED		OT	TW-LUPIN PHARMACEUTICALS INC.-2017-06368		31 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Thrombocytopenia	Escitalopram	S	Unknown	10 Mg, Qd	Lupin

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09-Feb-2018	14509295	EXPEDITED (15-DAY)	CA, OT		DE-TORRENT-00007729		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ebrantil			C	Unknown			Unknown
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet		Unknown
	Valsartan			C	Unknown	160 [Mg/D (Vater)]		Unknown
	Escitalopram			S	Transplacental	7.5 [Mg/D (Mutter)]		Unknown
	Folsan			C	Transplacental	0.4 [Mg/D (Mutter)]		Unknown
	Ramilich			C	Unknown	10 [Mg/D (Vater)]		Unknown
	Dekristol			C	Unknown	20000 [Ie/D (Alle 2 Wochen) (Vater)]		Unknown
	Paracetamol			C	Transplacental			Unknown
	Bicanorm			C	Unknown			Unknown
	Atozet			C	Unknown	40 [Mg/D] / 10 [Mg/D (Vater)]/ Probably Either Atozet Or Simvastatin		Unknown
	Ass 100			C	Unknown	100 [Mg/D (Vater)]		Unknown
	Amlodipine			C	Unknown	10 [Mg/D (Vater)]		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14509991	EXPEDITED (15-DAY)	HO		IT-ASTRAZENECA-2018SE14201		46 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation	Seroquel			S	Oral	50.0df Unknown		Zeneca
	Ciprallex			S	Oral	10.0df Unknown		Not Reported
	Tegretol			S	Oral	90.0df Unknown		Not Reported
	Depakin Chrono			S	Oral	20.0df Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14511576	NON-EXPEDITED			PHEH2018US004688		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Pyrexia	Gilenya			S	Oral	0.05 Mg/Kg, Qd		Novartis	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2018	14515470	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2251670-00			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Asthenia;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Basedow'S Disease;	Salicylic Acid			S	Topical			Not Reported	
Decreased Appetite;	Lexapro			S	Unknown			Not Reported	
Dermatitis; Disturbance In	Lisinopril			C				Not Reported	
Sexual Arousal; Dry Skin;	Pantoprazole			C				Not Reported	
Erectile Dysfunction;	Valium			C				Not Reported	
Fatigue; Gingival Atrophy;	Budesonide			C	Oral			Not Reported	
Gingivitis; Heart Rate	Carvedilol			C				Not Reported	
Increased; Libido									
Decreased; Pain Of Skin;									
Palpitations; Panic Attack;									
Prostatomegaly; Pruritus;									
Rash Macular; Rash									
Macular; Self-Injurious									
Ideation; Squamous Cell									
Carcinoma; Toothache;									
Urethral Stricture									
Postoperative; Weight									
Decreased									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2018	14360598	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1800461US		55 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Creatine	Escitalopram Oxalate - Bp	S	Oral		Allergan
Phosphokinase Increased; Hepatic Function	Escitalopram Oxalate - Bp	S	Oral	Overdose: Unknown Daily Dose	Allergan
Abnormal; Overdose; Pain In Extremity; Peripheral Swelling; Suicide Attempt	Lunesta	C	Oral	2 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2018	14474307	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1804728US		83 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
Asthenia; Chest	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
Discomfort; Chronic	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
Kidney Disease;	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg, Unknown		Allergan
Constipation; Depressed	Escitalopram Oxalate - Bp			S	Unknown	1.5 Mg, Qd		Not Reported
Mood; Dizziness; Gait	Fludex (Indapamide)			S	Unknown			Not Reported
Disturbance; Grief	Aspirin			C				Not Reported
Reaction; Hypokalaemia;	Ondansetron			C				Not Reported
Hyponatraemia; Malaise;	Redormin (Remifentanil			C		Unk		Not Reported
Malnutrition; Nausea;	Hydrochloride)			C				Not Reported
Panic Attack;	B12			C				Not Reported
Restlessness; Tension;	Rosuvastatin			C				Not Reported
Thinking Abnormal;	Zestril			C				Not Reported
Urinary Tract Infection;								
Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2018	14516175	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1806541US		70 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan
Gastrointestinal	Brexidol			S	Oral	1 Tablet A Day As Required. Used Late		Not Reported
Haemorrhage	Paralgin Forte			C	Oral	Unit Dose= 400 Mg Paracetamol+ 30 Mg Codeine2 Tablets 3 Times		Not Reported

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Micardiprus	C	Oral	A Day Unit Dose: 80 Mg Telmisartan + 12.5mg Hydrochlorotiazide	Not Reported
Sobril	C	Oral	1 Tablet As Required, Maximum 3 Times Per Day	Not Reported
Zolpidem	C	Oral	1-2 Tablets As Required In The Evening	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2018	14516176	EXPEDITED (15-DAY)		OT	IE-ALLERGAN- 1806408US		40 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Off Label Use; Pain In Extremity; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14520145	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2018M1008572		50 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Valsartan			S	Oral			Not Reported
	Xeroquel			S	Oral			Mylan
	Prazepam			S	Oral			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14523481	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US-		36 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor
	Amitriptyline			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14523594	EXPEDITED (15-DAY)		DS, OT	CA-ENDO PHARMACEUTICALS INC-2018-016820		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Off Label Use; Optic Atrophy; Pulmonary Oedema; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents	Adrenalin			S	Unknown	30 Mcg, Unknown		Par
	Amlodipine Besylate Tablets			S	Unknown	150 Mg, Od		Vintage
	Vasodilator			S	Unknown	Unk Unk, Unknown		Par
	Escitalopram			S	Unknown	60 Mg, Od		Not Reported
	Glucose			S	Unknown	Unk Unk, Unknown		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Mcg, Unknown		Not Reported
	Risperidone			S	Unknown	6 Mg, Od		Not Reported
	Activated Charcoal			C	Unknown	50 G, Unknown		Not Reported
	Insulin			C	Intravenous bolus	Unk Unk, Unknown		Not Reported
	Insulin			C	Unknown	70 Iu, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	13295490	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1707975US		46 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Abuse; Lactic Acidosis; Metabolic Disorder; Neurological Decompensation; Overdose	Escitalopram Oxalate - Bp	S	Oral	10 Tablets, Single	Allergan
	Depakin Chrono	S	Oral	20 Tablets, Single	Not Reported
	Seroquel	S	Oral	40 Tablets, Single	Not Reported
	Tegretol	S	Oral	90 Tablets, Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	13753331	EXPEDITED (15-DAY)		OT	AT-TAKEDA-2017TUS014761		46 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erectile Dysfunction; Headache; Pneumonia	Vortioxetine			S	Oral	5 Mg, Qd		Takeda
	Vortioxetine			S	Oral	10 Mg, Qd		Takeda
	Vortioxetine			S	Oral	15 Mg, Qd		Takeda
	Vortioxetine			S	Oral	20 Mg, Qd		Takeda
	Vortioxetine			S	Oral	15 Mg, Qd		Takeda
	Cipralex			S	Oral	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Unk		Not Reported
	Oleovit D3			C	Oral	40 Gtt, 1/Week		Not Reported
	Curocef /00454602/			C	Unknown	Unk, Qd		Not Reported
	Curocef /00454602/			C	Unknown	9 G, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Zoldem			C	Oral	10 Mg, Qd		Not Reported
	Zoldem			C	Oral	5 Mg, Qd		Not Reported
	Trittico			C	Oral	150 Mg, Qd		Not Reported
	Trittico			C	Oral	200 Mg, Qd		Not Reported
	Trittico			C	Oral	250 Mg, Qd		Not Reported
	Trittico			C	Oral	300 Mg, Qd		Not Reported
	Cal D Vita			C	Oral	Unk, Qd		Not Reported
	Aprednislon			C	Oral	5 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14277597	EXPEDITED (15-DAY)		HO	AT-OTSUKA-2017_001835		31 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Off Label Use	Abilify			S	Unknown	2.5 Mg, Qd		Otsuka
	Abilify			S	Unknown	5 Mg, Qd		Otsuka
	Abilify			S	Unknown	7.5 Mg, Qd		Otsuka
	Abilify			S	Unknown	10 Mg, Qd		Otsuka
	Abilify			S	Unknown	5 Mg, Qd		Otsuka
	Cipralex			S	Unknown	10 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	25 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	30 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	30 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	10 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	20 Mg, Unk		Not Reported
	Trittico			S	Unknown	150 Mg, Unk		Not Reported
	Trittico			S	Oral	250 Mg, Unk		Not Reported
	Trittico			S	Oral	300 Mg, Unk		Not Reported
	Trittico			S	Oral	150 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	150 Mg, Unk		Not Reported

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Trazodone Hydrochloride	S	Unknown	250 Mg, Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	300 Mg, Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	150 Mg, Unk	Not Reported
Olanzapine	S	Unknown	10 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	25 Mg, Unk	Not Reported
Olanzapine	S	Unknown	30 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	30 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Olanzapine	S	Unknown	10 Mg, Unk	Not Reported
Olanzapine	S	Unknown	20 Mg, Unk	Not Reported
Risperdal	C	Unknown	Unk	Not Reported
Zeldox	C	Unknown	20 Mg, Unk	Not Reported
Zeldox	C	Unknown	40 Mg, Unk	Not Reported
Zeldox	C	Unknown	80 Mg, Unk	Not Reported
Zeldox	C	Unknown	120 Mg, Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Quilonorm	C	Unknown	Unk	Not Reported
Sycrest	C	Unknown	Unk	Not Reported
Leponex	C	Unknown	Unk	Not Reported
Lamictal	C	Unknown	Unk	Not Reported
Neurotop	C	Unknown	Unk	Not Reported
Dominal (Acetylsalicylic Acid)	C	Unknown	Unk	Not Reported
Rivotril	C	Unknown	Unk	Not Reported
Truxal	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	Unk	Not Reported
Dibondrin	C	Unknown	Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported

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Nozinan	C	Unknown	Unk	Not Reported
Propranolol Hydrochloride	C	Unknown	Unk	Not Reported
Akineton	C	Unknown	Unk	Not Reported
Praxiten	C	Unknown	Unk	Not Reported
Fluctine	C	Unknown	Unk	Not Reported
Inderal	C	Unknown	Unk	Not Reported
Sifrol	C	Unknown	Unk	Not Reported
Nubain	C	Unknown	Unk	Not Reported
Adasuve	C	Unknown	Unk	Not Reported
Gastrozepin	C	Unknown	Unk	Not Reported
Risperidone	C	Unknown	Unk	Not Reported
Lamotrigine	C	Unknown	Unk	Not Reported
Carbamazepine	C	Unknown	Unk	Not Reported
Clonazepam	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	Unk	Not Reported
Zolpidem	C	Unknown	Unk	Not Reported
Levomepromazine	C	Unknown	Unk	Not Reported
Fluoxetine Hydrochloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14329870	EXPEDITED (15-DAY)	HO		DE-ALLERGAN-1773715US		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Off Label Use; Stupor; Vertigo	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported

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Risperdal	C	Unknown	1.5 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Qhs	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
L-Thyroxin	C	Oral	100 Mg, Qd	Not Reported
Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
Metformin	C	Oral	1500 Mg, Qd	Not Reported
Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14523853	EXPEDITED (15-DAY)		HO, OT	HU-CIPLA LTD.- 2018HU04055			Unknown	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea At Rest; Suicidal Ideation; Violence-Related Symptom	Escitalopram			S	Oral	10 Mg, Daily		Invagen	
	Lamolep			C	Oral	150 Mg, Daily, 1 Tablet Mornings And 2 Tablets Evenings		Not Reported	
	Kventiax			C	Oral	32.5 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524245	EXPEDITED (15-DAY)		OT	FI-CIPLA LTD.- 2018FI03366			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Oropharyngeal Oedema; Tracheal Oedema	Escitalopram			S	Oral	2.5 Mg, Daily		Invagen	
	Heinix			C	Oral	10 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524420	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR03922			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Long Qt Syndrome; Pneumonia Aspiration	Escitalopram	S	Oral	1 Df, Unk	Invagen
	Tercian /00759301/	S	Oral	15 Gtt, Unk	Not Reported
	Ogast	C	Oral	1 Df, Unk	Not Reported
	Kardegic	C	Oral	1 Df, Unk	Not Reported
	Orocal D3	C	Oral	1 Df, Unk	Not Reported
	Sectral	C	Oral	1 Df, Unk	Not Reported
	Forlax	C	Oral	1 Df, Unk	Not Reported
	Levothyrox	C	Oral	87.5 Mg, Unk	Not Reported
	Aldactazine	C	Oral	15 Mg, Unk	Not Reported
	Bromazepam	C	Oral	3 Mg, Unk	Not Reported
	Imovane	C	Oral	0.5 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524789	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000323		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Levothyroxine Sodium			S	Oral	Unk		Lannett
	Diltiazem			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524796	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000310		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate	S	Oral					Lannett	
	Bupropion	S	Oral	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524798	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000315		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett	
	Bupropion			S	Oral	Unk		Not Reported	
	Venlafaxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524799	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000317		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Diphenhydramine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524800	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000311		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S		Unk		Lannett	
	Ethanol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524801	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000312		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate	S	Oral	Unk	Lannett
	Amitriptyline	S	Oral	Unk	Not Reported
	Gabapentin	S	Oral	Unk	Not Reported
	Ibuprofen	S	Oral	Unk	Not Reported
	Ethanol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524802	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000316		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett	
	Lamotrigine			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524803	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000324		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Metformin			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Naproxen			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524804	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000278		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Loratadine			S	Oral	Unk		Lannett	
	Ethylene Glycol			S	Oral	Unk		Not Reported	

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Furosemide	S	Oral	Unk	Not Reported
Levothyroxine Sodium	S	Oral	Unk	Not Reported
Folic Acid	S	Oral	Unk	Not Reported
Vitamin B-1	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524805	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000319		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Acetaminophen			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524806	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000313		39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett
	Bupropionum			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Salicylate Sodium			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine Sodium			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524807	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000325		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Cocaine			S	Unknown	Unk		Not Reported	
	Bupropion			S	Oral	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Ethanol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524808	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000322		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Flecainide			S	Oral	Unk		Not Reported	
	Verapamil			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524809	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000314		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett	
	Amitriptyline			S	Oral			Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
	Lithium			S	Oral	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524810	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000320		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Oxycodone Hcl And Acetaminophen			S	Oral	Unk		Lannett	
	Montelukast Sodium			S	Oral	Unk		Lannett	
	Ondansetron			S	Oral	Unk		Lannett	
	Propranolol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Ibuprofen			S	Oral	Unk		Not Reported	
	Acyclovir /00587301/			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524811	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000318		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S		Unk		Lannett	
	Propranolol			S		Unk		Not Reported	
	Lamotrigine			S		Unk		Not Reported	
	Mirtazapine			S		Unk		Not Reported	
	Cyclobenzaprine			S		Unk		Not Reported	
	Buspirone /00803202/			S		Unk		Not Reported	
	Clonazepam			S		Unk		Not Reported	
	Activated Charcoal			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14524812	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000321		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral			Lannett	
	Phenytoin Sodium			S	Oral	Unk		Lannett	
	Primidone			S	Oral	Unk		Lannett	
	Carvedilol			S	Oral	Unk		Not Reported	
	Valproic Acid			S	Oral	Unk		Not Reported	
	Sitagliptin			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14526925	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1806933US		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Confusional State; Depression	Escitalopram Oxalate - Bp			S	Oral	1 Dosage Form, Unk		Allergan	
	Laroxyl			S	Oral	1 Dosage Form, Unk		Not Reported	
	Keppra			S	Oral	2 Dosage Forms, Qd		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	
	Eductyl			C	Rectal	Unk		Not Reported	
	Stilnox			C	Oral	10 Mg, Unk		Not Reported	
	Dimeticone			C	Oral	Unk		Not Reported	
	Movicol			C	Oral	Unk		Not Reported	
	Pantoprazole			C	Oral	40 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527022	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2018LAN000338		63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Fluoxetine Hydrochloride			S	Oral	Unk		Lannett	
	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Risperidone			S	Oral	Unk		Not Reported	
	Diphenhydramine Hcl			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527034	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2018M1009552		40 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S		10mg		Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527318	EXPEDITED (15-DAY)		HO, OT	NO-MYLANLABS-2018M1009189		21 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Alcohol Abuse; Bipolar Disorder; Depression; Derealisation; Disturbance In Attention; Disturbance In Social Behaviour; Dizziness; Drug Abuse; Drug Ineffective; Hypomania; Impaired Work Ability; Irritability; Judgement Impaired; Logorrhoea; Malaise; Mania; Memory Impairment; Personality Disorder; Quality Of Life Decreased; Restlessness	Olanzapine			S	Unknown	Unk		Not Reported	
	Cipralext			S	Unknown	Unk, Qd		Mylan	
	Efexor			S	Unknown	Unk		Mylan	
	Lamictal			S	Unknown	Unk		Mylan	
	Seroquel			S	Oral	Unk		Mylan	
	Seroxat			S	Unknown	Unk		Mylan	
	Seroxat			S	Unknown	20 Mg, Qd		Mylan	
	Zyprexa			S	Unknown	Unk		Mylan	
	Cipramil [Citalopram Hydrobromide]			S	Unknown	10 Mg, Qd		Mylan	
	Cipramil			S	Unknown	60 Mg, Qd		Mylan	
	Orfiril			S	Unknown	Unk		Mylan	

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Valproate Sodium	S	Unknown	Increasing Dose	Mylan
Lithionit	C		Unk	Mylan
Sobril	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527686	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806950US		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14075879	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1757166US		57 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	30 Mg, Qd		Allergan	
	Zyprexa Velotab			S	Unknown	10 Mg, Qd		Not Reported	
	Zyprexa Velotab			S	Unknown	15 Mg, Qd		Not Reported	
	Zyprexa Velotab			S	Unknown	5 Mg, Qd		Not Reported	
	Seroquel Xr			S	Oral	100 Mg, Qd		Not Reported	
	Seroquel Xr			S	Oral	200 Mg, Qd		Not Reported	
	Seroquel Xr			S	Oral	50 Mg, Qd		Not Reported	
	Seroquel Xr			S	Oral	200 Mg, Qd		Not Reported	
	Seroquel Xr			S	Oral	100 Mg, Qd		Not Reported	
	Pregabalin			S	Oral	150 Mg, Qd		Not Reported	
	Pregabalin			S	Oral	300 Mg, Qd		Not Reported	
	Pregabalin			S	Oral	450 Mg, Qd		Not Reported	
	Seroquel			S	Unknown	50 Mg, Qd		Not Reported	

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Seroquel	S	Unknown	400 Mg, Qd	Not Reported
Seroquel	S	Unknown	500 Mg, Qd	Not Reported
Seroquel	S	Unknown	450 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	400 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	50 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	100 Mg, Qd	Not Reported
Seroquel	S	Unknown	300 Mg, Qd	Not Reported
Seroquel	S		Unk	Not Reported
Quetiapin	C	Unknown	50 Mg, Qd	Not Reported
Quetiapin	C	Unknown	50 Mg, Qd	Not Reported
Lamotrigin	C	Unknown	50 Mg, Qd	Not Reported
Lamotrigin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	2.5 Mg, Qd	Not Reported
Temesta	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta	C	Unknown	1.25 Mg, Qd	Not Reported
Temesta	C	Unknown	5 Mg, Qd	Not Reported
Rivotril	C	Unknown		Not Reported
Thyrex	C	Unknown		Not Reported
Thyrex	C	Unknown	50 Mg, Unk	Not Reported
Combithyrex Mite	C	Unknown		Not Reported
Combithyrex Mite	C	Unknown		Not Reported

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Optifiber	C	Unknown	Unk	Not Reported
Optifiber	C	Unknown	Unk	Not Reported
Optifiber	C	Unknown	Unk	Not Reported
Optifiber	C	Unknown	Unk	Not Reported
Molaxole	C	Unknown	Unk	Not Reported
Molaxole	C	Unknown	Unk	Not Reported
Molaxole	C	Unknown	Unk	Not Reported
Molaxole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14319066	EXPEDITED (15-DAY)		OT	ES-SA-2017SA251565			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Myalgia; Pain In Extremity; Somnolence; Treatment Noncompliance	Glibenclamide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown	Strength: 50 Mg		Not Reported
	Amlodipine			S	Unknown	Strength: 5mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Tramadol Hydrochloride/Paracetamol			S	Unknown	Strength: 37.5/325 Mg		Not Reported
	Lormetazepam			S	Unknown			Not Reported

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Enalapril/Hydrochlorothiazide	S	Unknown	Strength: 20/12.5 Mg	Not Reported
Escitalopram	S	Unknown		Not Reported
Diazepam/Sulpiride	S	Unknown		Not Reported
Metoclopramide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14334326	EXPEDITED (15-DAY)		OT	PHHY2017CO189498			Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Faeces;	Signifor			S	Subcutaneous	0.6 Mg, Bid		Not Reported
Diabetes Insipidus;	Losartan			S	Unknown			Novartis
Diarrhoea; Fatigue; Gait	Amlodipine			S	Unknown			Not Reported
Disturbance; Lip Dry;	Escitalopram			S	Unknown			Not Reported
Neoplasm; Oedema	Levothyroxine			C	Unknown			Not Reported
Peripheral; Pain In	Ketoconazole			C	Unknown			Not Reported
Extremity; Pituitary	Apo-Clonazepam			C	Unknown	Unk		Not Reported
Tumour; Pruritus; Thirst;								
Weight Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14529507	EXPEDITED (15-DAY)		HO, LT, OT	JP-LUPIN PHARMACEUTICALS INC.-2018-00740			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyanosis Neonatal; Drug	Escitalopram Oxalate			S	Transplacental	10 Mg, Unk		Lupin
Interaction; Foetal	Ethyl Loflazepate			S	Transplacental	1 Mg, Unk		Not Reported
Exposure During								
Pregnancy; Neonatal								
Behavioural Syndrome;								
Neonatal Respiratory								
Depression; Respiratory								
Muscle Weakness								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530564	EXPEDITED (15-DAY)		DE	US-DEPOMED, INC.- US-2018DEP000304		36 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Depomed	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Ibuprofen			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530912	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1806944US		45 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Musculoskeletal Discomfort; Paraesthesia; Restlessness; Serotonin Syndrome; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530920	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806979US		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Xarelto			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530924	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1806913US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness;	Escitalopram Oxalate - Bp			S	Unknown			Allergan	

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Dyspnoea; Gastric Ulcer;
Insomnia; Nausea; Panic
Attack; Vertigo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	13381536	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1711973US		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Sopor	Escitalopram Oxalate Unk			S	Oral	Overdose: 270 Mg		Allergan	
	Carbolithium			S	Oral	5 Df, Overdose		Not Reported	
	Etiltox			S	Oral	9 Df, Overdose		Not Reported	
	Quetiapine			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14199748	EXPEDITED (15-DAY)		HO	IT-SA-2017SA221203		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Pulmonary Infarction	Aubagio			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Tirosint			S	Oral	Strength: 75 Mcg/1 MI		Not Reported	
	Xanax			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14265997	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-45081		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Od		Aurobindo	
	Aripiprazole			S	Oral	5mg, Od		Aurobindo	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Aurobindo	
	Escitalopram			S	Oral	15 Mg, Qd		Aurobindo	

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Escitalopram	S	Oral	20 Mg, Qd	Aurobindo
Risperdal	C	Unknown	1.5 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Unk (For Nights)	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Od	Not Reported
Risperdal	C	Unknown	1.5 Mg, Od	Not Reported
Risperdal	C		2 Mg, Hs	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
L-Thyroxin	C	Oral	100 Mg, Qd	Not Reported
Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
Metformin	C	Oral	1500 Mg, Qd	Not Reported
Metformin	C		1500 Mg, Od	Not Reported
Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Not Reported
Acetylsalicylic Acid	C		100 Mg, Od	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14324369	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2017-47018			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anhedonia; Apathy; Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Naproxen			S	Unknown	2 Df, Unk		Aurobindo
	Simvastatin			S	Unknown	1 Df, Unk		Aurobindo
	Simvastatin			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Unknown	1 Df, Unk		Aurobindo
	Topiramate			S	Unknown	1 Df, Unk		Aurobindo
	Topiramate			S	Unknown	0.5 Df, Unk		Aurobindo
	Amlodipine			S	Unknown	1 Df, Unk		Aurobindo
	Paracetamol			S	Unknown	3 Df, Unk		Aurobindo
	Escitalopram			S	Unknown	(1)		Aurobindo

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Glibenclamide	S	Unknown	2 Df, Unk	Not Reported
Diazepam	S	Unknown	(1)	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Amitriptyline	S		Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Diazepam	S	Unknown	0.5 Df, Unk	Not Reported
Tramadol/Acetaminophen	S	Unknown	3 Df, Unk	Not Reported
Lormetazepam	S	Unknown	1 Df, Unk	Not Reported
Enalapril/Hydrochlorothiazide	S	Unknown	1 Df= 20/12.5 Mg	Not Reported
Metoclopramide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14383364	EXPEDITED (15-DAY)		DE	NO-ROCHE-2050712		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drowning; Feeling Abnormal; Intentional Self- Injury; Overdose; Wrong Product Administered	Rivotril			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Sarotex			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Sobril			S	Unknown			Not Reported
	Truxal			S	Unknown	600 To 1200mg		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Oxynorm			S	Unknown	5 To 10mg		Not Reported
	Oxynorm			S	Unknown	Unk		Not Reported
	Nozinan			S	Unknown	Unk		Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Pinex Forte			S	Unknown	300/30 Mg And Pandeine		Not Reported
	Lamictal			S	Unknown	25, 50, 100 Mg.		Not Reported

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	Remeron	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown		Not Reported
	Nobligan	S	Unknown	50, 200mg	Not Reported
	Catapresan	S	Unknown	Unk	Not Reported
	Cipralex	S	Unknown		Not Reported
	Imovane	S	Oral	Unk	Not Reported
	Cyanocobalamin	C	Unknown		Not Reported
	Heroin	C	Unknown	Unk	Not Reported
	Codeine Phosphate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14533202	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR04681			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia	Escitalopram			S	Oral	5 Mg, Qd		Invagen	
	Oraciline /00001801/			C	Oral	Unk		Not Reported	
	Speciafoldine			C	Oral	15 Mg, Every Week		Not Reported	
	Doliprane			C	Oral	Unk		Not Reported	
	Atarax /00058401/			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14533212	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR04417			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia;	Escitalopram			S	Oral	880 Mg, Unk		Invagen	
Hypotension; Poisoning	Valsartan			S	Oral	14400 Mg, Unk		Not Reported	
Deliberate; Somnolence	Xeroquel			S	Oral	2500 Mg, Unk		Not Reported	
	Prazepam			S	Oral	1200 Mg, Unk		Not Reported	
	Bromazepam			S	Oral	144 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14533874	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR05203			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Disorientation; Fall	Escitalopram			S	Oral	2 Df, Daily		Invagen	
	Trospium			S	Oral	1 Df, Daily		Invagen	
	Theralene			S	Oral	24 Gtt, Daily		Not Reported	
	Seresta			S	Oral	0.5 Df, Daily		Not Reported	
	Seresta			S	Unknown	Unk		Not Reported	
	Tercian /00759301/			S	Oral	30 Gtt, Daily		Not Reported	
	Transipeg /00754501/			C	Oral	1 Df, Daily		Not Reported	
	Doliprane			C	Oral	3 Df, Daily		Not Reported	
	Tardyferon			C	Oral	1 Df, Daily		Not Reported	
	Symbicort			C	Respiratory (inhalation)	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14534508	EXPEDITED (15-DAY)		HO	FR-TAKEDA- 2018TEU000818		91 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Lansoprazole			S	Oral	30 Mg, Qd		Takeda	
	Stilnox			S	Oral	10 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Gliclazide			S	Oral	60 Mg, Qd		Not Reported	
	Efferalgan /00020001/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14535007	EXPEDITED (15-DAY)		DS	FI-PFIZER INC- 2018066074		19 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Female Orgasmic Disorder; Hypoaesthesia; Libido Decreased	Zoloft	S	Oral	50 Mg, Daily	Pfizer
	Cipralex	S	Oral	10 Mg, Daily	Not Reported
	Brintellix	S	Oral	10 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14535257	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018063817		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Confusional State; Drug Interaction; Electrocardiogram Qt Prolonged; Fall	Cordarone			S	Oral	1000 Mg, Weekly		Pfizer	
	Seroplex			S	Oral	5 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14535291	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018024606		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Abnormal; Condition Aggravated; Drug Ineffective; Mania; Rash; Sluggishness; Suicidal Ideation	Paroxetine			S	Unknown	Unk		Glaxosmithkline	
	Sertraline			S	Unknown	Unk		Glaxosmithkline	
	Carbamazepine			S	Unknown	Unk		Glaxosmithkline	
	Risperidone			S	Unknown	Unk		Glaxosmithkline	
	Quetiapine			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Duloxetine			S	Unknown	60 Mg, Daily		Glaxosmithkline	
	Oxcarbazepine			S	Unknown	Unk		Not Reported	
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline	
	Venlafaxine			S	Unknown	Unk		Glaxosmithkline	
	Lorazepam			S	Unknown	Unk		Glaxosmithkline	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	

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Nortriptyline	S	Unknown	Unk	Not Reported
Thioridazine	S	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown	Unk	Not Reported
Chlorpromazine	C	Unknown	100 Mg, Q.H.S.	Not Reported
Gabapentin	C	Unknown	300 Mg, Bid	Not Reported
Gabapentin	C	Unknown	600 Mg, Q.H.S.	Not Reported
Acamprosate	C	Unknown	666 Mg, Tid	Not Reported
Baclofen	C	Unknown	10 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14535392	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-856068		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Mirtazapine			S	Oral	45 Milligram Daily;		Teva	
	Escitalopram			S	Oral	30 Milligram Daily;		Ivax	
	Tiapridal			S	Oral	100 Milligram Daily;		Not Reported	
	Orozamudol			S	Oral	150 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14535959	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1807897US		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate Unk			S	Oral	Unk, Unknown		Allergan	
	Enoxaparina Sodica (2482so)			S	Subcutaneous			Not Reported	
	Sintrom			S	Oral	Unk Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536033	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-1807892US			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Pruritus; Urticaria		Escitalopram Oxalate - Bp		S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536129	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1807730US		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Furosemide			S	Oral			Not Reported	
	Xarelto			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536137	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1807096US		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematemesis; Malaise	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Previscan (Fluindione)			S	Oral			Not Reported	
	Uvedose			C	Unknown	Unk		Not Reported	
	Alteis			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536663	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-855922		45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral			Teva	
	Lexomil Roche			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Baclofene			S	Oral			Not Reported	
	Valium			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536683	DIRECT	Y	HO			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Encephalopathy; Lethargy; Therapy Cessation	Baclofen			S	Oral			Not Reported
	Oxycodone			S	Topical	50mcg Q3days Topical		Not Reported
	Lyrica			S				Not Reported
	Duragesic Patch			S				Not Reported
	Lexapro			S				Not Reported
	Diclofenac			S				Not Reported
	Lidoderm			S				Not Reported
	Nuedexta			C				Not Reported
	Xarelto			C				Not Reported
	Betapace			C				Not Reported
	Dulera			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14537043	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2018NSR000053		28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S		Unk		Northstar
	Escitalopram			S		Unk		Not Reported
	Lamotrigine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Activated Charcoal			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14537046	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE		36 YR	Female	USA

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HOLDINGS-US-
2018NSR000055

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Escitalopram			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Cocaine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14537185	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US- 2018PER001554		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Treximet			S	Oral	Unk		Pernix
	Metformin			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14537295	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2018NSR000066		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported

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Acetaminophen W/Oxycodone	S	Oral	Unk	Not Reported
Ibuprofen	S	Oral	Unk	Not Reported
Montelukast	S	Oral	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Acyclovir /00587301/	S	Oral	Unk	Not Reported
Alprazolam	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14537311	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2018NSR000068		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Diltiazem			S	Oral	Unk		Not Reported
	Metformin			S	Oral	Unk		Not Reported
	Glyburide			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Losartan			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14346920	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017551053		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Sedation	Alprazolam			S	Oral	0.125 Mg, Daily		Pfizer
	Risperdal			S	Oral	1.5 G, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14368636	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1774032US		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dystonia; Erythema; Erythromelalgia; Joint Swelling; Myalgia; Palpitations; Quality Of Life Decreased; Small Fibre Neuropathy; Tremor; Vomiting; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Motrin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14501798	EXPEDITED (15-DAY)		HO	PHHY2018FR017826		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Pantoprazol			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Xeloda			S	Oral			Not Reported
	Novorapid			S	Subcutaneous			Not Reported
	Primperan			S	Oral			Not Reported
	Lipanthyl			S	Oral	Non Renseign�e		Not Reported
	Movicol			S	Oral	Non Renseign�e		Not Reported
	Abasaglar			S	Subcutaneous			Not Reported
	Fondaparinux Sodique			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14538073	EXPEDITED (15-DAY)		DE	US-EGALET US INC-US-2018EGA000144		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Completed Suicide; Toxicity To Various Agents	Oxycodone Hydrochloride	S	Oral	Unk	Egalet
	Propranolol	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Lamotrigine	S	Oral	Unk	Not Reported
	Acetaminophen	S	Oral	Unk	Not Reported
	Ibuprofen	S	Oral	Unk	Not Reported
	Montelukast	S	Oral	Unk	Not Reported
	Ondansetron	S	Oral	Unk	Not Reported
	Acyclovir /00587301/ Alprazolam	S S	Oral Oral	Unk Unk	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14538098	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-163340		21 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertrichosis; Therapeutic Product Effect Incomplete; Weight Increased	Fluoxetine			S	Unknown	20 Mg, Daily		Sun
	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported
	Sertraline			S	Unknown	50 Mg, Daily		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14538464	EXPEDITED (15-DAY)		OT	IE-CIPLA LTD.- 2018IE04002			Unknown	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14539268	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS			Unknown	ESP

FDA Adverse Event Reporting System

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Detailed Report

US LTD-
MAC2018009837

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate			S	Oral	Unk		Macleods
	Enoxaparin Sodium			S	Subcutaneous	Unk		Not Reported
	Sintrom			S	Oral	Unk, Compressed Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14540547	EXPEDITED (15-DAY)		HO, OT	GB-OTSUKA- DJ20071760			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Carcinoid Tumour; Hot Flush	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Citalopram			S	Oral	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14540730	EXPEDITED (15-DAY)		HO	IE-OTSUKA- DJ20082802		26 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block Complete	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14540896	EXPEDITED (15-DAY)		HO	BE-OTSUKA- DJ20062354		17 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Galactorrhoea	Abilify			S	Oral	15 Mg, Unk		Otsuka

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Solian	S	Oral	600 Mg, Unk	Not Reported
Lexapro	S	Oral	10 Mg, Qd	Not Reported
Sipralexa	C	Unknown	Unk	Not Reported
Trazolan	C	Unknown	100 Mg, Qd	Not Reported
Xanax	C	Unknown	25 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14540950	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-2017_024917		< 1 DAY	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Abilify			S	Transplacental	1 Df, Qd (1 Df: 10-20mg)		Otsuka
	Dafalgan			S	Transplacental	1 G, Bid		Not Reported
	Seroquel			S	Transplacental	1 Df: 50 Mg Per Day Till Beginning Of Pregnancy Later 100 Mg Per Day And 25 Mg In Reserve		Not Reported
	Cipralex			S	Transplacental	20 Mg, Qd		Not Reported
	Cipralex			S	Transplacental	10 Mg, Qd		Not Reported
	Stilnox			S	Transplacental	10 Mg, Qd		Not Reported
	Stilnox			S	Transplacental	12.5 Mg, Qd		Not Reported
	Lamictal			S	Transplacental	150 Mg, Qd		Not Reported
	Temesta (Lorazepam)			S	Transplacental	1 Mg, Qd (In Reserve 1mg 4 Times/Day)		Not Reported
	Brufen			S	Transplacental	400 Mg, Tid		Not Reported
	Lyrica			S	Transplacental	100 Mg, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541114	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20110308			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour;	Abilify			S	Oral	10 Mg, Unk		Otsuka

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disinhibition; Hypomania; Initial Insomnia; Libido Increased; Logorrhoea; Sexually Inappropriate Behaviour	Abilify Abilify Seroplex Seroplex Lexapro Lexapro Xanax	S S S S S S C	Oral Oral Oral	Unk Unk Also 20mg/Day Reduced To 10mg/Day From 07oct10 1 Mg, Qd (Before Jun10 Also :5mg Dosageg:1-3 Tabs)	Otsuka Otsuka Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541133	EXPEDITED (15-DAY)		LT, OT	FR-OTSUKA-DJ20112408		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Status Epilepticus	Abilify			S	Oral	30 Mg, Unk		Otsuka
	Seroplex			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20mg 1 Df =2 Scored Film-Coated Tabs,Long Term To 20mar11		Not Reported
	Seresta			C	Oral	Unk		Not Reported
	Depamide			C	Unknown	Unk		Not Reported
	Gardenal			C	Oral	Unk		Not Reported
	Gardenal			C	Oral	Unk		Not Reported
	Keppra			C	Oral	500 Mg, Unk		Not Reported
	Omix			C	Oral	Unk		Not Reported
	Noctran			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541156	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ20107147		22 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Poisoning Deliberate	Abilify	S	Oral	Unk	Otsuka
	Seroplex	S	Oral	Unk	Not Reported
	Seresta	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541282	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20104518		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Abilify			S	Oral	5 Mg, Unk		Otsuka	
	Xanax			S	Unknown	0.5 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported	
	Coumadin			C	Unknown	5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541332	EXPEDITED (15-DAY)		OT	DE-OTSUKA-DJ20103638		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Generalised Oedema	Abilify			S	Oral	5 Mg, Unk		Otsuka	
	Quilonum			S	Oral	Unk		Not Reported	
	Cipralext			S	Oral	Unk		Not Reported	
	Lexapro			S	Oral	Taken Before 06apr2010		Not Reported	
	Lithium			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541345	EXPEDITED (15-DAY)		HO, OT	GB-OTSUKA-DJ20095729		37 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Body Temperature Increased;	Abilify			S	Oral	30 Mg, Unk		Otsuka	
	Clozaril			S	Oral	100 Mg, Unk		Not Reported	

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Cerebrovascular Accident;	Diazepam	S	Oral	Unk	Not Reported
Diarrhoea Infectious;	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
Dizziness; Fatigue;					
Headache; Heart Rate					
Increased; Malaise;					
Nausea; Vomiting					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541489	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20113089			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Sclerosis; Overdose; Suicide Attempt	Abilify			S	Unknown	Unk		Otsuka
	Trazodone Hcl			S	Unknown	Half A Bottle		Not Reported
	Lexapro			S	Unknown	Half A Bottle		Not Reported
	Copaxone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541507	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ20100128		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Chondromalacia; Hepatitis; Obstructive Airways Disorder; Osteoarthritis; Pneumonia; Umbilical Hernia	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Lamictal			S	Unknown	100 Mg, Bid		Not Reported
	Lamictal			S	Unknown	25mg Bid (1x1wk,Bidx2wk)		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported
	Lexapro			S	Oral	Unk		Not Reported
	Xanax			S	Unknown	0.5 Mg, Prn		Not Reported
	Imdur			C	Unknown	Unk		Not Reported
	Nexium			C	Unknown	Unk		Not Reported
	Potassium			C	Unknown	Unk		Not Reported

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Wellbutrin	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Requip	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Effexor	C	Unknown	Unk	Not Reported
Prozac	C	Unknown	Unk	Not Reported
Paxil	C	Unknown	Unk	Not Reported
Glucophage	C	Unknown	Unk	Not Reported
Actos	C	Unknown	Unk	Not Reported
Amaryl	C	Unknown	Unk	Not Reported
Lopressor	C	Unknown	Unk	Not Reported
Norvasc	C	Unknown	Unk	Not Reported
Asa	C	Unknown	Unk	Not Reported
Multiple Vitamins	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541516	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20104644			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Rash	Abilify			S	Oral	Unk		Otsuka
	Atenolol			S	Unknown	Unk		Not Reported
	Ferrous Sulfate			S	Unknown	Unk		Not Reported
	Feldene			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Digoxin			S	Unknown	Unk		Not Reported
	Zyrtec			S	Oral	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported

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Norvir	S	Oral	Unk	Not Reported
Diphenhydramine	S	Unknown	Unk	Not Reported
Loperamide	S	Unknown	Unk	Not Reported
Atrovent	S	Unknown	Unk	Not Reported
Cozaar	S	Oral	Unk	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Epogen	S	Unknown	Unk	Not Reported
Carvedilol	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Lactose	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541527	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20102951		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oesophageal Spasm	Abilify			S	Oral	5 Mg, Unk		Otsuka	
	Abilify			S				Otsuka	
	Abilify			S				Otsuka	
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported	
	Seroquel			S	Unknown	100 Mg, Bid		Not Reported	
	Daytrana			S	Unknown	Patch		Not Reported	
	Clonidine			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541582	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-DJ20084398		50 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Abilify			S				Otsuka	
	Anafranil			S	Oral	50 Mg, Qd		Not Reported	

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	Seroplex		S	Oral	10 Mg, Qd		Not Reported		
	Tercian		S	Oral	100 Mg, Qd		Not Reported		
	Tercian		S				Not Reported		
	Lexapro		S	Oral	10 Mg, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541944	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121209		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Unilateral	Abilify			S	Oral	1 Mg, Unk		Otsuka	
	Lipitor			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Xanax			S	Unknown	0.5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541949	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20122139		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Oedema Due To Cardiac Disease; Pericardial Effusion; Weight Increased	Abilify			S	Oral	2 Mg, Unk		Otsuka	
	Celexa			S	Oral	60 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Effexor			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541957	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121415			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombosis	Abilify			S	Unknown	5 Mg, Unk		Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541960	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20121356			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Hypertension; Wrong Technique In Product Usage Process	Abilify			S	Oral	1 Mg, Unk		Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14541985	EXPEDITED (15-DAY)		DS	AT-OTSUKA-DJ20122876		20 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Spinal Disorder; Weight Increased	Abilify			S	Unknown	15 Mg, Unk		Otsuka	
	Abilify			S				Otsuka	
	Cipralex			S	Unknown	Unk		Not Reported	
	Quilonorm			S	Unknown	Unk		Not Reported	
	Quilonorm			S				Not Reported	
	Quetiapine Fumarate			S	Unknown	Unk		Not Reported	
	Quetiapine Fumarate			S				Not Reported	
	Zeldox			S	Unknown	Unk		Not Reported	
	Zeldox			S				Not Reported	
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Trittico			C	Unknown	150 Mg, Qd		Not Reported	
	Euthyrox			C	Unknown	Unk		Not Reported	
	Pantoloc			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542013	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ20129784		51 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Angle Closure Glaucoma	Abilify	S	Oral	15 Mg, Unk	Otsuka
	Loxapac	S	Oral	Unk	Not Reported
	Risperdal	S	Oral	12 Mg, Qd	Not Reported
	Parkinane	S	Oral	Unk	Not Reported
	Clopixol	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	40 Mg, Qd	Not Reported
	Trivastal	C	Unknown	Unk	Not Reported
	Valium	C	Unknown	Unk	Not Reported
	Levothyrox	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542035	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ201303162		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Mania; Pressure Of Speech	Abilify			S	Unknown	5 Mg, Unk		Otsuka	
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542123	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ201303700		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Rash; Sleep Apnoea Syndrome	Abilify			S	Oral	10 Mg, Unk		Otsuka	
	Seroplex			S	Oral	Unk		Not Reported	
	Zyprexa			S	Unknown	Unk		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542213	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201300088		57 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hyponatraemia	Abilify			S	Oral	10 Milligram 1 Day		Otsuka
	Atacand			S	Oral	16 Milligram 1 Day		Not Reported
	Seroplex			S	Oral	5 Milligram 1 Day		Not Reported
	Depakote			S	Unknown	750 Milligram 1 Day		Not Reported
	Depakote			S	Unknown	1 Gram 1 Day		Not Reported
	Depakote			S	Unknown	500 Milligram 1 Day		Not Reported
	Lexapro			S	Oral	Film Coated Tabs		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542229	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20126877		20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Depression; Expired Product Administered; Feeling Jittery; Mania; Muscle Twitching; Wrong Technique In Product Usage Process	Abilify			S	Oral	1 Df, Unk		Otsuka
	Lithium			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542264	EXPEDITED (15-DAY)		OT	US-OTSUKA-DJ20125943			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Triglycerides Increased; Constipation; Diarrhoea; Ejaculation Disorder; Libido Decreased; Muscle Spasms; Sleep Disorder; Suicidal Ideation; Thirst; Urinary Retention	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Chantix			S	Unknown	Unk		Not Reported
	Geodon			S	Unknown	40 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Xanax			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	1 Df = 20/25 Mg/Daily		Not Reported

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16-Feb-2018	14542271	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ20115156		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Cerebral	Abilify			S	Oral	15 Mg, Unk		Otsuka	
Haematoma;	Seroplex			S	Oral	Unk		Not Reported	
Cerebrovascular Accident;	Parkinane			S	Oral	Unk		Not Reported	
Fall; Hemiplegia	Lexapro			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542366	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20127159			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Feeling	Abilify			S	Unknown	20 Mg, Unk		Otsuka	
Abnormal; Knee	Lexapro			S	Unknown	Unk		Not Reported	
Arthroplasty; Pain; Wrong									
Technique In Product									
Usage Process									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542478	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ201404958		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State;	Abilify			S	Oral	5 Mg, Unk		Otsuka	
Memory Impairment;	Abilify			S				Otsuka	
Myocardial Infarction; Off	Lexapro			S	Unknown	Unk		Not Reported	
Label Use	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542577	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-DJ201400835			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Adverse Event; Dissociation; Feeling Abnormal; Myalgia; Panic Attack; Suicidal Ideation	Abilify	S	Unknown	7.5 Mg, Unk	Otsuka
	Lexapro	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542670	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ201400616		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dysarthria; Off Label Use	Abilify			S	Oral	15 Mg, Unk		Otsuka	
	Seroplex			S	Oral	10 Mg, Unk		Not Reported	
	Lexapro			S	Oral	Seroplex 10 Mg, Scored Film-Coated Tablet		Not Reported	
	Valium			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542687	EXPEDITED (15-DAY)		HO	FR-OTSUKA-DJ201406511		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pyrexia; Renal Failure; Rhabdomyolysis	Abilify			S	Unknown	10 Mg, Unk		Otsuka	
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported	
	Mianserin			S	Oral	60 Mg, Unk		Not Reported	
	Seroplex			S	Unknown	20 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	In Morning		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542688	EXPEDITED (15-DAY)		LT	FR-OTSUKA-DJ201400090		20 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Liver Injury; Mydriasis; Rhabdomyolysis	Abilify			S	Unknown	Unk		Otsuka	
	Paracetamol			S	Unknown	Unk		Not Reported	

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Zolpidem	S	Unknown	Unk	Not Reported
Paroxetine	S	Unknown	Unk	Not Reported
Hept-A-Myl	S	Unknown	Unk	Not Reported
Cymbalta	S	Unknown	Unk	Not Reported
Lamotrigine	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Agomelatine	S	Unknown	Unk	Not Reported
Avlocardyl	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542703	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ201407883		12 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Cyst; Drug Level Above Therapeutic; Headache; Mania; Off Label Use; Unevaluable Event; Weight Increased	Abilify			S	Oral	3 Mg, Unk		Otsuka
	Abilify			S				Otsuka
	Lexapro			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542704	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201406274		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gambling Disorder; Persistent Depressive Disorder; Suicidal Ideation	Abilify			S	Oral	15 Mg, Unk		Otsuka
	Lamictal			S	Oral	1 Df: 200 To 300 Mg		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Nozinan			S	Oral	100 Mg, Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, Unk		Not Reported

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16-Feb-2018	14542733	EXPEDITED (15-DAY)		OT	US-OTSUKA-J201408697		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Diabetes Mellitus	Abilify			S	Unknown	Unk		Otsuka	
	Aripiprazole			S	Unknown	Unk		Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14542739	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-DJ201400327		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Overdose; Seizure; Suicide Attempt	Abilify			S	Oral	1 Df, Unk		Otsuka	
	Xanax			S	Oral	Unk		Not Reported	
	Theralene			S	Unknown	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Tercian			S	Unknown	Unk		Not Reported	
	Depakote			S	Oral	Unk		Not Reported	
	Teralithe			S	Oral	Unk		Not Reported	
	Lexapro			S		1 Df, Unk		Not Reported	
	Lysanxia			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2018	14544835	EXPEDITED (15-DAY)		HO, LT	ES-AUROBINDO-AUR-APL-2018-007895		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma	Escitalopram			S	Oral	Unk		Aurobindo	
	Enoxaparina			S	Subcutaneous	Unk		Not Reported	
	Sintrom			S	Oral	1 Mg, Unk		Not Reported	

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17-Feb-2018	14559879	DIRECT		OT			< 1 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankyloglossia Congenital; Jaundice; Lip Disorder	Latuda			S		5 - 18 Wks Gestation		Not Reported	
	Lamictal			S		0 - 18 Wks Gestation		Not Reported	
	Lexapro			S		5 - 18 Wks Gestation		Not Reported	
	Humira			S		0 - 39 Wks Gestation		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2018	14559880	DIRECT		OT			33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gestational Diabetes; Premature Labour	Latuda			S		5 Wks - 18 Wks		Not Reported	
	Lamictal			S		Conception - 18 Wks		Not Reported	
	Lexapro			S		5 Wks - 18 Wks		Not Reported	
	Humira			S		Conception - Delivery		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2018	14554653	DIRECT		OT			28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Panic Attack; Product Substitution Issue	Escitalopram Oxalate			S	Oral	Quantity:1.5 Tablet(S);		Aurobindo	
	Vitamin D Nos			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14265388	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1770344US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Qd	Allergan
	Amitriptyline	S	Unknown	5 Mg, Qd	Not Reported
	Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
	Amitriptyline	S	Unknown	25 Mg, Qd	Not Reported
	Paracetamol	S	Unknown	3 Df, Qd	Not Reported
	Amlodipine	S	Unknown	1 Df, Qd	Not Reported
	Simvastatin	S	Unknown	40 Mg, Qd	Not Reported
	Simvastatin	S	Unknown	20 Mg, Unk	Not Reported
	Topiramate	S	Unknown	50 Mg, Qd	Not Reported
	Topiramate	S	Unknown	0.5 Df, Qd	Not Reported
	Paracetamol, Tramadol	S	Unknown	3 Df, Qd	Not Reported
	Paracetamol, Tramadol	S		1 Df, Qd	Not Reported
	Naproxen	S	Unknown	1 Df, Bid	Not Reported
	Hydrochlorothiazide, Enalapril Maleate	S	Unknown	1 Df, Qd	Not Reported
	Diazepam	S	Unknown	0.5 Df, Qd	Not Reported
	Glibenclamide	S	Unknown	2 Df, Qd	Not Reported
	Omeprazole	S	Unknown	1 Df, Qd	Not Reported
	Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
	Diazepam, Sulpiride	S	Unknown	Unk, Qd	Not Reported
	Metoclopramide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14325856	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1773533US		41 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pulmonary Embolism; Thrombosis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Tirosint			S	Unknown	75 Mg, Qd		Not Reported
	Aubagio			S	Oral	14 Mg, Qd		Not Reported
	Xanax			S	Unknown	Unk		Not Reported

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19-Feb-2018	14440594	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1769176US		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Furosemide			S	Oral	30 Mg, Qd		Not Reported	
	Terbutaline			S	Respiratory (inhalation)			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported	
	Xarelto			S	Oral			Not Reported	
	Metformin			S	Oral			Not Reported	
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported	
	Diazepam			S	Oral	3 Times A Day If Needed		Not Reported	
	Tavanic			S	Oral	250 Mg, Bid		Not Reported	
	Nefopam			S	Oral	1 Df, Tid		Not Reported	
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported	
	Dafalgan			S	Oral	1000 Mg, Tid		Not Reported	
	Bisoprolol			S	Oral	1.25 Mg, Qd		Not Reported	
	Diffu K			S	Oral	3 Df, Bid		Not Reported	
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported	
	Pantoprazole			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14545977	EXPEDITED (15-DAY)		HO	FR-KRKA, D.D., NOVO MESTO-2042205		91 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Lansoprazole			S	Oral			Krka Dd Novo Mesto	
	Escitalopram			S	Oral			Not Reported	

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	Gliclazide	S	Oral						Not Reported
	Stilnox 10 Mg	S	Oral						Not Reported
	Efferalgan	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546988	NON-EXPEDITED			US-PFIZER INC-2018067988		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Oxaprozin			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547471	EXPEDITED (15-DAY)		HO, LT	JP-MYLANLABS-2018M1011657			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Drug Interaction; Foetal Exposure During Pregnancy; Hypopnoea; Irregular Breathing; Respiratory Muscle Weakness	Escitalopram			S	Transplacental	Since 34th Weeks Of Gestation		Not Reported	
	Ethyl Loflazepate			S	Transplacental	Since 34th Weeks Of Gestation		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547802	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1808319US		14 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Off Label Use; Toxicity To Various Agents; Vertigo	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Dafalgan			S	Oral			Not Reported	
	Lumirelax (Methocarbamol)			S	Oral			Not Reported	
	Dafalgan Codeine			S	Oral			Not Reported	

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19-Feb-2018	14547964	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1808308US		37 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Postpartum Haemorrhage; Pregnancy; Premature Delivery	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Speciafoldine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14549412	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01916			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Duloxetine			S	Unknown	Unk		Not Reported	
	Lamotrigine			S	Unknown	Unk		Alkem	
	Olanzapine			S	Unknown	Unk		Alkem	
	Risperidone			S	Unknown	Unk		Not Reported	
	Quetiapine Fumarate			S	Unknown	Unk		Alkem	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14549413	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM-2017-01917			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	

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	Duloxetine	S	Unknown	Unk	Not Reported
	Lamotrigine	S	Unknown	Unk	Alkem
	Olanzapine	S	Unknown	Unk	Alkem
	Risperidone	S	Unknown	Unk	Not Reported
	Quetiapine Fumarate	S	Unknown	Unk	Alkem

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14549414	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM- 2017-01915			Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Citalopram			S	Unknown	Unk		Not Reported
	Zolpidem Pharmacor			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Alkem
	Olanzapine			S	Unknown	Unk		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14549435	EXPEDITED (15-DAY)		OT	BR-TORRENT- 00004285		53 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Surgery; Urinary Incontinence	Espran			S	Oral	One Tablet Daily In The Morning		Torrent
	Rivotril			C	Oral	1 Tab (Morning) 1 Tab (Night)		Unknown
	Neuleptil			C	Oral	1 Tab At Night		Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14550150	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006611			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Drug Interaction; Memory Impairment; Prescribed Underdose	Nuplazid			S	Unknown	17 Mg, Qd		Acadia Pharmaceuticals	
	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals	
	Nuplazid			S				Acadia Pharmaceuticals	
	Pramipexole			C	Oral	2.5 Mg, Qhs		Acadia Pharmaceuticals	
	Clonazepam			C	Oral	0.5 Df, Qhs		Not Reported	
	Clonazepam			C	Oral	0.25 Mg, Qam		Not Reported	
	Synthroid			C	Oral	100 Mcg, Qd		Not Reported	
	Benicar			C	Oral	10 Mg, Qd		Not Reported	
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported	
	Aspirin			C	Oral	81 Mg, Qd		Not Reported	
	Carbidopa/Levodopa			C	Oral	50-200mg-1tab		Not Reported	
	Crestor			C	Oral	5 Mg, M/W/F Only At Hs		Not Reported	
	Aricept			S	Oral	10 Mg, Qd		Not Reported	
	Aricept			S	Unknown	Unk		Not Reported	
	Multivitamin			C				Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14550194	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006669			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Euphoric Mood; Libido Increased; Psychomotor	Nuplazid			S	Unknown	34 Mg, Qd		Acadia Pharmaceuticals	
	Nuplazid			S				Acadia	

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Hyperactivity	Nuplazid	S							Pharmaceuticals Acadia
	Lexapro	S	Unknown						Pharmaceuticals Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	13413209	EXPEDITED (15-DAY)		HO, OT	AU-009507513-1703AUS014177		21 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered; Serotonin Syndrome	Mirtazapine			S	Oral	870 Mg, Unk		Merck
	Desvenlafaxine			S		500 Mg, Unk		Not Reported
	Escitalopram			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14185768	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-43477		90 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyponatraemia	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	5 Mg, Daily		Aurobindo
	Eliquis			C	Oral	2 Df, Unk		Not Reported
	Esidrex			S	Oral	0.5 Df, Daily		Not Reported
	Bisocor			C	Oral	2 Df, Unk		Not Reported
	Imovane			C	Oral	0.5 Df, Daily		Not Reported
	Levothyrox			C	Oral	112.5 U/G, Unk		Not Reported
	Levothyrox			C				Not Reported
	Ramipril Mylan			S	Oral	5 Mg, Daily		Not Reported
	Speciafoldine			C	Oral	1 Df, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14330267	EXPEDITED (15-DAY)		OT	ES-CANTON LABORATORIES, LLC-2037833			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depression; Dizziness; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Naprosyn	S	Unknown	Canton Laboratories
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Amlodipine	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Diazepam And Sulpride	S	Unknown	Not Reported
	Enalapril Maleate And Hydrochlorothiazide	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Glibenclamide	S	Unknown	Not Reported
	Lormetazepam	S	Unknown	Not Reported
	Omeprazole	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Tramadol Hydrochloride And Paracetamol	S	Unknown	Not Reported
	Metoclopramide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14448867	EXPEDITED (15-DAY)		OT	AT-TEVA-2018-AT- 848642		46 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Headache; Pneumonia	Venlafaxine Hydrochloride			S	Unknown			Not Reported	
	Brintellix			S	Oral			Not Reported	
	Brintellix			S	Oral			Not Reported	
	Brintellix			S	Oral			Not Reported	
	Brintellix			S	Oral			Not Reported	
	Brintellix			S	Oral			Not Reported	
	Cipralext			S	Oral	Unknown		Not Reported	
	Duloxetine Hydrochloride			S	Unknown			Teva	

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Trittico Ret.	C	Oral		Not Reported
Trittico Ret.	C	Oral	Since Months	Not Reported
Trittico Ret.	C	Oral		Not Reported
Trittico Ret.	C	Oral		Not Reported
Oleovit D3	C	Oral	N/A	Not Reported
Aprednisolon	C	Oral		Not Reported
Cal-D-Vita	C	Oral	Since Years	Not Reported
Curocef	C	Unknown		Not Reported
Curocef	C	Unknown		Not Reported
Zoldem	C	Oral		Not Reported
Zoldem	C	Oral		Not Reported
Zoldem	C	Oral	Since Months	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14488317	EXPEDITED (15-DAY)	HO		ES-ALLERGAN-1804295US		71 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Chronic Gastritis; Condition Aggravated; Depressed Mood; Drug Ineffective; Dysphagia; Feeding Disorder; Gait Disturbance; Irritability; Judgement Impaired; Loss Of Personal Independence In Daily Activities; Parkinsonism; Psychiatric Symptom; Psychomotor Retardation; Speech Disorder; Therapeutic Product Effect Incomplete; Tremor; Vitamin B12 Deficiency; Weight Decreased	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported
	Aripiprazole			S	Unknown	10 Mg, Unk		Not Reported
	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14516230	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT021144		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Sopor; Suicide Attempt	Escitalopram			S	Oral	30 MI, Unk		Not Reported	
	Alprazolam			S	Oral	16 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14552402	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2018SE18722		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Quetiapine			S	Oral			Zeneca	
	Escitalopram			S	Oral	270.0mg Once/Single Administration		Not Reported	
	Etilotx			S	Oral	9.0df Once/Single Administration		Not Reported	
	Carbolithium			S	Oral	5.0df Once/Single Administration		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14554382	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018049112		78 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Aspavor			S	Oral	20 Mg, Unk		Pfizer	
	Lyrica			S	Oral	150 Mg, Unk		Pfizer	
	Lexamil			S	Oral	10 Mg, Unk		Not Reported	
	Lancap			S	Oral	30 Mg, Unk		Not Reported	
	Betacor /00008501/			S	Oral	5 Mg, Unk		Not Reported	
	Be-Tabs Prednisone			S	Oral	5 Mg, Unk		Not Reported	
	Unat /01036501/			S	Oral	5 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14554528	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-856961		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax	Not Reported
	Rulid			S	Oral				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14554590	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018070723		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Drug Interaction	Amiodarone Hcl			S	Oral	Unk		Pfizer	Not Reported
	Escitalopram Oxalate			S	Oral	Unk			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14554608	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-856849		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Milligram Daily;		Ivax	Not Reported
	Ebrantil			C	Unknown				
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet		Not Reported	Not Reported
	Valsartan			C	Unknown				
	Folsan			C	Transplacental	0.4 Mg/Day (Mother)		Not Reported	Not Reported
	Ramilich			C	Unknown	10 Mg/Day (Father)		Not Reported	
	Dekristol			C	Unknown	20000 Iu/Day (Every Second Week) (Father)		Not Reported	Not Reported
	Paracetamol			C	Transplacental			Not Reported	
	Bicanorm			C	Unknown			Not Reported	

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Atozet	C	Unknown	40 Mg/Day / 10 Mg/D (Father) / Probably Either Atozet Or Simvastatin	Not Reported
Ass 100	C	Unknown	100 Mg/Day (Father)	Not Reported
Amlodipine	C	Unknown	10 Mg/Day (Father)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	7990218	EXPEDITED (15-DAY)		OT	GB-TEVA-285135ISR		21 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Disturbance In Social Behaviour; Oculogyric Crisis	Risperidone			S	Oral	0.25-1.5mg		Pliva
	Risperidone			S	Oral			Pliva
	Risperidone			S	Oral	1.5 Milligram Daily;		Pliva
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported
	Escitalopram			S	Oral	20 Milligram Daily;		Not Reported
	Escitalopram			S		Was Reduced And Then Stopped		Not Reported
	Diazepam			C		1-2 Mg		Not Reported
	Diazepam			C		4 Mg		Not Reported
	Aripiprazole			C		5 Milligram Daily; Every Morning		Not Reported
	Aripiprazole			C		5 Milligram Daily;		Not Reported
	Procyclidine			C		5 Milligram Daily;		Not Reported
	Procyclidine			C		7.5 Milligram Daily;		Not Reported
	Procyclidine			C				Not Reported
	Orphenadrine			C		150 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14473791	EXPEDITED (15-DAY)		HO, OT	FR-DRREDDYS-GER/FRA/18/0095929		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cerebrovascular Accident	Fondaparinux	S	Subcutaneous		Not Reported
	Xeloda	S	Oral	Non Renseign�e	Not Reported
	Novorapid	S	Subcutaneous	Non Renseign�e	Not Reported
	Primperan	S	Oral	Non Renseign�e	Not Reported
	Lipanthyl	S	Oral	Non Renseign�e	Not Reported
	Pantoprazole	S	Oral	Non Renseign�e	Not Reported
	Escitalopram	S	Oral	Non Renseign�e	Not Reported
	Abasaglar	S	Subcutaneous	Non Renseign�e	Not Reported
	Movicol	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14488629	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-851020		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown			Ivax	
	Aripiprazole			S	Unknown	10 Milligram Daily;		Teva	
	Fluvoxamine			S	Unknown	200 Milligram Daily;		Not Reported	
	Clomipramine			S	Unknown	150 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14556553	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2018-004439		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Hyponatraemia	Enalapril 20 Mg			S	Oral	28 Tablets		Not Reported	
	Heipram 10 Mg			S	Oral	Compressed Films With Film Efg , 56 Tablets		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14557671	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018066399		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Pulmonary Embolism; Pulmonary Infarction	Xanax	S		Unk	Pfizer
	Tirosint	S		75 Ug, 1x/Day	Not Reported
	Aubagio	S	Oral	14 Mg, 1x/Day	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14559343	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809593US		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Ceftriaxone Sodique			S	Unknown	Unk, Unknown		Not Reported
	Risperidone			S	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14559348	EXPEDITED (15-DAY)		CA	NL-ALLERGAN-1809603US			Unknown	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Oral Malformation; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Folic Acid			C	Transplacental	Unk, Unknown		Not Reported
	Davitamon			C	Transplacental	Unk, Unknown		Not Reported
	Cyklokapron			C	Transplacental	Unk, Unknown		Not Reported
	Calcium			C	Transplacental	Unk, Unknown		Not Reported
	Carbonate/Colecalciferol							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14560345	EXPEDITED (15-DAY)		HO, LT, OT	TR-VISTAPHARM, INC.-VER201712-001467		24 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Hypernatraemia; Hypocalcaemia; Intentional Overdose; Leukopenia; Respiratory	Valproic Acid			S	Oral			Vistapharm
	Olanzapine			S	Oral			Not Reported

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Depression; Suicide Attempt; Toxicity To Various Agents	Escitalopram	S	Oral							Not Reported
	Fluoxetine	S	Oral							Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14560905	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018010044			Unknown	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Abuse; Off Label Use; Sopor; Toxicity To Various Agents	Escitalopram			S	Oral	270 Mg, Unk		Macleods		
	Quetiapine			S	Oral	Unk		Macleods		
	Carbolithium 300 Mg Rigid Capsules			S	Oral	5 Df, Unk		Not Reported		
	Etilton 200 Mg Tablets			S	Oral	9 Df, Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14562573	EXPEDITED (15-DAY)		OT	FR-JNJFOC- 20180227778		72 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Diverticulitis; Lower Gastrointestinal Haemorrhage	Xarelto			S	Oral			Not Reported		
	Escitalopram			S	Unknown			Not Reported		
	Androtardyl			C	Unknown			Not Reported		
	Requip			C	Unknown			Not Reported		
	Sinemet			C	Unknown			Not Reported		
	Zofenil			C	Unknown			Not Reported		
	Augmentin			C	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14562933	EXPEDITED (15-DAY)		OT	GB-ALLERGAN- 1809608US		69 YR	Female	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stevens-Johnson Syndrome	Citalopram Hydrobromide - Bp	S	Unknown	Unk	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
	Cabergoline	S	Unknown	Unk	Not Reported
	Carbidopa	S	Unknown	Unk	Not Reported
	Stalevo	S	Unknown	Unk	Not Reported
	Entacapone	S	Unknown	Unk	Not Reported
	Levodopa	S	Unknown	Unk	Not Reported
	Trimethoprim	S	Unknown	Unk	Not Reported
	Septtrin	S	Unknown	Unk	Not Reported
	Co-Beneldopa	C	Unknown		Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Duloxetine Hydrochloride	C	Unknown	Unk	Not Reported
	Adcal D3	C	Unknown	Unk	Not Reported
	Rivastigmine Hydrogen Tartrate	C	Transdermal	Unk	Not Reported
	Quetiapine	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14563255	DIRECT		DS			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Twitching; Nerve Injury	Lexapro, 10mg Mg			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14563638	NON-EXPEDITED		HO	US-AMNEAL PHARMACEUTICALS- 2018AMN00076		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	15 Mg, 1x/Day		Amneal
	Escitalopram			S	Unknown	20 Mg, 1x/Day		Amneal

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram	S	Oral	10 Mg, 1x/Day	Amneal
Aripiprazole	S	Oral	10 Mg, 1x/Day	Not Reported
Aripiprazole	S	Oral	5 Mg, 1x/Day	Not Reported
Candesartan	S	Unknown	16 Mg, 1x/Day	Not Reported
Risperidone	C	Unknown	2 Mg, 1x/Day	Not Reported
Risperidone	C	Oral	1.5 Mg, 1x/Day	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown		Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Amisulpride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14566619	DIRECT	Y	OT			47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depression; Fatigue; Loss Of Personal Independence In Daily Activities; Product Substitution Issue	Escitalopram 20mg Tabs Unknown			S	Oral	20mg 1 Q Am Po	1 MTH	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	11966717	EXPEDITED (15-DAY)		DE	CA-FRI-1000082253		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiomegaly; Drug Therapy; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Syncope; Therapeutic Product Effect Increased	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Qd		Allergan
	Citalopram Hydrobromide - Bp			S				Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Ativan			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diltiazem	C	Unknown	Unk	Not Reported
Ethanol	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	13526163	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017004894			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram 10mg Tablet			S	Oral	10 Mg, Qd		Macleods
	Escitalopram 10mg Tablet			S				Macleods
	Xanax			S	Oral	0.25 Mg, Unk		Not Reported
	Xanax			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	13569657	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1721000US		55 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Overdose	Escitalopram Oxalate Unk			S	Oral	140 Mg, In Total		Allergan
	Lorazepam			S	Oral	20 Mg, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	13629865	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1723529US		50 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Use Disorder; Intentional Overdose; Intentional Self-Injury; Sopor	Escitalopram Oxalate - Bp			S	Oral	15 MI, Unk		Allergan
	Alprazolam			S	Oral	10 MI, Unk		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14034968	EXPEDITED (15-DAY)		HO	JP-ASTRAZENECA-2017SE99613		68 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duodenal Perforation	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 Dosage Form Two Times Daily		Not Reported	
	Nexium			S	Oral			Not Reported	
	Nexium			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Iguratimod			S	Oral			Not Reported	
	Iguratimod			S	Oral			Not Reported	
	Diclofenac Sodium			S	Oral			Not Reported	
	Prednisolone			S	Oral	4 Mg/Day, Three Times A Day		Not Reported	
	Prednisolone			S	Oral	4 Mg/Day, Three Times A Day		Not Reported	
	Calcium Lactate			C	Oral			Not Reported	
	Calcium Lactate			C	Oral			Not Reported	
	Eldecalcitol			C	Oral			Not Reported	
	Eldecalcitol			C	Oral			Not Reported	
	Minodronic Acid Hydrate			C	Oral			Not Reported	
	Micamlo			C	Oral			Not Reported	
	Ketoprofen			C	Transdermal	Optimal Dose, Dose Unknown, Every Day		Not Reported	
	Meropenem			C				Not Reported	
	Sennoside			C	Oral			Not Reported	
	Omeprazole Sodium			C				Not Reported	
	Elieten			C	Intravenous (not otherwise specified)			Not Reported	
	Antibiotics-Resistant Lactic Acid			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bacteriae	C	Oral		Not Reported
Bifidobacterium Bifidum	C	Oral	250.0mg Unknown	Not Reported
Mucodyne	C	Oral		Not Reported
Codeine Phosphate	C	Oral		Not Reported
Meylon	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14541784	EXPEDITED (15-DAY)		DS, HO	DE-TEVA-2018-DE-858284		57 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Chest Pain; Diarrhoea; Gait Disturbance; Haematoma; Haemorrhage; Muscle Disorder; Myalgia; Nerve Injury; Staphylococcal Infection; Walking Aid User	Valproic Acid			S	Unknown	1800 Milligram Daily;		Teva
	Ciprallex			S	Unknown	5 Milligram Daily;		Not Reported
	Ibuprofen			C	Unknown	2400 Milligram Daily;		Not Reported
	Xarelto			C	Unknown	10 Milligram Daily;		Not Reported
	Novaminsulfon			C	Unknown	1500 Milligram Daily;		Not Reported
	Cefazolin			C	Unknown	2 G, Unk		Not Reported
	Ass			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565136	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-008964		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Escitalopram			S	Oral	Non Renseignée ()		Aurobindo
	Pantoprazole			S	Oral	Non Renseignée ()		Aurobindo
	Primperan			S	Oral	Non Renseignée ()		Not Reported
	Lipanthyl			S	Oral	Non Renseignée ()		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignée ()		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Non Renseignée ()		Not Reported
	Xeloda			S	Oral	Non Renseignée ()		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abasaglar	S	Subcutaneous	Non Renseignée ()	Not Reported
Movicol /01749801/	S	Oral	Non Renseignée ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565365	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2018-009384		69 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Citalopram			S	Unknown	()		Aurobindo
	Escitalopram			S	Unknown	()		Aurobindo
	Trimethoprim			S	Unknown	()		Not Reported
	Entacapone			S	Unknown	()		Not Reported
	Levodopa			S	Unknown	()		Not Reported
	Septrin			S	Unknown	()		Not Reported
	Stalevo /01530202/			S	Unknown	()		Not Reported
	Duloxetine			C				Not Reported
	Co-Beneldopa			C				Not Reported
	Macrogol			C				Not Reported
	Cabergoline			S	Unknown	()		Not Reported
	Carbidopa			S	Unknown	()		Not Reported
	Adcal D3			C				Not Reported
	Rivastigmine			C				Not Reported
	Quetiapine			C		25 Mg, Unk		Not Reported
	Paracetamol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565497	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2018IT05314			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Abnormal; Intentional Overdose; Intentional Self- Injury; Nausea; Tremor	Escitalopram			S	Oral	200mg, In Total		Invagen

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565501	EXPEDITED (15-DAY)		DE	FR-CIPLA LTD.- 2018FR05962			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Subdural Haematoma	Escitalopram			S	Oral	5 Mg, Per Day		Invagen	
	Pradaxa			S	Oral	1 Df, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565726	EXPEDITED (15-DAY)		OT	IN-CIPLA (EU) LIMITED- 2018IN05428			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Employment; Memory Impairment; Suicidal Ideation; Treatment Failure	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen	
	Mirtazapine			S	Unknown	45 Mg, Per Day		Not Reported	
	Amitriptyline			S	Unknown	100 Mg, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565729	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US06048			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Drug Withdrawal Syndrome; Fear; Panic Attack; Product Size Issue	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Escitalopram			S				Invagen	
	B Complex /00322001/			C	Unknown	Unk, Qd		Not Reported	
	Magnesium			C	Unknown	Unk, Qd		Not Reported	
	Tylenol Pm			C	Unknown	Unk		Not Reported	
	Advil Pm /05810501/			C	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	0.5 Mg, Prn		Not Reported	
	Prozac			C	Unknown	10 Mg, Unk		Not Reported	
	Zoloft			C	Unknown	50 Mg, Unk		Not Reported	

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Zoloft	C	25 Mg, Unk, For A Week	Not Reported
Chamomile /00512601/	C	Unknown	Unk
Lavender /01649201/	C	Unknown	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565942	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-164390		91 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Lansoprazole			S	Oral	30 Mg, Daily		Sun
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Gliclazide			S	Oral	60 Mg, Daily		Not Reported
	Stilnox 10 Mg, Comprimé			S	Oral	1 Df, Daily		Not Reported
	Pelliculé Sécable							
	Efferalgan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566201	EXPEDITED (15-DAY)	CA		NL-AUROBINDO-AUR- APL-2018-009253			Unknown	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Oral Malformation	Escitalopram 10 Mg			S		1 Dd 1		Aurobindo
	Foliumzuur			C		Unk		Not Reported
	Davitamon			C		Unk		Not Reported
	Cyklokapron			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566600	EXPEDITED (15-DAY)	CA, OT		NL-MACLEODS PHARMACEUTICALS US LTD- MAC2018010241			Unknown	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram Oxalate	S	Transplacental	10 Mg, Qd, 1 Dd 1	Macleods
	Foliumzuur	C	Oral	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Cyklokapron	C	Oral	Unk, Use: Up To Ad 5 Weeks And From 12-12 Up To And Including 20-12 (Ad13 Weeks),	Not Reported
	Colecalciferol, Calcium Carbonate	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566864	EXPEDITED (15-DAY)		OT	GB-GLENMARK PHARMACEUTICALS- 2018GMK032292			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Citalopram Hydrobromide			S	Unknown	Unk		Glenmark
	Escitalopram			S	Unknown	Unk		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Carbidopa			S	Unknown	Unk		Not Reported
	Stalevo /01530202/			S	Unknown	Unk		Not Reported
	Entacapone			S	Unknown	Unk		Not Reported
	Levodopa			S	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Macrogol			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported
	Rivastigmine			C	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported

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Paracetamol			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566943	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809800US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Contusion; Feeling Abnormal; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Pallor; Prescribed Overdose; Psychomotor Skills Impaired; Pyrexia; Spinal Cord Neoplasm; Vertigo	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan	
	Fluanxol			S	Unknown	20 Mg, Qd		Not Reported	
	Fluanxol			S	Unknown	20 Mg, Qd		Not Reported	
	Fluanxol			S	Unknown	10 Mg, Qd		Not Reported	
	Solian			S	Unknown	50 Mg, Qd		Not Reported	
	Solian			S	Unknown	300 Mg, Qd		Not Reported	
	Seresta			S	Unknown	150 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14567010	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-009574		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Risperidone			S		Unk		Aurobindo	
	Escitalopram			S		Unk		Aurobindo	
	Ceftriaxone Sodium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14567961	EXPEDITED (15-DAY)		OT	SE-ASTRAZENECA-2018SE20938		59 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Nexium			S	Oral			Not Reported	
	Faslodex			S	Intramuscular			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Ibrance			S	Oral			Not Reported	

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Ibrance	S	Oral	Not Reported
Ibrance	S	Oral	Not Reported
Ibrance	S	Oral	Not Reported
Motilium	S	Oral	Not Reported
Motilium	S	Oral	Not Reported
Ondansetron	S	Oral	Not Reported
Risperidone	S	Oral	Not Reported
Imodium	S	Oral	Not Reported
Imovane	C		Not Reported
Calcimagon D3	C		Not Reported
Condrosulf	C		Not Reported
Euthyrox	C		Not Reported
Dafalgan	C		Not Reported
Irfen	C		Not Reported
Flector [Diclofenac Sodium]	C		Not Reported
Temgesic	C		Not Reported
Targin	C		Not Reported
Oxynorm	C		Not Reported
Movicol	C		Not Reported
Laxoberon	C		Not Reported
Clexane	C		Not Reported
Mycostatin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14572604	DIRECT					12 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Depression; Drug Ineffective; Manufacturing Materials Issue; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Walgreen
	Prevacid			C				Not Reported
	Zyrtec			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14573451	DIRECT		HO, OT			< 1 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Continuous Positive Airway Pressure; Respiratory Distress	Abilify 2mg	S	Dates Of Use 0-4 Wks	Not Reported
	Abilify 1 Mg/ML Oral Solution	S	Dates Of Use - 5-Delivery For Depression	Not Reported
	Lexapro 10 Mg	S	Dates Of Use - 0-Delivery For Depression	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14573532	DIRECT		HO, OT			< 1 DAY	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Jaundice; Premature Baby	Abilify 2 Mg			S		Dates Of Use - Co-4 Wks @ 2mg		Not Reported
	Abilify 1mg			S		Dates Of Use - 5-Delivery @ 1mg For Depression		Not Reported
	Lexapro 10 Mg			S		Dates Of Use (0-Delivery) For Depression		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14573538	DIRECT		HO			< 1 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus; Premature Baby; Respiratory Distress	Abilify			S		0 - 4 Wks 5 - Delivery		Not Reported
	Lexapro			S		0 - Delivery		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14573543	DIRECT		HO, OT			34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section; Foetal Growth Restriction; Multiple Pregnancy;	Abilify			S		0 - 4 Wks 5 - 33 Wks		Not Reported

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Premature Labour	Lexapro		S			0 - Delivery		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2018	14569504	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018010283			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 MI, Single		Macleods	
	Alprazolam			S	Oral	10 MI, Single		Not Reported	
	Esomeprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2018	14569505	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018010289			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	9761033	NON-EXPEDITED			US-PFIZER INC- 2013356177		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Arthrotec			S		Unk		Pfizer	
	Promethazine Hcl			S		Unk		Pfizer	
	Erythromycin			S				Pfizer	
	Codeine			S		Unk		Not Reported	
	Metamucil			S		Unk		Not Reported	
	Erythromycin Ethylsuccinate			S		Unk		Not Reported	

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	Buspar	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Ultracet	S	Unk	Not Reported
	Norco	S		Not Reported
	Phenergan	S		Not Reported
	Probiotica	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	13243640	EXPEDITED (15-DAY)		OT	PHHY2017ES024355		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Ondansetron			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Temozolomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	13497031	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017184429		51 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Xanax			S	Oral	0.25 Mg, Total		Pfizer
	Escitalopram			S	Oral	10 Mg, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14013130	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1754578US		20 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Ashwagandha			S	Oral	Unk, Prn		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

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Propranolol Hydrochloride	S	Oral	Unk	Not Reported
Lorazepam	S	Oral	Unk	Not Reported
Quetiapine Fumarate	S	Oral	Unk	Not Reported
Etizolam	C	Oral	Unk	Not Reported
Perospirone Hydrochloride Hydrate	C	Oral	Unk	Not Reported
Bromazepam	C	Oral	Unk	Not Reported
Tandospirone Citrate	C	Oral	Unk	Not Reported
Levomepromazine Maleate	C	Oral	Unk	Not Reported
Sulpiride	C	Oral	Unk	Not Reported
Mosapride Citrate Hydrate	C	Oral	Unk	Not Reported
Brotizolam	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14240220	EXPEDITED (15-DAY)		HO, OT	FR-SA-2017SA236468		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Alprazolam			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
						Form: Film Coated Divisible Tablet 250 Mg, 2x/Day (Bid)		
	Furosemide			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
						Form- Divisible Tablet 10		

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Diffu K	S	Oral	Mg, 3x/Day (Tid) Dose: 2 Df In Morning And 1 Df In Noon	Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Colchicine Opocalcium	S	Oral		Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)		Not Reported
Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
Xarelto	S	Oral		Not Reported
Xarelto	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14412531	EXPEDITED (15-DAY)	HO		JP-ALLERGAN- 1802864US		94 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block Complete; Dermatitis Allergic; Hypothyroidism	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Herbesser			S	Oral	100 Mg, Qd		Not Reported
	Diazepam			C	Oral	Unk, Qd		Not Reported
	Isosorbide Dinitrate			C	Oral	20 Mg, Bid		Not Reported
	Pitavastatin Calcium			C	Oral	1 Mg, Qd		Not Reported
	Primperan			C	Oral	5 Mg, Tid		Not Reported
	Dipyridamole			C	Oral	25 Mg, Tid		Not Reported
	Limaprost Alfadex			C	Oral	5 Mg, Tid		Not Reported
	Magnesium Oxide			C	Oral	500 Mg, Tid		Not Reported
	Bayaspirin			C	Oral	100 Mg, Qd		Not Reported
	Rabeprazole Na			C	Oral	10 Mg, Qd		Not Reported
	Alfacalcidol			C	Oral	1 Mg, Unk		Not Reported
	Candesartan			C	Oral	8 Mg, Qd		Not Reported
	Sodium Ferrous Citrate			C	Oral	50 Mg, Qd		Not Reported
	Amlodipine Od			C	Oral	2.5 Mg, Qd		Not Reported

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Thyradin S			C	Oral	50 Mg, Unk			Not Reported	
Ebastine			C	Oral	10 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14570330	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-164170		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Ranbaxy	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14570481	EXPEDITED (15-DAY)		OT	IT-ACCORD-063904		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Esomeprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14570837	EXPEDITED (15-DAY)		DE	SE-CIPLA LTD.- 2018SE07451			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Escitalopram			S	Unknown	15 Mg, Unk		Invagen	
	Anafranil			S	Unknown	50 Mg, Unk		Not Reported	
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14571517	EXPEDITED (15-DAY)		OT	SE-CIPLA LTD.- 2018SE07485			Unknown	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Fatigue; Hyperhidrosis; Premenstrual Syndrome; Sleep Disorder	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14573453	EXPEDITED (15-DAY)		HO	FR-SA-2018SA047972		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma; Overdose; Sinus Bradycardia	Plavix			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Zopiclone			S	Oral			Not Reported	
	Coveram			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Bisocce			S	Oral			Not Reported	
	Aldactazine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14573542	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2018078070		69 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Cabergoline			S		Unk		Pfizer	
	Trimethoprim			S	Unknown	Unk		Not Reported	
	Stalevo /01631201/			S	Unknown	Unk		Not Reported	
	Entacapone			S		Unk		Not Reported	
	Citalopram			S	Unknown	Unk		Not Reported	
	Levodopa			S		Unk		Not Reported	
	Seprtin			S	Unknown	Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	

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Carbidopa	S	Unk	Not Reported
Co-Beneldopa	C	50 Mg/12.5 Mg	Not Reported
Co-Beneldopa	C	25/100 Mr Capsules	Not Reported
Co-Beneldopa	C	25/100	Not Reported
Macrogol	C	Unk	Not Reported
Duloxetine	C	90 Mg, Unk	Not Reported
Adcal D3	C	Unk	Not Reported
Rivastigmine	C	Transdermal 4.6 Mg, Unk	Not Reported
Quetiapine	C	25 Mg, Unk	Not Reported
Paracetamol	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14349055	EXPEDITED (15-DAY)	HO		DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017007810			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Level Decreased; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd, Tablet		Macleods	
	Escitalopram			S	Oral	40 Mg, Qd, Overdose: 40 Mg		Macleods	
	Olanzapine			C	Unknown	10 Mg, Qd		Macleods	
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported	
	Pangrol			C	Unknown	2 Df, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14575743	EXPEDITED (15-DAY)	DS		AU-009507513- 1802AUS011005		45 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar I Disorder; Major Depression; Psychotic Disorder; Suicidal Ideation	Avanza			S		15 Mg, 1 Time		Merck	
	Efexor			S		75 Mg, Qd		Not Reported	
	Lexapro			S		20 Mg, Qd		Not Reported	

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28-Feb-2018	13628282	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017247045		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 MI, Total		Pfizer	
	Escitalopram Oxalate			S	Oral	15 MI, Total		Not Reported	
	Esomeprazole Sodium			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	13656341	EXPEDITED (15-DAY)		DE, HO, OT	FR-ASTELLAS-2017US023138		43 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Venous Thrombosis; Pneumonia; Pseudomonas Infection; Subarachnoid Haemorrhage	Vesicare			S	Oral	1 Df, Once Daily (0-0-1)		Astellas	
	Biotin			S	Oral			Not Reported	
	Baclofen			S	Oral	1.5-1-1.5, Thrice Daily (Also Reported As 45 Mg Once Daily)		Not Reported	
	Xatral			S	Oral	1 Df, Once Daily (0-0-1)		Not Reported	
	Seroplex			S	Oral	1 Df, Once Daily (0-0-1)		Not Reported	
	Dafalgan			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	13934120	EXPEDITED (15-DAY)		LT, OT	IN-HORMOSAN-2017-05038		57 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram Tablets			S	Unknown	10 Mg, Unk, For 3 Months		Lupin	
	Quetiapine			S	Unknown	50 Mg, Unk, For 1 Month		Not Reported	
	Quetiapine			S				Not Reported	
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14224455	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2017DE00351		32 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Dyskinesia;	Escitalopram			S	Oral	5 Mg, Qd		Hetero	
Extrapyramidal Disorder;	Trimipramine			S	Oral	25 Mg, Qd		Not Reported	
Muscle Twitching; Muscle	Trimipramine			S	Oral	75 Mg, Qd		Not Reported	
Twitching; Restlessness									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14293993	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2017IT25436			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Abuse;	Escitalopram			S	Oral	14 Df, In Total		Invagen	
Sopor; Tremor	Bromazepam			S	Oral	40 MI, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14579974	EXPEDITED (15-DAY)		DS, OT	IT-CIPLA LTD.- 2018IT06408			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Product	Escitalopram			S	Unknown	Unk		Invagen	
Quality Issue; Product									
Substitution Issue									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14580319	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2018IT06741			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Lactic	Escitalopram			S	Oral	10 Df, In Total		Invagen	
Acidosis; Metabolic	Tegretol			S	Oral	90 Df, In Total		Not Reported	
Disorder; Neurological	Seroquel			S	Oral	50 Df, In Total		Not Reported	
Decompensation									

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Depakin Chrono /00228502/

S

Oral

20 Df, In Total

Not Reported

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28-Feb-2018	14580367	EXPEDITED (15-DAY)		OT	DK-CIPLA LTD.- 2018DK06856			Unknown	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Head Discomfort; Muscle Discomfort; Restlessness; Serotonin Syndrome; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg, Unk, Styrke: 20 Mg		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14582768	NON-EXPEDITED			US-MYLANLABS- 2018M1009370		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Creatinine Increased; Diarrhoea; Dizziness; Drug Interaction; Dry Skin; Micturition Urgency; Muscle Spasms; Pruritus	Midodrine Hydrochloride Tablets Usp			S	Oral	10 Mg, Tid		Mylan
	Midodrine Hydrochloride Tablets Usp			S	Oral	20mg In Am And Noon, 10mg Before 6 Pm		Mylan
	Multaq			S		Unk		Mylan
	Seroquel			S		Unk		Mylan
	Lexapro			S		Unk		Mylan
	Chlortab /00072502/			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14583344	EXPEDITED (15-DAY)		HO	CH-OTSUKA- DJ20112148		38 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Restlessness; Withdrawal Syndrome	Abilify			S	Oral	7.5 Mg, Unk		Otsuka
	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	2.5 Mg, Unk		Otsuka
	Cipralex			S	Unknown	Unk		Not Reported

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Cipralelex	S	Unknown	Unk	Not Reported
Heroin	S	Unknown	Unk	Not Reported
Cocaine	S	Unknown	Unk	Not Reported
Methadone	S	Oral	Unk	Not Reported
Methadone	S	Oral	Unk	Not Reported
Quetiapine	S	Oral	1df= 25–200 Mg Daily	Not Reported
Lexapro	S	Oral	22sep-14oct10 20mg 15oct10-Ong 25mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	12546845	EXPEDITED (15-DAY)		HO, LT, OT	FR- ELI_LILLY_AND_COMP ANY-FR201607001668			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Antipsychotic	Zyprexa			S	Unknown	10 Mg, Each Morning		Eli Lilly And Co
Drug Level Above	Zyprexa			S	Unknown	20 Mg, Each Evening		Eli Lilly And Co
Therapeutic;	Zyprexa			S	Oral	1050 Mg, Single		Eli Lilly And Co
Benzodiazepine Drug	Zyprexa			S	Oral	1350 Mg, Single		Eli Lilly And Co
Level; Body Temperature	Zyprexa			S	Oral	1350 Mg, Single		Eli Lilly And Co
Decreased; Coma;	Zopiclone			S	Unknown	7.5 Mg, At Bedtime		Not Reported
Confusional State;	Zopiclone			S	Oral	210 Mg, Single		Not Reported
Electrocardiogram Qt	Lysanxia			S	Unknown	10 Mg, Each Morning		Not Reported
Prolonged; Hypotension;	Lysanxia			S	Oral	1440 Mg, Single		Not Reported
Hypotonia; Intentional	Lysanxia			S	Oral	1440 Mg, Single		Not Reported
Overdose; Loss Of	Lysanxia			S	Oral	1440 Mg, Single		Not Reported
Consciousness; Miosis;	Seroplex			S	Unknown	10 Mg, Each Evening		Not Reported
Pneumonia Aspiration;	Seroplex			S	Oral	140 Mg, Single		Not Reported
Prescribed Overdose;	Seroplex			S	Oral	140 Mg, Single		Not Reported
Respiratory Rate	Abilify			S	Oral	0.5 Df, Each Morning		Not Reported
Increased	Abilify			S	Oral	10 Mg, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14535460	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-006963		78 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Disorientation; Hallucination, Visual; Persecutory Delusion	Escitalopram Film-Coated Tablets	S	Oral	1 Cp	Aurobindo
	Modopar	S	Oral	1 Cp (1)	Not Reported
	Modopar	S	Oral	1 Cp (1)	Not Reported
	Modopar	S	Oral	50 Mg/12.5 Mg	Not Reported
	Modopar	S	Oral	62.5 Mg, Two Times A Day	Not Reported
	Modopar	S	Oral	1 Dosage Form 3 Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14584955	EXPEDITED (15-DAY)		HO, OT	IN-TORRENT-00001601		58 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Back Pain; Constipation; Inappropriate Antidiuretic Hormone Secretion	Hydroxychloroquine			C	Oral			Unknown	
	Prednisolone			C				Unknown	
	Escitalopram			S				Unknown	
	Insulin			C		Combination Of Fast And Long Acting Insulin		Unknown	
	Methotrexate			C				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14585030	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010288		86 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Concordia	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14585341	EXPEDITED (15-DAY)		LT, OT	IN-ALKEM LABORATORIES LIMITED-IN-ALKEM-2018-00877		57 YR	Male	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypothyroidism; Myxoedema Coma	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Quetiapine Fumarate			S	Unknown	50 Mg, Unk		Alkem	
	Amlodipine			C	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14585908	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR07338			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hyponatraemia	Ramipril			S	Oral	5 Mg, Unk		Invagen	
	Escitalopram			S	Oral	1 Df, Unk		Invagen	
	Esidrex			S	Oral	0.5 Df, Unk		Not Reported	
	Speciafoldine			C	Oral	1 Df, Unk		Not Reported	
	Bisocce			C	Oral	2 Df, Unk		Not Reported	
	Imovane			C	Oral	0.5 Df, Unk		Not Reported	
	Levothyrox			C	Oral	112.5 Mg, Unk		Not Reported	
	Eliquis			C	Oral	2 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14586350	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR07389			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Escitalopram			S	Oral	1 Df, Per Day		Invagen	
	Furosemide			S	Oral	20 Mg, Per Day		Not Reported	
	Xarelto			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14589611	EXPEDITED (15-DAY)		DE, HO, OT	DE-ASTRAZENECA- 2018SE25370		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Seroquel	S	Oral	200.0mg Unknown	Not Reported
	Seroquel	S	Oral	Quetiapine200.0mg Unknown	Not Reported
	Escitalopram Oxalate	S	Oral	10.0mg Unknown	Not Reported
	Lexapro	S	Oral		Not Reported
	Lexapro	S	Oral		Not Reported
	Tavor [Lorazepam]	S	Oral	2.0mg Unknown	Not Reported
	Tavor	S	Oral	2.0mg Unknown	Not Reported
	Tavor	S	Oral	6.0mg Unknown	Not Reported
	Tavor	S	Oral	6.0mg Unknown	Not Reported
	Abilify	S	Oral	20.0mg Unknown	Not Reported
	Abilify	S	Oral	15.0mg Unknown	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Simeticone	C	Unknown	Unk	Not Reported
	Eferox	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14590149	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2018US010550		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Drug Interaction; Hallucination, Visual	Vesicare			S	Oral			Astellas	
	Artotec			S	Oral			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Atarax /00058402/			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14590507	EXPEDITED (15-DAY)		HO	PHHY2018FR033854		50 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Valsartan	S	Oral	14400 Mg, Unk	Novartis
	Escitalopram	S	Oral	880 Mg, Unk	Not Reported
	Bromazepam	S	Oral	144 Mg, Unk	Not Reported
	Xeroquel	S	Oral	2500 Mg, Unk	Not Reported
	Prazepam	S	Oral	1200 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14593279	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC- 2018084042		66 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Injury	Aspavor			S		20 Mg, Unk		Pfizer	
	Cipralex			S		10 Mg, Unk		Not Reported	
	Carloc			S		6.25 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14594494	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA- 863789		32 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Depression Suicidal	Bupropion Sr			S	Oral			Teva	
	Escitalopram			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14594611	EXPEDITED (15-DAY)		OT	CN-ALLERGAN- 1811602US		40 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Condition Aggravated; Negative Thoughts; Off Label Use; Pain; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Bid		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Clomipramine			C	Oral	2 Df, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14595375	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018010659			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral	5 Mg, Unk		Macleods	
	Levonelle			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2018	14596247	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2017-40125		30 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Mg, Once A Day		Aurobindo	
	Escitalopram			S	Unknown	7.5mgdaily		Aurobindo	
	Escitalopram			S	Oral	20mgdaily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2018	14599091	DIRECT		OT			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Migraine; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla	
	Vistaril			C				Not Reported	
	Buspirone			C				Not Reported	
	Loratadine			C				Not Reported	
	Cpap			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Citrucel			C				Not Reported	

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04-Mar-2018	14596528	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018010686			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma; Sinus Bradycardia	Escitalopram Oxalate			S	Oral	1120 Mg, Unk		Macleods	
	Plavix			S	Oral	2250 Mg, Film-Coated Tablets		Not Reported	
	Coveram 10 Mg/10 Mg, Compressed			S	Oral	60 Df, Unk		Not Reported	
	Seresta 50 Mg, Scored Tablet			S	Oral	1000 Mg, Unk		Not Reported	
	Bisocle 10 Mg, Dry Film Tablet			S	Oral	300 Mg, Unk		Not Reported	
	Zopiclone			S	Oral	315 Mg, Unk		Not Reported	
	Aldactazine, Scored Film-Coated Tablet			S	Oral	30 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2018	14596622	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-011358		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor; Suicide Attempt	Alprazolam Tablets			S	Oral	In Total		Aurobindo	
	Escitalopram			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2018	14596759	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2018-010901		25 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Aurobindo	
	Levonelle /00318901/			C		()		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14102612	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1759226US		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Disinhibition; Drug Interaction; Mental Disorder; Off Label Use; Overdose	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Gtt, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Gtt, Qd		Allergan	
	Abilify			S	Oral	Unk		Not Reported	
	Calcium 600 Plus Vitamin D			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14349569	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-48574		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Sedation	Alprazolam			S	Oral	Alprazolam 0,25 1/2 Cp/J		Aurobindo	
	Alprazolam			S				Aurobindo	
	Escitalopram			S	Oral	10 Mg, Unk		Aurobindo	
	Escitalopram			S				Aurobindo	
	Risperdal			S	Oral	1.5 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14596964	EXPEDITED (15-DAY)		OT	TR-STRIDES ARCOLAB LIMITED-2018SP001362			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Bradycardia; Dizziness; Hypotension	Cetirizine			S	Oral	10 Mg Per Day (Administered On The 26th Hospital Day At 2 Pm)		Strides	
	Escitalopram			S	Unknown	10 Mg, Per Day (Had Been Started On 11th Hospital Day)		Not Reported	

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Enoxaparin	C	Unknown	60 Mg, Per Day	Not Reported
Ampicillin	C	Intravenous (not otherwise specified)	2 G, Every 4 Hrs	Not Reported
Pantoprazole	C	Unknown	40 Mg, Per Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14598942	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-011408			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Sinus Bradycardia	Escitalopram			S	Oral	1120 Milligram		Aurobindo
	Zopiclone			S	Oral	315 Milligram		Not Reported
	Aldactazine			S	Oral	30 Dosage Form		Not Reported
	Bisoce			S	Oral	300 Milligram		Not Reported
	Coveram			S	Oral	60 Dosage Form		Not Reported
	Plavix			S	Oral	2250 Milligram		Not Reported
	Seresta			S	Oral	1000 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14604097	DIRECT	Y	HO			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Vomiting	Escitalopram			S				Not Reported
	Levothyroxine			C				Not Reported
	Losartan			C				Not Reported
	Amlodipine			C				Not Reported
	Methocarbamol			C				Not Reported
	Metoprolol Succinate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	13584689	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-051708		55 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Abuse	Escitalopram		S	Oral				Accord	
	Lorazepam		S	Oral				Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	13945282	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017379748		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Abuse; Coma; Drug Abuse; Hypotension; Intentional Self-Injury	Alprazolam				S	Oral	20 Gtt, Total		Pfizer
	Halcion				S	Oral	10 Df, Total		Pfizer
	Cipralex /01588501/				S	Oral	15 Gtt, Total		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14018921	EXPEDITED (15-DAY)		DE, HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005538		43 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Venous Thrombosis	Alfuzosin				S	Oral			Concordia
	Baclofen				S	Oral			Not Reported
	Vesicare				S	Oral			Not Reported
	Seroplex				S	Oral			Not Reported
	Dafalgan				S	Oral			Not Reported
	Qizenday 100 Mg, Gélule				S	Oral			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14571724	NON-EXPEDITED			US-PFIZER INC-2018074907			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Celebrex				S		Unk		Pfizer
	Gabapentin				S		Unk		Pfizer
	Ibuprofen				S		Unk		Pfizer

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	Methotrexate Sodium	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Leflunomide	S	Unk	Not Reported
	Motrin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14587258	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180229948		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Ceftriaxone Sodium			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14601870	EXPEDITED (15-DAY)		HO, OT	JP-CIPLA LTD.-2018JP10258			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypotonia; Neonatal Respiratory Depression; Premature Baby	Escitalopram			S	Transplacental	Unk		Invagen	
	Ethyl Loflazepate			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14601911	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR08282			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dystonia; Resting Tremor	Risperidone			S	Oral	1 Df Per Day		Cipla	
	Escitalopram			S	Oral	1 Df Per Day		Invagen	
	Nebivolol			C	Oral	2.5 Mg Per Day		Not Reported	

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Kenzen			C		Oral		1 Df Per Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
06-Mar-2018	14602002	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2018010752			Unknown	ESP	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram Oxalate			S	Unknown	Unk		Macleods		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
06-Mar-2018	14602207	EXPEDITED (15-DAY)		LT	FR-CIPLA LTD.- 2018FR08515			Unknown	FRA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Postpartum Haemorrhage; Premature Delivery	Escitalopram Folic Acid			S S	Oral Unknown	10 Mg, Unk Unk		Invagen Invagen		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
06-Mar-2018	14602269	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2018IT08541			Unknown	ITA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Cerebral Haemorrhage; Drug Interaction	Escitalopram Plavix			S S	Oral Oral	10 Mg, Qd Unk		Invagen Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
06-Mar-2018	14603741	EXPEDITED (15-DAY)		HO, OT	CH- GLAXOSMITHKLINE- CH2018033185		< 1 DAY	Male	CHE	

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Escitalopram			S	Transplacental			Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Ventolin			S	Transplacental	Unk		Glaxosmithkline
	Seebri Breezhaler			S	Transplacental	50 ?G, Unk		Not Reported
	Celestone			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14604190	EXPEDITED (15-DAY)		HO	FR-MARINA BIOTECH, INC.- 2018MARINA000503			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Intentional Overdose; Sinus Bradycardia	Coveram			S	Oral	60 (10mg/10mg) Tablets		Unknown
	Plavix			S	Oral	2250 Mg		Not Reported
	Seresta			S	Oral	1000 Mg		Not Reported
	Escitalopram Oxalate			S	Oral	1120 Mg		Not Reported
	Bisoc			S	Oral	300 Mg		Not Reported
	Zopiclone			S	Oral	315 Mg		Not Reported
	Aldactazine			S	Oral	30 Df		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14605099	EXPEDITED (15-DAY)		HO	IN-MYLANLABS- 2018M1014989		26 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Catatonia; Extrapyramidal Disorder	Olanzapine			S	Unknown	20 Mg		Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Aripiprazole			S	Unknown	Gradually Titrated Up To 20mg (Initial Dose Not Known)		Mylan

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07-Mar-2018	9736117	EXPEDITED (15-DAY)		DE, LT, OT	NO-GLAXOSMITHKLINE-B0951220A		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Lamictal			S	Unknown	25, 50, 100 Mg		Glaxosmithkline	
	Sarotex			S	Unknown	Unk		Glaxosmithkline	
	Seroquel			S	Unknown	Unk		Glaxosmithkline	
	Ciprallex			S	Unknown	Unk		Glaxosmithkline	
	Atarax			S	Unknown	Unk		Glaxosmithkline	
	Sobril			S	Unknown	Unk		Glaxosmithkline	
	Imovane			S	Oral	Unk		Glaxosmithkline	
	Hydroxyzine Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
	Diazepam			S	Unknown	Unk		Glaxosmithkline	
	Orfiril			S	Unknown	600 To 1200 Mg		Not Reported	
	Nobligan			S	Unknown	50 To 200 Mg		Not Reported	
	Nobligan			S	Unknown	Unk		Not Reported	
	Cipramil [Citalopram Hydrobromide]			S	Unknown	Unk		Not Reported	
	Rivotril			S	Unknown	Unk		Not Reported	
	Nozinan			S	Unknown	Unk		Not Reported	
	Catapresan			S	Unknown	25 To 50 Mg		Not Reported	
	Vival			S	Unknown	Unk		Not Reported	
	Pinex Forte			S	Unknown	500/30 Mg And Pandeine		Not Reported	
	Truxal			S	Unknown	Unk		Not Reported	
	Oxynorm			S	Unknown	5 To 10 Mg		Not Reported	
	Remeron			S	Unknown	Unk		Not Reported	
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported	
	Cyanocobalamin			C	Unknown	Unk		Glaxosmithkline	
	Codeine Phosphate			C	Unknown			Not Reported	

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Heroin			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	12341717	EXPEDITED (15-DAY)		OT	CA-FRI-1000084495		33 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Therapeutic Product Effect Decreased	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	12439819	EXPEDITED (15-DAY)		DS	CA-FRI-1000085086		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Feeling Abnormal; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14325935	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1773508US		71 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Withdrawal Syndrome; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10-20 Mg/Day		Allergan	
	Amlodipine(Amlodipine Besilate)			C	Oral	2.5 Mg, Unk		Not Reported	
	Isosorbide Dinitrate			C	Transdermal	40 Mg, Qd		Not Reported	
	Lansoprazole			C	Oral	1 Df, Unk		Not Reported	
	Donepezil Hydrochloride			C	Oral	5 Mg, Unk		Not Reported	
	Rozerem(Ramelteon)			C	Oral	8 Mg, Unk		Not Reported	
	Rozerem(Ramelteon)			C	Oral	4 Mg, Unk		Not Reported	
	Miya Bm(Clostridium Butyricum)			C	Oral	1 Df, Unk		Not Reported	
	Iopamidol			C	Intravenous (not otherwise specified)	Unk		Not Reported	

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07-Mar-2018	14381851	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018014915		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Overdose; Sopor; Suicide Attempt	Alprazolam			S	Oral	16 Mg, Unk		Pfizer	
	Escitalopram			S	Oral	30 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14449057	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1804000US		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	30 MI, Unk		Allergan	
	Alprazolam			S	Oral	16 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14606081	EXPEDITED (15-DAY)		OT	JP-CIPLA LTD.-2018JP10256			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Unknown	10 Mg, Qd		Invagen	
	Ethyl Loflazepate			S	Unknown	1 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14606880	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-165307		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Paracetamol		Y	S	Unknown	Unk ()		Ohm Lab	
	Irbesartan			S	Unknown	Unk ()		Not Reported	
	Galantamine			S	Unknown	Unk ()		Not Reported	

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Escitalopram			S		Unknown		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Mar-2018	14606907	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010336		63 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hepatitis Cholestatic	Prednisolone			S	Oral			Concordia		
	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported		
	Lomustine			S	Oral			Not Reported		
	Seroplex Film-Coated Tablets			S	Oral			Not Reported		
	Silodyx			C	Unknown			Not Reported		
	Xanax			C	Unknown			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607598	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1812074US		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma; Off Label Use; Overdose; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	1120 Mg, Single		Allergan	
	Plavix			S	Oral	2250 Mg, Single		Not Reported	
	Coveram			S	Oral	60 Df, Single		Not Reported	
	Seresta			S	Oral	1000 Mg, Single		Not Reported	
	Bisoce			S	Oral	300 Mg, Single		Not Reported	
	Zopiclone			S	Oral	315 Mg, Single		Not Reported	
	Aldactazine			S	Oral	30 Df, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607616	EXPEDITED (15-DAY)		HO	DE-ALLERGAN- 1811881US		39 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebrovascular Accident; Fall; Product Use Issue; Tobacco Interaction	Escitalopram Oxalate - Bp	S	Unknown	20 Mg, Bid	Allergan
	Clozapin	S	Oral	100 Mg, Qd	Not Reported
	Amisulprid	S	Unknown	500 Mg, Qd	Not Reported
	Tavor [Lorazepam]	C		Taken Only If Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607617	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1811893US		30 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
Asthenia; Decreased	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
Appetite; Dizziness;	Escitalopram Oxalate - Bp			S	Oral	7.5 Mg, Qd		Allergan
Fatigue; Galactorrhoea;								
Headache; Intentional								
Self-Injury; Nightmare;								
Orgasm Abnormal; Sexual								
Dysfunction; Sleep								
Disorder; Suicidal								
Ideation; Tremor								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607637	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1811873US		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Avastin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Belustine			S	Oral	40 Mg, Cyclical		Not Reported
	Solupred (Prednisolone)			S	Oral	40 Mg, Qd		Not Reported
	Silodyx			C				Not Reported
	Xanax			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607638	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1811820US		31 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Emotional Poverty; Fatigue; Feeling Of Body Temperature Change; Head Discomfort; Hyperhidrosis; Limb Discomfort; Loss Of Libido; Sensory Loss; Somnolence	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607761	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1811815US		38 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Depersonalisation/Derealisation Disorder; Drug Withdrawal Syndrome; Emotional Disorder; Fatigue; Headache; Irritability; Night Sweats; Vertigo	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607762	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1811803US		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Sedation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
	Risperdal			S	Oral	1.5 G, Unknown		Not Reported	
	Alprazolam			S	Oral	0.125 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607805	EXPEDITED (15-DAY)		DE, HO, OT	DE-GLENMARK PHARMACEUTICALS-2018GMK032885			Unknown	DEU

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Glenmark
	Spironolactone			S	Unknown	Unk		Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Sildenafil Citrate			S	Unknown	Unk		Not Reported
	Varivax /06643101/			S	Intramuscular	1 Df		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Exodus /01588502/			S	Unknown	Unk		Not Reported
	Nutrition Care Formula 55at			C	Other	(4)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14608776	NON-EXPEDITED			US-ABBVIE-17K-163-2047366-00		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Confusional State; Disturbance In Attention; Dizziness; Drug Interaction; Hypoacusis; Injury; Joint Swelling; Memory Impairment; Pain; Product Dose Omission; Somnolence; Swelling Face; Weight Increased	Androgel			S	Topical			Not Reported
	Lyrica			S	Oral	Two A Day		Not Reported
	Lyrica			S	Oral	2 At Morning And 1 At Night		Not Reported
	Xanax			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Clopidogrel			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Metoprolol Tartrate			S	Unknown			Not Reported
	Metformin Hcl			S	Unknown			Not Reported
	Tricor			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Nitroglycerin			S	Unknown			Not Reported

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Pataday	S	Unknown	Once Every 3 Or So Month	Not Reported
Breo	S	Unknown	100 Mcg/25 Mcg	Not Reported
Oxygen	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14609771	EXPEDITED (15-DAY)	HO		ZA-PFIZER INC-2018090842		66 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Celebrex			S		100 Mg, Unk		Pfizer	
	Amloc (Amlodipine Besilate)			S		5 Mg, Unk		Pfizer	
	Bilocor			S		5 Mg, Unk		Not Reported	
	Forvent			S		18 Mch		Not Reported	
	Be-Tabs Folic Acid			S		5 Mg, Unk		Not Reported	
	Be-Tabs Prednisone			S		5 Mg, Unk		Not Reported	
	Foxair			S		25/250 Mcg		Not Reported	
	Ipvent Hfa			S		40 Ucg		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
	Symbicord			S		160 Ug, Unk		Not Reported	
	Tambocor			S		100 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14609877	DIRECT						Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Citalopram			S				Not Reported	
	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14609924	DIRECT						Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14610010	DIRECT					43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Erectile Dysfunction; Genital Disorder Male; Libido Decreased; Penile Size Reduced; Sensory Disturbance; Sexual Dysfunction; Testicular Atrophy	Lexapro			S	Oral			Allergan	
	Deplin			C				Not Reported	
	Advil			C				Not Reported	
	Benadryl			C				Not Reported	
	Multi-Vitamin			C				Not Reported	
	Cbd			C				Not Reported	
	Probiotic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	13575475	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017005064			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram Tablet			S	Oral	140 Mg, 1 Total		Macleods	
	Lorzepam			S	Oral	20 Mg, Unk, 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14309887	EXPEDITED (15-DAY)		HO, OT	AT-JNJFOC- 20170924847		60 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Blood Triglycerides Increased;	Topamax			S	Oral			Not Reported	
Drug Interaction; Fatigue;	Topamax			S	Oral			Not Reported	
Frustration Tolerance Decreased; Intention	Topamax			S	Oral			Not Reported	

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Tremor; Lethargy; Liver Injury; Neutrophil Count Decreased; Resting Tremor; Sedation; Social Avoidant Behaviour; Splenomegaly; Tremor; Weight Increased	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Risperdal	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cipralex	S	Oral	Not Reported
	Cymbalta	S	Oral	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Rivotril	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14321206	EXPEDITED (15-DAY)		OT	DE-TORRENT-00007432			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea;	Escitalopram			S	Unknown	20 Mg, Daily		Unknown	
Depression;	Valdoxan			S				Unknown	
Dysmenorrhoea;	Zoely			S	Oral	1 Dosage Forms Daily;		Unknown	
Hypomenorrhoea;						One Df Contains 2.5mg			
Menorrhagia						Nomegestrel And 1.5mg			
						Estradiol			

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14610855	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2018IT08687			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	In Total		Invagen	
	Xanax			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14610897	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.- 2018AU10004			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Mg, Per Day		Invagen	
	Ramipril			S	Unknown	2.5 Mg, Per Day		Invagen	
	Atorvastatin			S	Unknown	10 Mg, Per Day		Invagen	
	Furosemide			S	Unknown	20 Mg, Per Day		Not Reported	
	Omeprazole			S	Unknown	20 Mg, Per Day		Not Reported	
	Testosterone			S	Unknown	1 G, Per Day (Every 10 To 14 Weeks)		Not Reported	
	Amisulpride			S	Unknown	300 Mg, Per Day		Not Reported	
	Spironolactone			S	Unknown	25 Mg, Per Day		Not Reported	
	Melatonin			S	Unknown	2 Mg, Per Day		Not Reported	
	Bisoprolol			S	Unknown	2.5 Mg, Per Day		Not Reported	
	Ferrograd /00023503/			S	Unknown	325 Mg, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14611101	EXPEDITED (15-DAY)		HO	IT-CIPLA LTD.- 2018IT08649			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Asthenia; Drug Abuse; Restlessness	Escitalopram			S	Oral	20 Df, In Total		Invagen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14611395	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2017006318			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage; Hypoproteinaemia; Oedema; Pain In Extremity; Pulmonary Congestion	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Oral	5 Mg, Qd At Breakfast, For Several Years		Macleods	
	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited			S	Unknown	Unk		Macleods	
	Emconcor 2.5 Mg			C	Oral	1.25 Mg, Bid At Breakfast And Dinner, Every 12 Hours		Not Reported	
	Simvastatin Cinfa 20 Mg			C	Oral	20 Mg, Qd At Dinner		Not Reported	
	Hibor (Bemiparin Sodium)			C	Subcutaneous	1 Unk, Qd 3500 Iu Anti- Xa/0.2 MI Solution For Injection In Pre-Filled Syringe; In The Evening		Not Reported	
	Hibor (Bemiparin Sodium)			C	Subcutaneous	2500 Iu, Unk		Not Reported	
	Hibor (Bemiparin Sodium)			C	Subcutaneous	10000 Iu, Unk		Not Reported	
	Hibor (Bemiparin Sodium)			C	Subcutaneous	7500 Iu, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14612388	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-011864		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Paracetamol			S	Unknown	Unk ()		Aurobindo	
	Escitalopram 10 Mg			S	Unknown	10 Mg, Unk		Aurobindo	
	Irbesartan			S	Unknown	Unk ()		Aurobindo	
	Galantamine			S	Unknown	Unk ()		Aurobindo	
	Diuretics			S	Unknown	()		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14613076	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1802CHE013562		< 1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Celestone Chronodose			S	Transplacental	Unk		Merck	
	Seebri Breezhaler			S	Transplacental	50 Microgram, Unk		Not Reported	
	Seretide			S	Transplacental	Unk		Not Reported	
	Ventolin (Albuterol)			S	Transplacental	Unk		Not Reported	
	Escitalopram			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14613978	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-863392		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor; Suicide Attempt	Escitalopram			S	Oral	30 Milliliters		Ivax	
	Alprazolam			S	Oral	16 Milligrams		Actavis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14614212	DIRECT		DE			23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Use; Antidepressant Drug Level Above Therapeutic; Completed Suicide; Product Label Confusion	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);		Walgreen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14324359	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2017-46836		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abnormal Behaviour;	Aripiprazole	S	Oral	Unk	Aurobindo
Accidental Overdose;	Cipralelex /01588501/	S	Oral	5 Gtt, Daily	Not Reported
Disinhibition; Drug	Cipralelex /01588501/	S	Oral	10 Gtt, Daily	Not Reported
Interaction; Mental	Cipralelex /01588501/	S	Oral	20 Gtt, Daily	Not Reported
Disorder; Product Use	Abilify	S			Not Reported
Issue; Therapy Change	Calcium Carbonate W/Vitamin D /01204201/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14593065	EXPEDITED (15-DAY)		OT	TR-JNJFOC-20180234219		34 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Bradycardia; Dizziness; Hypotension	Cetirizine Hydrochloride		Y	S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Oral	Administered On The 26th Hospital Day At 2 Pm And Discontinued On The 28th Hospital Day		Not Reported
	Escitalopram			S	Unknown	Escitalopram Had Been Started On 11th Hospital Day		Not Reported
	Enoxaparin			C	Unknown			Not Reported
	Ampicillin			C	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14595961	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR-APL-2018-010653		45 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use	Sertraline			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14607798	EXPEDITED (15-DAY)		DE, OT	CA-ALLERGAN-1812080US		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Homicide; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615777	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR09300			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown	Unk		Cipla	
	Escitalopram			S	Unknown	Unk		Invagen	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615856	EXPEDITED (15-DAY)		OT	TR-CIPLA LTD.-2018TR10743			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Bradycardia; Dizziness; Hypotension	Escitalopram			S	Unknown	10 Mg, Daily, Escitalopram Had Been Started On 11th Hospital Day		Invagen	
	Cetirizine			S	Oral	10 Mg, Administered On The 26th Hospital Day At 2 Pm And Discontinued On The 28th Hospital Day		Cipla	
	Enoxaparin			C	Unknown	60 Mg, Daily		Not Reported	
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, Four Hourly		Not Reported	
	Pantoprazole			C	Unknown	40 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615872	EXPEDITED (15-DAY)		CA	NL-CIPLA LTD.- 2018NL09073			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	10 Mg, Daily		Invagen	
	Foliumzuur			C	Transplacental	Unk		Not Reported	
	Davitamon			C	Transplacental	Unk		Not Reported	
	Cyklokapron			C	Transplacental	Unk		Not Reported	
	Calcium Carbonate W/Colecalciferol			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616078	EXPEDITED (15-DAY)		LT, OT	IT-ACCORD-064258		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Prescribed Underdose	Escitalopram			S	Oral			Not Reported	
	Abilify			S	Oral	10 Mg, Qd		Not Reported	
	Ciprallex			S	Oral	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616192	EXPEDITED (15-DAY)		HO, OT	AU-IPCA LABORATORIES LIMITED-IPC-2018-AU- 000441		38 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal	Furosemide			S	Unknown	20 Mg, Qd		Ipca	
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported	
	Ramipril			S	Unknown	2.5 Mg, Qd		Not Reported	
	Atorvastatin			S	Unknown	10 Mg, Qd		Not Reported	
	Bisoprolol			S	Unknown	2.5 Mg, Qd		Not Reported	
	Melatonin			S		2 Mg, Qd		Not Reported	

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	Omeprazole	S	Unknown	20 Mg, Qd		Not Reported
	Testosterone Depot	S	Unknown	1 G, Qd		Not Reported
	Amisulpride	S	Unknown	300 Mg, Qd		Not Reported
	Spironolactone	S	Unknown	25 Mg, Qd		Not Reported
	Ferrograd	S	Unknown	325 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616715	EXPEDITED (15-DAY)	HO		IT-CIPLA LTD.- 2018IT09862			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse	Escitalopram			S	Oral	140 Mg, In Total		Invagen
	Lorazepam			S	Oral	20 Mg, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14617179	EXPEDITED (15-DAY)	OT		IT-AUROBINDO-AUR- APL-2018-012750		52 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Loss Of Consciousness; Malaise	Escitalopram Film-Coated Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Depakin			S	Oral	1000 Milligram, Daily		Not Reported
	Carbolithium			S	Oral	900 Milligram, Daily		Not Reported
	Frontal			S	Oral	2 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14617603	EXPEDITED (15-DAY)	HO, OT		GB-AUROBINDO-AUR- APL-2018-011761			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo
	Alendronic Acid			C	Unknown			Not Reported
	Bendroflumethiazide			C	Unknown			Not Reported
	Colecalciferol			C				Not Reported

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Ergocalciferol	C	Not Reported
Gabapentin	C	Not Reported
Morphine Sulphate	C	Not Reported
Prucalopride	C	Not Reported
Salbutamol	C	Not Reported
Tiotropium	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14617759	EXPEDITED (15-DAY)		DE	JP-LANNETT COMPANY, INC.-JP- 2018LAN000512		57 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drowning; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Alcohol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14619130	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-012446		70 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Hallucinations, Mixed; Overdose	Escitalopram			S	Oral	110 Drop, 1 Days, Total		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14619416	EXPEDITED (15-DAY)		DE, HO, OT	DE-AUROBINDO-AUR- APL-2018-012498		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Quetiapine			S		200 Milligram		Aurobindo	
	Lorazepam			S	Oral	6 Milligram, Once A Day		Not Reported	
	Abilify			S	Oral	20 Milligram		Not Reported	
	Abilify			S	Oral	15 Unk		Not Reported	
	Cipralext /01588501/			S	Oral	10 Milligram		Not Reported	
	Lexapro			S	Oral	10 Milligram		Not Reported	

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	Lexapro		S						Not Reported
	Seroquel		S	Oral	200 Milligram				Not Reported
	Movicol /01749801/		S	Unknown					Not Reported
	Tavor /00273201/		S	Oral	2 Milligram				Not Reported
	Tavor /00273201/		S		6 Mg				Not Reported
	Simeticone		C	Unknown					Not Reported
	Eferox		C	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14619428	EXPEDITED (15-DAY)		LT	IT-AUROBINDO-AUR- APL-2018-012581		37 YR	Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Prescribed Underdose	Escitalopram			S	Unknown	5 Milligram, Once A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14620612	EXPEDITED (15-DAY)		DE	JP-ALLERGAN- 1813162US		40 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Overdose; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2018	14621213	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-012662		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Spironolactone			S	Oral	50 Milligram, Once A Day		Aurobindo
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2018	14621468	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-012653			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Tardive Dyskinesia	Aripiprazole			S	Unknown			Aurobindo	
	Aripiprazole			S	Unknown	5 Milligram		Aurobindo	
	Seroplex			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2018	14621704	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-012780		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Aripiprazole			S				Aurobindo	
	Mirtazapine			S				Aurobindo	
	Lexapro			S				Not Reported	
	Norset			S				Not Reported	
	Seroplex			S				Not Reported	
	Aprovel			C				Not Reported	
	Inipomp			C				Not Reported	
	Irbesartan			C				Not Reported	
	Kardegic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2018	14626631	DIRECT	Y	HO, RI			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Dyskinesia; Hyperhidrosis; Hyperreflexia; Hyperthermia; Hypertonia; Mental Status Changes; Myoclonus; Serotonin Syndrome	Escitalopram			S	Oral	1/2 Tab Every Day Po		Not Reported	
	Ondansetron			S	Oral			Not Reported	

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11-Mar-2018	12341721	EXPEDITED (15-DAY)		DE	CA-FRI-1000084391		49 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Completed Suicide; Drug Ineffective; Feelings Of Worthlessness; Insomnia	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan	
	Seroquel			S	Oral	25 Mg, Q8hr		Not Reported	
	Seroquel			S				Not Reported	
	Seroquel Xr			S	Oral	50 Mg, Qhs		Not Reported	
	Seroquel Xr			S				Not Reported	
	Trazodone			C	Oral	25-100 Mg, Qhs		Not Reported	
	Vitamin B12			C	Unknown	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2018	14623003	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813156US		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Xarelto			S	Unknown	20 Mg, Unk		Not Reported	
	Zofenil			C	Unknown	Unk		Not Reported	
	Carbidopa, Levodopa			C	Unknown	Unk		Not Reported	
	Androtardyl			C	Unknown	Unk		Not Reported	
	Amoxicillin Sodium, Potassium Clavulanate			C	Unknown	Unk		Not Reported	
	Requip			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2018	14623005	EXPEDITED (15-DAY)		DS	AT-ALLERGAN-1813129US		25 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram Oxalate - Bp	S	Unknown	1 Df, Unk	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2018	14623006	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1813125US		47 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	100 Mg, Single		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	13511018	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1717261US		51 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Crying; Drug Abuse; Intentional Self-Injury; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, In Total		Allergan
	Xanax			S	Oral	0.25 Mg, In Total		Not Reported
	Morphine Derivative			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	13519973	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-33450		51 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram Film-Coated Tablets			S	Oral	10 Mg, Total		Aurobindo
	Xanax			S	Oral	In Total		Not Reported
	Xanax			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14000447	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1754095US		70 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disorientation; Hallucinations, Mixed; Overdose	Escitalopram Oxalate - Bp			S	Oral	110 Gtt In Total		Allergan
	Alprazolam			C	Unknown	0.25 Mg, Qhs		Not Reported
	Plendil			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14327111	EXPEDITED (15-DAY)		HO	PHHY2017DE194307		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Candesartan Cilexetil			S	Oral	16 Mg, Qd		Novartis
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	100 Ug, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14438734	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180110996		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Balanitis Candida; Depression;	Stelara			S	Subcutaneous			Not Reported

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Gastrointestinal	Seroplex	S	Oral			Not Reported
Candidiasis; Type 2	Cardiocalm	S	Oral	3		Not Reported
Diabetes Mellitus	Stresam	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14625256	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2018SUN000898			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypothermia Neonatal; Jaundice Neonatal; Poor Weight Gain Neonatal; Premature Baby	Glycopyrrolate Escitalopram Seretide Ventolin Celestone			S S S S S	Transplacental Transplacental Transplacental Transplacental Transdermal	Maternal Dose: 50 Ug Unk Unk Unk Unk		Sunovion Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14626886	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1812909US		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Homicidal Ideation	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14627149	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1014689		90 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyponatraemia	Ramipril Mylan 5 Mg, Comprimé			S	Oral	5 Mg, Unk		Mylan
	Sécable							
	Esidrex			S	Oral	0.5 Df, Unk		Mylan
	Escitalopram Arrow			S	Oral	1 Df, Unk		Mylan
	Speciafoldine			C	Oral	1 Df, Unk		Mylan
	Bisoce			C	Oral	2 Df, Unk		Mylan

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	Imovane	C	Oral	0.5 Df, Unk				Mylan	
	Levothyrox	C	Oral	112.5 Mg, Unk				Mylan	
	Eliquis	C	Oral					Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14627395	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1014723		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Mg, Qd			Not Reported
	Seroplex (Escitalopram Oxalate)			S	Oral	1 Df, Qd			Mylan
	Xarelto			C		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14627520	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20180306444			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Topamax			S	Oral				Not Reported
	Abilify			S	Oral	10-15 Mg Daily			Not Reported
	Cipralex			S	Unknown				Not Reported
	Elvanse			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14627768	NON-EXPEDITED			US-MYLANLABS-2018M1011933		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Abnormal; Drug Ineffective; Insomnia; Restlessness	Lorazepam			S	Oral	0.5 Mg, Qid			Not Reported
	Lorazepam			S					Not Reported
	Metoprolol			S		25 Mg, Unk			Not Reported
	Risperdal			S		25 Mg, Unk			Mylan
	Lexapro			S		10 Mg, Unk			Mylan

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Lipitor	S	20 Mg, Unk	Mylan
Flonase /00908302/	S		Mylan
Omeprazole	S	40 Mg, Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14628052	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813211US		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Tardive Dyskinesia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Aripiprazole			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14628053	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1813188US		25 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Atarax			S	Oral			Not Reported
	Rivotril			S	Oral	2,5 Mg/ML, Solution Buvable En Goutte		Not Reported
	Marinol (Dronabinol)			S	Oral			Not Reported
	Acupan			S	Subcutaneous	Unk, Single		Not Reported
	Donormyl (Doxylamine Succinate)			S	Oral			Not Reported
	Levocarnil			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Theralene			C	Oral	4 Pour Cent, Sollution Buvable En Gouttes		Not Reported
	Melatonine			C	Oral	3 Mg, Qd		Not Reported
	Dafalgan Codeine			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14629343	DIRECT		DE			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Cipla	
	Synthroid			C				Not Reported	
	Birth Control Pills			C				Not Reported	
	Vitamin C			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14629444	DIRECT		DS			82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Product Contamination Physical	Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Accord	
	Atorvastatin			C				Not Reported	
	Buspirone			C				Not Reported	
	Choryhalidone			C				Not Reported	
	Hydrocodone Acetaminophen			C				Not Reported	
	Metoprolol Succinate			C				Not Reported	
	Ranitidine			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Aspirin			C				Not Reported	
	Coenzyme			C				Not Reported	
	Cranberry			C				Not Reported	
	Docusate Sodium			C				Not Reported	
	Fish Oil			C				Not Reported	
	Probiotic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	13997335	EXPEDITED (15-DAY)		HO, OT	NO-TEVA-806651ACC		17 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Aggression;	Olanzapine			S	Unknown			Not Reported	

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Agitation; Alcohol Abuse;	Seroxat	S		20 Milligram Daily;	Not Reported
Bipolar Disorder;	Seroxat	S			Not Reported
Depression; Derealisation;	Efexor Depot	S	Unknown		Not Reported
Disturbance In Attention;	Efexor Depot	S	Unknown		Not Reported
Disturbance In Social	Efexor Depot	S			Not Reported
Behaviour; Dizziness;	Efexor Depot	S			Not Reported
Drug Abuse; Drug Abuse;	Efexor Depot	S			Not Reported
Drug Ineffective;	Lamictal	S	Unknown		Not Reported
Hypomania; Impaired	Seroquel	S	Oral		Not Reported
Work Ability; Irritability;	Seroquel	S			Not Reported
Judgement Impaired;	Zyprexa	S			Not Reported
Logorrhoea; Malaise;	Cipralax	S	Unknown	Daily	Not Reported
Mania; Mania; Memory	Orfiril	S	Unknown		Not Reported
Impairment; Personality	Cipramil [Citalopram	S		60 Milligram Daily;	Not Reported
Disorder; Quality Of Life	Hydrobromide]				
Decreased; Restlessness	Cipramil	S		10 Milligram Daily; 10 Mg,	Not Reported
				Daily	
	Valproat	S		Increasing Dose	Not Reported
	Lithionit	C	Unknown		Not Reported
	Lithionit	C			Not Reported
	Lithionit	C			Not Reported
	Lithionit	C			Not Reported
	Sobril	C		As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14070085	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1756954US		58 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sedation; Tremor	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Lyrica			S	Oral	750 Mg, Qd		Not Reported
	Lyrica			S	Oral	450 Mg, Qd		Not Reported
	Lyrica			S	Oral	375 Mg, Qd		Not Reported
	Lyrica			S	Oral	300 Mg, Qd		Not Reported

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	Lyrica	S	Oral	150 Mg, Qd	Not Reported
	Topamax	S	Oral	100 Mg, Qd	Not Reported
	Topamax	S	Oral	25 Mg, Qd	Not Reported
	Risperdal	S	Unknown	2 Mg, Qd	Not Reported
	Risperdal	S	Oral	2 Mg, Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14364747	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1800622US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Zoely			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Nomegestrel And 1.5mg Estradiol		Not Reported	
	Valdoxan			S	Unknown	25 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14622999	EXPEDITED (15-DAY)			JP-ALLERGAN-1812886US		20 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14628526	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.-2018FR10378			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Depersonalisation/Derealisation Disorder; Drug	Escitalopram			S	Oral	Unk		Invagen	

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Withdrawal Syndrome;
Emotional Disorder;
Fatigue; Headache;
Irritability; Night Sweats;
Vertigo

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13-Mar-2018	14629607	EXPEDITED (15-DAY)		HO	IN-HETERO CORPORATE- HET2018IN00171		26 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catatonia	Aripiprazole			S	Unknown	20 Mg		Hetero	
	Escitalopram			S	Unknown	20 Mg		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14630383	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1813217US		90 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Loss Anaemia; International Normalised Ratio Increased; Melaena	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Previscan (Fluindione)			S	Unknown	Unk		Allergan	
	Previscan (Fluindione)			S		15 Mg, Qd		Allergan	
	Esomeprazole			C	Unknown			Not Reported	
	Bromazepam			C	Unknown			Not Reported	
	Seretide			C	Unknown			Not Reported	
	Celiprolol			C	Unknown			Not Reported	
	Transipeg (Macrogol 3350)			C	Unknown			Not Reported	
	Fumafer			C	Unknown			Not Reported	
	Pravastatin Sodium			C	Unknown			Not Reported	
	Titanoreine			C	Rectal			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14630384	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1813270US		52 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Frontal			S	Oral	2 Mg, Qd		Not Reported	
	Carbolithium			S	Oral	900 Mg, Qd		Not Reported	
	Depakin			S	Oral	1000 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14630782	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2018M1015511		50 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Delusion;	Clozaril			S	Oral	Unk		Mylan	
Eczema; Emotional	Clozaril			S	Oral	700 Mg, Pm		Mylan	
Distress; Eosinophil Count	Escitalopram			S		10 Mg, Am		Not Reported	
Decreased; Feeling Cold;	Escitalopram			S		20 Mg, Am		Not Reported	
Frustration Tolerance	Olanzapine			S		5 Mg, Bid		Not Reported	
Decreased; Haemoglobin	Olanzapine			S		15 Mg, Pm		Not Reported	
Decreased; Hallucination,	Paliperidone			S		100 Mg, Unk		Mylan	
Auditory; Hyperhidrosis;	Paliperidone			S		150 Mg, Unk		Mylan	
Intentional Self-Injury;	Caltrate /00944201/			C		10 Mg, Pm		Mylan	
Lymphocyte Count	Lorazepam			C		2 Mg, Pm		Mylan	
Decreased; Mean Cell	Lurasidone			C		120 Mg, Pm		Mylan	
Haemoglobin Decreased;	Metformin			C		850 Mg, Tid		Mylan	
Mental Impairment;	Mirtazepine Teva			C		30 Mg, Pm		Mylan	
Metamyelocyte Count	Crestor			C		10 Mg, Pm		Mylan	
Increased; Monocyte	Zuclopenthixol			C		400 Mg, Unk		Mylan	
Count Decreased;	Calcium Carbonate			C		Unk		Mylan	
Myelocyte Count	Rosuvastatin			C		Unk		Mylan	
Increased; Neutropenia;	Coloxyl /00061602/			C		Unk		Mylan	
Platelet Count Increased;	Senna /00142201/			C		Unk		Mylan	
Thermal Burn; Tinea									
Infection; Vitamin B12									
Deficiency; White Blood									
Cell Count Decreased									

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Movicol	C	Unk	Mylan
Vitamin B12 /00056201/	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14633047	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1013754			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Mood; Drug Ineffective; Dry Mouth; Hangover; Inappropriate Schedule Of Product Administration; Prescription Drug Used Without A Prescription; Stress; Urinary Retention; Wrong Technique In Product Usage Process	Loxalate			S		Unk Unk, Qd		Mylan
	Loxalate			S				Mylan
	Imrest			S		Unk		Mylan
	Kalma 1 (Alprazolam)			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14633358	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2018SE29413		64 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Abdomen; Drug Interaction	Seroquel			S	Oral	125 Dosage Form, 50-25-50		Zeneca
	Ciprallex			S	Unknown			Not Reported
	Leponex			C		100-0-75		Not Reported
	Levomepromazine			C				Not Reported
	Eisensulfat			C				Not Reported
	Kalinor (Potassium Chloride)			C		1-0-0		Not Reported
	Delix (Ramipril)			C				Not Reported
Pantoprazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14637746	DIRECT						Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Libido Decreased; Weight Increased	Lexapro Bupropion			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	13580465	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2017-34344		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram Film-Coated Tablets Lorazepam Tablets			S S	Oral Oral	140 Mg, Daily 20 Mg, Daily		Aurobindo Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14364608	EXPEDITED (15-DAY)		HO, OT	FR- ELI_LILLY_AND_COMP ANY-FR201712012922		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Abasaglar			S	Subcutaneous	Unk Unk, Unknown		Not Reported	
	Xeloda			S	Oral	Unk, Unknown		Not Reported	
	Novorapid			S	Subcutaneous	Unk, Unknown		Not Reported	
	Primperan			S	Oral	Unk, Unknown		Not Reported	
	Lipanthyl			S	Oral	Unk, Unknown		Not Reported	
	Movicol			S	Oral	Unk Unk, Unknown		Not Reported	
	Pantoprazole			S	Oral	Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk, Unknown		Not Reported	
	Fondaparinux Sodique			S	Subcutaneous	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14633536	EXPEDITED (15-DAY)		HO	US-AMGEN- USACT2018032047		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Decreased Appetite; Weight Decreased	Blinatumomab	S	Intravenous (not otherwise specified)	15 Mcg/M2, Qd	Amgen
	Methotrexate	S	Oral	20 Mg/M2, Unk	Not Reported
	Vincristine	S	Intravenous (not otherwise specified)	1.5 Mg/M2, Unk	Not Reported
	Mercaptopurine	S	Oral	75 Mg/M2, Unk	Not Reported
	Vancomycin	S	Unknown	Unk	Not Reported
	Ativan	S	Oral	Unk	Not Reported
	Clonazepam	S	Unknown	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Morphine	S	Oral	Unk	Not Reported
	Norethindrone	S	Unknown	Unk	Not Reported
	Scopolamine	S	Topical	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14633739	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-166068		15 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Binge Eating; Overdose; Treatment Failure; Weight Increased	Risperidone			S	Unknown	Unk		Ranbaxy
	Risperidone			S				Ranbaxy
	Aripiprazole			S	Unknown	Unk		Not Reported
	Aripiprazole			S				Not Reported
	Quetiapine			S	Unknown	Unk		Sun
	Quetiapine			S				Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Fluoxetine			S	Unknown	Unk		Sun
	Fluoxetine			S				Sun
	Cyamemazine			S	Unknown	Unk		Not Reported
	Cyamemazine			S				Not Reported
	Propericiazine			S	Unknown	Unk		Not Reported

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	Propericiazine	S						Not Reported
	Carbamazepine	S	Unknown	Unk				Not Reported
	Carbamazepine	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14634232	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.- 2018DE10716			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	20 Mg, Every Day		Invagen
	Escitalopram			S	Oral	15 Mg, Every Day		Invagen
	Escitalopram			S	Unknown	7.5 Mg, Every Day		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14634347	EXPEDITED (15-DAY)		OT	NO-CIPLA LTD.- 2018NO10698			Unknown	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Galactorrhoea; Insomnia	Escitalopram			S	Oral	Oct/2016: 10 Mg-15 Mg May/2017: 20 Mg Oct/2018: 10 Mg ()		Invagen
	Mirena			C	Intra-uterine	Unk		Not Reported
	Wellbutrin			C	Oral	150 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14635024	EXPEDITED (15-DAY)		DE, HO, OT	DE-ALLERGAN- 1813174US		55 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hyperhidrosis; Off Label Use; Restlessness;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan

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Schizoaffective Disorder	Tavor [Lorazepam]	S	Oral	2 Mg, Unk	Not Reported
	Tavor	S	Oral	6 Mg, Unk	Not Reported
	Seroquel	S	Oral	200 Mg, Unk	Not Reported
	Lorazepam	S	Oral	6 Mg, Qd	Not Reported
	Quetiapine	S	Oral	200 Mg, Qd	Not Reported
	Abilify	S	Oral	20 Mg, Unk	Not Reported
	Abilify	S	Oral	15 Mg, Unknown	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Simeticone	C	Unknown	Unk	Not Reported
	Eferox	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14635027	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1813396US		51 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Uric Acid Increased; Epilepsy; Fall; Increased Appetite; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Fexofenadine Hydrochloride			C	Oral			Not Reported
	Famotidine			C	Oral			Not Reported
	E Keppra			C	Oral			Not Reported
	Depakene			C	Oral			Not Reported
	Azilva			C	Oral			Not Reported
	Loxoprofen Na			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14635028	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1767213US		24 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Drug Abuse; Intentional Product Misuse; Overdose; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Df, Single		Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14635029	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ALLERGAN-S06-FRA-01387-01		26 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Cardiac Arrest; Chills; Delusion; Feeling Hot; Lactic Acidosis; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest; Retained Placenta Or Membranes	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported
	Tiapridal			S	Oral	100 Mg, Unk		Not Reported
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Cytotec			S	Unknown	400 Mg, Bid		Not Reported
	Misoprostol			S	Unknown	800 Mg, Unk		Not Reported
	Mifegyne			S	Oral	600 Mg, Qd		Not Reported
	Mifegyne			S	Oral	200 Mg, Unk		Not Reported
	Lysanxia			C	Unknown	50 Mg, Qd		Not Reported
	Imovane			C	Oral	7 Mg, Qd		Not Reported
	Zopiclone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14635898	EXPEDITED (15-DAY)		OT	DE-TEVA-804347GER			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Zoely 2,5 Mg/1,5 Mg Filmtabletten			S	Oral	1 Dosage Forms Daily; One Df Contains 2.5mg Norgestrel And 1.5mg Estradiol		Not Reported
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Valdoxan			S	Unknown	25 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14637721	EXPEDITED (15-DAY)		HO, OT	PHHY2018AU043275		50 YR	Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delusion;	Clozaril			S	Oral	Unk		Not Reported
Eczema; Emotional	Clozaril			S	Oral	700 Mg, Qd (Pm)		Not Reported
Distress; Eosinophil Count	Escitalopram			S	Unknown	10 Mg, Qd (Am)		Not Reported
Decreased; Feeling Cold;	Escitalopram			S	Unknown	20 Mg, Qd (Am)		Not Reported
Frustration Tolerance	Olanzapine			S	Unknown	5 Mg, Bid		Novartis
Decreased; Haemoglobin	Olanzapine			S	Unknown	15 Mg, Qd (Nocte)		Novartis
Decreased; Hallucination,	Paliperidone			S	Unknown	100 Mg, Unk		Not Reported
Auditory; Hyperhidrosis;	Paliperidone			S	Unknown	150 Mg, Unk		Not Reported
Intentional Self-Injury;	Caltrate			C	Unknown	10 Ug, Qd (Pm)		Not Reported
Lymphocyte Count	Lorazepam			C	Unknown	2 Mg, Qd (Pm)		Not Reported
Decreased; Mean Cell	Lurasidone			C	Unknown	120 Mg, Qd (Pm)		Not Reported
Haemoglobin Decreased;	Metformin			C	Unknown	850 Mg, Tid		Not Reported
Mental Impairment;	Mirtazepine Teva			C	Unknown	30 Mg, Qd (Pm)		Not Reported
Metamyelocyte Count	Crestor			C	Unknown	10 Mg, Qd		Not Reported
Increased; Monocyte	Zuclopenthixol			C	Unknown	400 Mg, Unk		Not Reported
Count Decreased;	Calcium Carbonate			C	Unknown	Unk		Not Reported
Myelocyte Count	Rosuvastatin			C	Unknown	Unk		Not Reported
Increased; Neutropenia;	Coloxyl			C	Unknown	Unk		Not Reported
Platelet Count Increased;	Senna			C	Unknown	Unk		Not Reported
Thermal Burn; Tinea	Movicol			C	Unknown	Unk		Not Reported
Infection; Vitamin B12	Vitamin B12			C	Unknown	Unk		Not Reported
Deficiency; White Blood								
Cell Count Decreased								

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Miosis; Overdose; Pneumonia Aspiration	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Unk	Allergan
	Zopiclone	S	Oral	210 Mg, Qd	Not Reported
	Zopiclone	S	Oral	7.5 Mg, Qhs	Not Reported
	Zyprexa	S	Oral	1 Df, Unk	Not Reported
	Zyprexa	S	Oral	10 Mg, Qam	Not Reported
	Zyprexa	S	Oral	20 Mg, Qpm	Not Reported
	Lysanxia	S	Oral	1440 Mg, Single	Not Reported
	Lysanxia	S	Oral	10 Mg, Qam	Not Reported
	Abilify	S	Oral	5 Mg, Qd	Not Reported
	Olanzapine	S	Oral	1 Df, Unk	Not Reported
	Olanzapine	S	Oral	10 Mg, Qam	Not Reported
	Olanzapine	S	Oral	20 Mg, Qpm	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	13873202	EXPEDITED (15-DAY)		OT	GB-TORRENT-00015503		21 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Bruxism	Escitalopram Oxalate			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14369458	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2017008165			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine 400mg Tablet			S	Oral	400 Mg, Qd		Macleods
	Quetiapine 400mg Tablet			S	Oral	Unk		Macleods
	Quetiapine 400mg Tablet			S	Oral	Unk		Macleods
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S	Oral	Unk		Not Reported

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Abilify	S	Oral	Unk	Not Reported
Laroxyl	S		400 Mg, Qd	Not Reported
Laroxyl	S	Unknown	Unk	Not Reported
Laroxyl	S	Unknown	Unk	Not Reported
Lexapro	S	Oral	10 Mg, Qd	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Lexapro	S	Oral	Unk	Not Reported
Lepticur	S	Unknown	15 Mg, Unk	Not Reported
Lepticur	S	Unknown	Unk	Not Reported
Lepticur	S	Unknown	Unk	Not Reported
Methylphenidate Hydrochloride	S	Oral	100 Mg, Unk, ((80 Mg In The Morning And 20 Mg At 4pm))	Not Reported
Methylphenidate Hydrochloride	S	Oral	110 Mg, Qd, (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Methylphenidate Hydrochloride	S	Oral	Unk, (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg, Unk	Not Reported
Ritaline	S	Oral	110 Mg, Qd	Not Reported
Ritaline	S	Unknown	Unk	Not Reported
Seroplex	S	Oral	10 Mg, Qd	Not Reported
Seroplex	S	Unknown	Unk	Not Reported
Seroplex	S	Unknown	Unk	Not Reported
Xeroquel	S	Oral	400 Mg, Qd	Not Reported
Xeroquel	S	Unknown	Unk	Not Reported
Xeroquel	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14638996	EXPEDITED (15-DAY)	HO		FR-CIPLA LTD.- 2018FR10804			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Escitalopram			S	Oral	1 Df Daily		Invagen
	Irbesartan			S	Oral	300 Mg, Unk		Cipla
	Levofloxacin			S	Oral	2 Df, Unk		Cipla
	Amlodipine			S	Oral	10 Mg, Unk		Invagen
	Terbutaline			S	Respiratory (inhalation)	1 Df, Unk		Not Reported
	Pantoprazole			S	Oral	20 Mg, Unk		Not Reported
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Xarelto			S	Oral	1 Df, Unk		Not Reported
	Alprazolam			S	Oral	0.75 Mg, Unk		Not Reported
	Metformine /00082701/			S	Oral	1000 Mg, Unk		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Unk		Not Reported
	Valium			S	Oral	3 Df, Unk		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, Unk		Not Reported
	Nefopam /00396102/			S	Oral	3 Df, Unk		Not Reported
	Dafalgan			S	Oral	6 Df, Unk		Not Reported
	Furosemide			S	Oral	30 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14639713	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016233		25 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Unknown
	Levonelle			C				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14640395	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02007		56 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Oxycodone And Acetaminophen			S	Oral	Unk		Not Reported	
	Ibuprofen			S	Oral	Unk		Not Reported	
	Montelukast			S	Oral	Unk		Not Reported	
	Ondansetron			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Aciclovir			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14641024	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02009		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Carvedilol			S	Oral	Unk		Lupin	
	Escitalopram			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Valproic Acid			S	Oral	Unk		Not Reported	
	Sitagliptin			S	Oral	Unk		Not Reported	
	Phenytoin			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14648387	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Acne Pustular; Emotional Distress; Erythema;	Escitalopram (Lexapro)			S	Oral	Quantity:1 Tablet(S);		Lupin	
	Pravastatin Sodium			C				Not Reported	

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Glycosylated Haemoglobin	Nasacort Aq	C	Not Reported
Increased;	Lutein & Zeaxanthin	C	Not Reported
Hypersensitivity;	Selenium	C	Not Reported
Lymphadenopathy; Oral	Multiple Viatamin W/Iron	C	Not Reported
Herpes; Rash; Secretion	Vitamin D3	C	Not Reported
Discharge; Stomatitis			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	12673734	EXPEDITED (15-DAY)		HO, LT, OT	CH-OTSUKA-2016_020311		55 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased;	Abilify Maintena			S	Intramuscular	400 Mg, Qm (Every 28 Days)		Otsuka
Confusional State;	Abilify Maintena			S				Otsuka
Disturbance In Attention;	Abilify			S	Oral	15 Mg, Qd		Otsuka
Dysphagia; Fall;	Abilify			S	Oral	5 Mg, Qd		Otsuka
Hyperreflexia; Muscle Rigidity; Mutism;	Escitalopram			S	Unknown	Unk		Not Reported
Neuroleptic Malignant Syndrome; Product Use In	Quetiapine Actavis			C	Oral	300 Mg, Bid		Not Reported
Unapproved Indication;	Temesta (Lorazepam)			C	Oral	0.5 Mg, Every 6 Hours		Not Reported
Serotonin Syndrome;	Amlodipin			C	Oral	5 Mg, Qd		Not Reported
Tremor	Escitalopram Sandoz			C	Oral	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	13514741	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1716961US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt Prolonged; Foetal Exposure During Pregnancy; Hypotonia Neonatal; Neonatal Respiratory Distress; Premature Baby; Tachycardia Foetal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14249147	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1768550US		27 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activation Syndrome; Inappropriate Schedule Of Product Administration	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Flunitrazepam			C	Oral	1 Mg, Qd		Not Reported	
	Flunitrazepam			C	Oral	1 Mg, Unk		Not Reported	
	Vegetamin B			C	Oral	1 Df, Unk		Not Reported	
	Vegetamin A			C		Unk		Not Reported	
	Sertraline			C		Unk		Not Reported	
	Benzalin (Nitrazepam)			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14321006	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE- HET2017DE00433		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Hetero	
	Aripiprazole			S	Oral	5 Mg, Qd		Hetero	
	Escitalopram			S	Oral	10 Mg, Qd		Hetero	
	Escitalopram			S	Oral	15 Mg, Qd		Hetero	
	Escitalopram			S	Oral	20 Mg, Qd		Hetero	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	2 Mg		Not Reported	

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Risperdal	C	Unknown	2 Mg, Qd	Not Reported
L-Thyroxin	C	Oral	100 Mg, Qd	Not Reported
Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
Metformin	C	Oral	1500 Mg, Qd	Not Reported
Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
Acetylsalicylic Acid	C	Unknown	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14596678	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-011012		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Aurobindo	
	Bisoprolol			S	Unknown	()		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14647521	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018011308			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intracranial Haematoma	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods	
	Amlodipine Besylate			C	Unknown	5 Mg, Qd		Macleods	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Levocetirizine Dihydrochloride			C	Unknown	5 Mg, Qd		Not Reported	
	Levothyrox			C	Unknown	50 Mg, Qd, Scored Tablet		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14647972	EXPEDITED (15-DAY)		OT	IE-TEVA-2018-IE-869027		40 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Discomfort;	Escitalopram (G)			S	Unknown			Ivax	

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Insomnia; Motor
Dysfunction; Pain In
Extremity; Paraesthesia;
Paraesthesia

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16-Mar-2018	14648213	EXPEDITED (15-DAY)		DE, HO, OT	DE-PFIZER INC- 2018108729		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral	6 Mg, Qd		Pfizer	
	Tavor [Lorazepam]			S	Oral	2 Mg, Unk		Pfizer	
	Tavor [Lorazepam]			S	Oral	6 Mg, Unk		Pfizer	
	Abilify 3 Mg			S	Oral	20 Mg, Unk		Not Reported	
	Abilify 3 Mg			S	Oral	15 Mg, Unknown		Not Reported	
	Cipralext			S	Oral	10 Mg, Unk		Not Reported	
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Seroquel			S	Oral	200 Mg, Unk		Not Reported	
	Movicol			C	Unknown	Unk		Not Reported	
	Simeticone			C	Unknown	Unk		Not Reported	
	Eferox			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14648301	EXPEDITED (15-DAY)		OT	CH-PFIZER INC- 2018106526		23 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Foetal Death; Nausea	Xanax			S	Oral	0.5 Mg, In Reserve (About 2x Per Day), Practically During The Whole Pregnancy		Pfizer	
	Temesta (Lorazepam)			S	Oral	Unk		Pfizer	

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	Insulin	S	Subcutaneous	Unk			Not Reported		
	Escitalopram	S	Oral	10 Mg, 1x/Day			Not Reported		
	Citalopram	S	Oral	Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14648898	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-007062		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose, 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14649576	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2017PRN00552			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysphagia; Lip Dry; Panic Attack; Tremor	Escitalopram			S				Prinston Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14649577	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN00065		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Fatigue; Heart Rate Increased; Insomnia; Nausea; Palpitations; Panic Reaction; Somnolence; Thirst	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical	
	Topamax			S		Unk		Not Reported	
	Butalbital, Acetaminophen And Caffeine			C		Unk, 1x/Day		Not Reported	
	Lorazepam			C		0.5 Mg, 1x/Day		Not Reported	
	Multivitamin			C				Not Reported	
	Coconut Oil			C		Unk, 1x/Day		Not Reported	

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Probiotic			C			Unk, 1x/Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651913	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE- HET2018US00204		67 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Colitis Microscopic	Escitalopram			S	Unknown			Hetero	
	Lansoprazole			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14660317	DIRECT		DS			54 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Headache; Influenza Like Illness; Nausea	Escitalopram Oxalate			S	Oral	Quantity:2 Mg;		Camber	
	Alprazolam			S	Oral	Quantity:120 Tablet(S);		Dava	
	Milk Thistle			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2018	14036676	EXPEDITED (15-DAY)		LT	JP-ALLERGAN- 1756139US		27 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Zyprexa			C	Oral	2.5 Mg, Unk		Not Reported	
	Zyprexa			C	Oral	2.5		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	13214920	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1705051US		33 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Neutropenia	Escitalopram Oxalate - Bp			S	Oral			Allergan	

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Venlafaxine	S	Oral	Unk	Not Reported
Tranxene	S	Oral		Not Reported
Loxapac	C	Oral	20 Mg, 813 In Total	Not Reported
Bromazepam	C	Oral	12 Mg, Qd	Not Reported
Debridat	C	Oral	2 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14215559	EXPEDITED (15-DAY)		DE, HO, OT	DE-ASTRAZENECA-2017SF18150		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Synagis			S	Intramuscular	150.0mg Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Varivax			S	Intramuscular	1.0df Unknown		Not Reported
	Topiramate			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Spironolactone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14655492	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC-2018-IPXL-00813		29 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anger; Crying; Decreased Appetite; Delusion; Grief Reaction; Headache; Hypomania; Insomnia; Intentional Self-Injury; Suicidal Ideation; Weight Increased	Cabergoline			S	Unknown	0.5 Mg, 1 /Week		Impax
	Escitalopram			S	Unknown	5-10 Mg, Daily		Not Reported
	Escitalopram			S				Not Reported
	Olanzapine			S	Unknown	10 Mg, Daily		Not Reported

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19-Mar-2018	14656190	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-869032			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Amnesia;	Atenolol			S	Unknown			Not Reported	
Arthralgia; Blood Thyroid	Simvastatin			S	Unknown			Ivax	
Stimulating Hormone;	Zyloric 200 Mg, Comprimé			S	Unknown			Not Reported	
Diarrhoea; Dry Skin; Eye	Levothyrox 175 Microgrammes,			S	Oral			Not Reported	
Burns; Fatigue; Feeling	Comprimé Sécable								
Hot; Feeling Jittery;	Cotareg 160 Mg/25 Mg,			S	Unknown			Not Reported	
Insomnia; Irritability;	Comprimé Pelliculé								
Muscle Spasms; Myalgia;	Amlor 10 Mg, Gélule			S	Unknown			Not Reported	
Nasal Dryness;	Seresta 50 Mg, Comprimé			S	Unknown			Not Reported	
Paraesthesia; Pruritus;	Sécable								
Urticaria; Vertigo; Vision	Uvedose			S	Unknown			Not Reported	
Blurred	Imovane			S	Unknown			Not Reported	
	Seroplex 10 Mg, Comprimé			S	Unknown			Not Reported	
	Pelliculé Sécable								
	Endotelon			S	Unknown	2 À 3 Cp/J		Not Reported	
	Voltarene Lp 75 Mg, Comprimé			S	Unknown	2x/Semaine		Not Reported	
	Enrobé À Libération Prolongée								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14656693	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1016963		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal	Escitalopram			S	Unknown	Unk		Not Reported	
Ulcer	Lansoprazole			C	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14664680	DIRECT	Y				64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Drug Ineffective		Escitalopram		S	Oral		Cipla		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14659521	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02244		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Metformin			S	Oral	Unk		Lupin	
	Escitalopram			S	Oral	Unk		Not Reported	
	Losartan			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
	Diltiazem			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Glyburide			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14659893	EXPEDITED (15-DAY)		HO	IT-MYLANLABS- 2018M1016528		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Quetiapine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	270 Mg, Total		Not Reported	
	Etiltox			S	Oral	9 Df, Total		Mylan	
	Carbolithium			S	Oral	5 Df, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14661168	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018108695		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Drug Interaction; Hallucination,	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer	

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Visual	Artotec	S	Oral	2 Df, 1x/Day	Pfizer
	Atarax /00058401/	S	Oral	25 Mg, 1x/Day	Not Reported
	Seroplex	S	Oral	15 Mg, 1x/Day	Not Reported
	Vesicare	S	Oral	10 Mg, 1x/Day	Not Reported
	Cotareg	C		Unk	Not Reported
	Actonel	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14661710	EXPEDITED (15-DAY)		HO	DE-OTSUKA-DJ201500377		50 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Drug Interaction; Restlessness	Abilify			S	Oral	5 Mg, Unk		Otsuka
	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Cipralext			S	Oral	10 Mg, Qd		Not Reported
	Venlafaxin			S	Oral	150 Mg, Qd		Not Reported
	Venlafaxin			S	Oral	75 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	11548643	EXPEDITED (15-DAY)		OT	CN-FRI-1000079616		43 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Condition	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
Aggravated; Daydreaming;	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Depression; Discomfort;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Dissociation; Drug	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan
Dependence; Drug	Escitalopram Oxalate - Bp			S	Oral	80 Mg, Qd		Allergan
Ineffective For	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Unapproved Indication;	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Bid		Allergan
Dysphemia; Emotional	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan
Disorder; General Physical	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Condition Abnormal;	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Homicidal Ideation;	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Inappropriate Schedule Of	Escitalopram Oxalate - Bp			S	Oral	60 Mg, Qd		Allergan
Product Administration;								

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Intentional Overdose;	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
Irritability; Malaise;	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Qd	Allergan
Nervousness; Night	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Qd	Allergan
Sweats; Obsessive-	Escitalopram Oxalate - Bp	S	Oral	120 Mg, Qd	Allergan
Compulsive Disorder; Off	Escitalopram Oxalate - Bp	S	Oral	40 Mg, Bid	Allergan
Label Use; Peripheral	Escitalopram Oxalate - Bp	S	Oral	2 Df, Bid	Allergan
Coldness; Prescribed	Escitalopram Oxalate - Bp	S	Oral	1 Df, Tid	Not Reported
Overdose; Psychiatric	Escitalopram Oxalate - Bp	S	Oral	Unk	Not Reported
Symptom; Somnolence;	Buspirone	C	Unknown	75 Mg, Bid	Not Reported
Stress; Suicidal Ideation	Venlafaxine	C	Unknown		
	Fluvoxamine	C	Unknown		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14422332	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-160708		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Olanzapine			S	Unknown	15 Mg, Daily		Sun	
Drug Ineffective;	Olanzapine			S				Sun	
Homicidal Ideation;	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported	
Suicidal Ideation	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14662213	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR11619			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma;	Escitalopram			S	Oral	1120 Mg, Unk		Invagen	
Sinus Bradycardia	Zopiclone			S	Oral	315 Mg, Unk		Not Reported	
	Plavix			S	Oral	2250 Mg, Unk		Not Reported	
	Coveram			S	Oral	60 Df, Unk		Not Reported	
	Seresta			S	Oral	1000 Mg, Unk		Not Reported	
	Bisoce			S	Oral	300 Mg, Unk		Not Reported	

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Aldactazine			S	Oral	30 Df, Unk			Not Reported	
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21-Mar-2018	14662616	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR11633			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Sedation	Risperidone			S	Oral	1.5 G, Unk		Cipla	
	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Alprazolam			S	Oral	0.13 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14662733	EXPEDITED (15-DAY)		OT	NL-CIPLA LTD.- 2018NL11792			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrooesophageal Reflux Disease	Escitalopram			S	Unknown	10 Mg, Daily		Invagen	
	Levothyroxinenatrium Teva			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14663382	NON-EXPEDITED			US-PFIZER INC- 2018107422		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition Aggravated; Nervousness	Effexor Xr			S		Unk (She Was Taking 10 Or 20mg Of The Effexor)		Pfizer	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14665238	EXPEDITED (15-DAY)		OT	PHHY2018US040075		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Diarrhoea; Mucosal	Lansoprazole			S	Unknown			Novartis	

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Ulceration; Rectal Ulcer		Escitalopram		S	Unknown		Not Reported		
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21-Mar-2018	14665671	EXPEDITED (15-DAY)		HO, LT	CH-ALLERGAN-1815228US		53 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Poisoning	Escitalopram Oxalate - Bp			S	Oral	Overdose: 80 Mg		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Quilonorm			S	Oral	50 Mg, Qd		Not Reported	
	Nebivolol			C	Oral	5 Mg, Qd		Not Reported	
	Lansoprax			C	Oral	15 Mg, Qd		Not Reported	
	Symbicort			C	Other	200/6 Mg, Q12h		Not Reported	
	Spiriva			C	Other	18 Mg, Qd		Not Reported	
	Durogesic			C	Transdermal	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14665676	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1815221US		40 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thyroid Mass	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14666038	EXPEDITED (15-DAY)		OT	CH-SHIRE-CH201809425			Unknown	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Elvanse			S	Unknown			Shire	
	Abilify			S	Oral	10-15 Mg, 1x/Day:Qd		Not Reported	
	Cipralext			S	Unknown			Not Reported	
	Topamax			S	Unknown			Not Reported	

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21-Mar-2018	14668932	DIRECT						Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Lexapro			S				Not Reported	
	Celexa			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	11910446	EXPEDITED (15-DAY)		HO	FR-FRI-1000082056		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Off Label Use; Raynaud'S Phenomenon	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Abilify			S	Oral	15 Mg, Qd		Not Reported	
	Abilify			S				Not Reported	
	Abilify			S				Not Reported	
	Laroxyl			S	Unknown	Unk		Not Reported	
	Laroxyl			S				Not Reported	
	Laroxyl			S				Not Reported	
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported	
	Xeroquel			S				Not Reported	
	Xeroquel			S				Not Reported	
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported	
	Lepticur			S				Not Reported	
	Lepticur			S				Not Reported	
	Ritaline			S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4 Pm)		Not Reported	
	Ritaline			S	Oral	90 Mg, Qd		Not Reported	
	Ritaline			S	Oral	110 Mg, Qd		Not Reported	

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22-Mar-2018	13514665	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1026501		51 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral	10 Mg, Total		Not Reported	
	Xanax			S	Oral	0.25 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14274308	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-OTSUKA-DJ20060604		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest	Abilify			S	Oral	15 Mg, Unk		Otsuka	
	Tiapridal			S	Oral	100 Mg, Qd		Not Reported	
	Seroplex			S	Oral	15 Mg, Qd		Not Reported	
	Cytotec			S	Vaginal	800 Mg, Unk		Not Reported	
	Misoprostol			S	Unknown	800 Mg, Unk		Not Reported	
	Lexapro			S	Unknown	15 Mg, Qd		Not Reported	
	Imovane			C	Unknown	7 Mg, Unk		Not Reported	
	Lysanxia			C	Unknown	10 Mg, Unk (10 Mg To 40 Mg)		Not Reported	
	Mifegyne			C	Oral	600 Mg, Unk (200 Mg, Unk)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14321373	EXPEDITED (15-DAY)		HO	DE-TORRENT-00007417		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	5 Mg, Qd		Unknown	
	L-Thyroxin			C	Oral	100 G, Qd		Unknown	

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Amisulid	C	Unknown	200 Mg, Qd	Unknown
Metformin	C	Oral	1500 Mg, Qd	Unknown
Atorvastatin	C	Oral	20 Mg, Qd	Unknown
Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Unknown
Candesartan	S	Oral	16 Mg, Qd	Unknown
Escitalopram	S	Oral	10 Mg, Qd	Unknown
Risperdal	C		2 Mg, Unk (For Nights)	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14475395	EXPEDITED (15-DAY)		HO, LT	GR-ALLERGAN-1804920US		67 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported	
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14667239	EXPEDITED (15-DAY)		OT	US-ZYDUS-019308		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Diarrhoea; Rectal Ulcer	Escitalopram			S	Unknown			Zydus Pharm	
	Lansoprazole			C	Unknown			Not Reported	

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22-Mar-2018	14667431	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-015223		40 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thyroid Mass	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14667523	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018011593			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thyroid Mass	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14670220	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018094170		38 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Lyrica			S		1000 Mg, Daily For 5 Months		Pfizer	
	Lyrica			S		5 Df, Daily (2 Df In The Morning And 3 Df In The Evening) For One Month		Pfizer	
	Seroplex			S		2 Df, Daily 1 Tablet In The Morning And In The Evening For 1 Month		Not Reported	
	Seroplex			S		1 Df, Daily (Pharmacist Dispensed Escitalopram 20 Mg At 1 Tablet Daily As A Maximal Daily Dose)		Not Reported	
	Urbanyl			S		0.5 Df, 3x/Day (Half A Tablet In The Morning, At Noon And In The Evening		Not Reported	

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Monocrixo	S	For 1 Month) 150 Mg, 1x/Day (One Hard Capsule At Bedtime For One Month)	Not Reported

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22-Mar-2018	14670544	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1815440US		22 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Medication Error	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Ritalin			S	Oral	10 Mg, Unk		Not Reported
	Valium			S	Oral	5 Mg, Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Stesolid			S	Oral	5 Mg, Unk		Not Reported
	Atarax			S	Oral	25 Mg, Unk		Not Reported
	Rohypnol			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Vallergan			S	Oral	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14670582	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1815443US		40 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Paraesthesia; Product Dose Omission; Sexual Dysfunction	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

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23-Mar-2018	12573239	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-120492		66 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Rosuvastatin			S	Unknown			Sun	
	Perindopril			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Lercanidipine			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Sun	
	Atenolol			S	Unknown			Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14282969	EXPEDITED (15-DAY)		HO	DE-TEVA-2017-DE- 830307		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Teva	
	Aripiprazole			S	Oral	5 Mg, Qd		Teva	
	Escitalopram			S	Oral	10 Mg, Qd		Ivax	
	Escitalopram			S	Oral	15 Mg, Qd		Ivax	
	Escitalopram			S	Oral	20 Mg, Qd		Ivax	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported	
	Risperdal			C	Unknown	2 Mg, Unk (For Nights)		Not Reported	
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported	
	L-Thyroxin /00068001/			C	Oral	100 Mg, Qd		Not Reported	
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported	
	Metformin			C	Oral	1500 Mg, Qd		Not Reported	
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported	

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Acetylsalicylic Acid			C	Oral	100 Mg, Qd			Not Reported	
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23-Mar-2018	14419460	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1004408		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Parkinsonism; Therapeutic Product Effect Incomplete	Fluvoxamine			S	Unknown	200 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Clomipramine			S	Unknown	150 Mg, Qd		Not Reported	
	Aripiprazole			S	Unknown	10 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14570558	EXPEDITED (15-DAY)		DE, OT	SK-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2018- BI-01		72 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage Intracranial	Pradaxa			S	Oral			Boehringer Ingelheim	
	Pradaxa			S				Boehringer Ingelheim	
	Cipralext			S	Unknown			Not Reported	
	Vitacalcin			C	Unknown			Not Reported	
	Siofor			C	Unknown			Not Reported	
	Carvedilol			C	Unknown			Not Reported	
	Valsacor			C	Unknown			Not Reported	
	Cynt			C	Unknown			Not Reported	
	Preductal			C	Unknown			Not Reported	
	Detralex			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Helidac			C	Unknown			Not Reported	
	Aricept			C				Not Reported	

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23-Mar-2018	14665576	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018112213		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14671493	EXPEDITED (15-DAY)		HO	LT-MACLEODS PHARMACEUTICALS US LTD- MAC2018011708			Unknown	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Insomnia; Overdose; Speech Disorder	Escitalopram Oxalate			S	Oral	Unk Overdose		Macleods	
	Quetiapine			S	Oral	Unk		Macleods	
	Zolpidem			S	Oral	Unk		Not Reported	
	Etoricoxib			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14672009	EXPEDITED (15-DAY)		OT	US-ALEMBIC PHARMACUETICALS LIMITED- 2018SCAL000221			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine Hydrochloride			S	Unknown	Unk		Alembic	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, (Single)		Not Reported	

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23-Mar-2018	14672825	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02418		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Metformin			S	Oral	Unk		Lupin	
	Alprazolam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Naproxen			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14673052	EXPEDITED (15-DAY)		OT	PHHY2018AU048414		63 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myeloid Leukaemia;	Famciclovir			S	Unknown			Novartis	
Anion Gap Increased;	Baclofen			S	Unknown			Not Reported	
Blood Albumin Decreased;	Allopurinol			S	Unknown			Not Reported	
Blood Lactate	Escitalopram			S	Unknown			Not Reported	
Dehydrogenase	Idarubicin			S	Unknown			Not Reported	
Increased; Bundle Branch	Pantoprazole			S	Unknown			Not Reported	
Block Left; Dysplasia;	Duodart			S	Unknown			Not Reported	
Fungal Infection;									
Haematocrit Decreased;									
Haemoglobin Decreased;									
Lung Infection;									
Myelodysplastic									
Syndrome; Platelet Count									
Decreased; Red Blood									
Cell Count Decreased;									
Red Cell Distribution									
Width Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14673530	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS- 2018GMK033547		63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose,In Total		Glenmark
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14674366	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE- GLAXOSMITHKLINE- BE2018046286			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Sipralexa			S	Transplacental	10 Mg, Unk		Glaxosmithkline
	Fluticasone Furoate + Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Glaxosmithkline
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Ventolin			S	Transplacental	100 ?G, Unk		Glaxosmithkline
	Mepolizumab			S	Transplacental	100 Mg, Unk		Glaxosmithkline
	Avamys			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Xyzall			S	Transplacental	5 Mg, Qd		Glaxosmithkline
	Flixotide			S	Transplacental	500 ?G, Qd		Glaxosmithkline
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental	Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14674696	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS- 2018M1017497		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug	Topiramate			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported

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Interaction; Irritability; Overdose; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram	S	Unknown	Unk	Not Reported
	Temazepam	S	Oral	Pills	Not Reported
	Quetiapine	S	Oral	Pills	Not Reported
	Naloxone	S	Intramuscular	0.8 Mg	Not Reported
	Oxazepam	S	Oral	Pills	Mylan
	Atorvastatin	C	Unknown	Unk	Mylan
	Ferrous Gluconate	C	Unknown	Unk	Mylan
	Furosemide	C	Unknown	Unk	Mylan
	Metoprolol	C	Unknown	Unk	Mylan
	Ramipril	C	Unknown	Unk	Mylan
	Spironolactone	C	Unknown	Unk	Mylan
	Fluticasone W/Salmeterol	C	Unknown	Unk	Mylan
	Ipratropium	C	Unknown	Unk	Mylan
	Salbutamol	C		Metered Dose Inhalers	Mylan
	Clopidogrel	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14675255	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18- 02		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Hikma
	Ondansetron			S	Intravenous (not otherwise specified)			Hikma
	Venlafaxine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14675261	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1815674US		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colitis Microscopic		Escitalopram Oxalate - Bp		S	Oral		Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14675262	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1815692US		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14676021	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-873207		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14676160	EXPEDITED (15-DAY)		OT	PHHY2018AU045141			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anion Gap Increased; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Left; Disease Progression; Dysplasia; Fungal Infection; Haematocrit Decreased; Haemoglobin Decreased; Lung Infection; Platelet	Famciclovir			S	Unknown			Novartis	
	Baclofen			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Allopurinol			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Idarubicin			S	Unknown			Not Reported	
	Dutasteride			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Count Decreased; Red
Blood Cell Count
Decreased; Red Cell
Distribution Width
Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	14676805	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2017004988			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self- Injury; Nausea; Tremor	Escitalopram			S	Oral	200 Mg, Total		Macleods	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2018	14677434	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2018M1017318		91 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fall	Lansoprazole			S	Oral	30 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Gliclazide			S	Oral	60 Mg, Qd		Not Reported	
	Stilnox			S	Oral	1 Df, Qd		Mylan	
	Efferalgan Cod.			C		Unk		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2018	14677444	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2018M1017341		69 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Stevens-Johnson Syndrome	Citalopram			S	Unknown			Not Reported	
	Trimethoprim			S	Unknown			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Septrin	S	Unknown		Mylan
Escitalopram	S	Unknown		Mylan
Cabergoline	S	Unknown		Mylan
Carbidopa	S	Unknown		Mylan
Entacapone	S	Unknown		Mylan
Levodopa	S	Unknown		Mylan
Stalevo /01530202/	S	Unknown		Mylan
Co-Beneldopa	C		25/100 Capsules	Mylan
Co-Beneldopa	C			Mylan
Macrogol	C			Mylan
Duloxetine	C		Duloxetine 90mg Capsule	Mylan
Adcal D3	C			Mylan
Rivastigmine	C			Mylan
Quetiapine	C			Mylan
Paracetamol	C			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14076460	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1757544US		68 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Green Tea			S	Unknown	Unk		Not Reported
	Green Tea			S	Unknown	Unk		Not Reported
	Emconcor Cor			C	Oral	Unk		Not Reported
	Simvastatina Cinfa			C	Oral	20 Mg, Qd		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	3500 Iu, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14672367	NON-EXPEDITED			US-ASTRAZENECA-2018SE34792		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Glucose Increased; Erectile Dysfunction; Heart Rate Increased; Inappropriate Schedule Of Product Administration; Off Label Use	Metoprolol Succinate	S	Oral			Not Reported
	Metoprolol Succinate	S	Oral			Not Reported
	Seroquel	S	Oral			Zeneca
	Seroquel	S	Oral			Zeneca
	Escitalopram	S	Oral	Generic 10mg, Daily		Not Reported
	Cardizem	S	Oral			Not Reported
	Clonazepam	S	Oral			Not Reported
	Clonazepam	S	Oral			Not Reported
	Lipitor	S	Oral			Not Reported
	Metoprolol	S	Oral			Not Reported
	Metoprolol	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14678981	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.- 2018IT12257			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree	Escitalopram			S	Oral	10 Mg Per Day		Invagen
	Abilify			S	Oral	10 Mg Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14679048	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1815704US		93 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intracranial Haematoma	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Kardegic			S	Oral			Not Reported
	Levocetirizine Dihydrochloride			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14679739	EXPEDITED (15-DAY)		HO	CH-BAYER-2018-054408		82 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenia	Xarelto			S	Oral	10 Mg, Qd		Unknown	
	Aspirin Cardio 100 Mg			S	Oral	100 Mg, Qd		Bayer	
	Calcimagon			S	Oral	500 Mg, Qd, Correct Dose: 500mg/800 E		Not Reported	
	Cipralex			S	Oral	5 Mg, Qd		Not Reported	
	Pantoprazole Sodium			S	Oral	20 Mg, Qd		Not Reported	
	Remeron			S	Oral	15 Mg, Qd		Not Reported	
	Risperdal			S	Oral	1 Mg, Qd		Not Reported	
	Dafalgan			S	Oral	500 Mg, Qid		Not Reported	
	Torem			S	Oral	30 Mg, Qd, Correct Dose:X5 Mg 4-2-0		Not Reported	
	Aldactone [Spironolactone]			S	Oral	25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680056	EXPEDITED (15-DAY)		DE	FI-BAYER-2018-052023			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ventricular Fibrillation	Ciprofloxacin			S				Bayer	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680419	EXPEDITED (15-DAY)			US-ARALEZ PHARMACEUTICALS R&D INC.-2018-ARA-000643		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Inappropriate Schedule Of	Metoprolol Succinate			S	Oral	50 Mg, Bid		Aralez Pharmaceuticals	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Administration; Off Label Use	Metoprolol Succinate	S						Aralez Pharmaceuticals Not Reported
	Escitalopram	S	Oral	10 Mg, Qd				Not Reported
	Cardizem /00489701/	S	Oral	180 Mg, Qd				Not Reported
	Clonazepam	S	Oral	1 Mg, Qd				Not Reported
	Clonazepam	S						Not Reported
	Lipitor	S	Oral	40 Mg, Qd				Not Reported
	Seroquel	S	Oral	50 Mg, Qd				Not Reported
	Seroquel	S	Oral	150 Mg, Qd				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680697	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-872661			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coeliac Disease; Diarrhoea; Drug Ineffective; Nausea; Vomiting	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14681827	EXPEDITED (15-DAY)		OT	NO-PFIZER INC-2018120857		22 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Medication Error	Efexor Depot			S		Unk		Pfizer
	Sobril			S		Unk		Pfizer
	Ritalin			S	Oral	10 Mg, Unk		Not Reported
	Valium			S	Oral	5 Mg, Unk		Not Reported
	Stesolid			S	Oral	5 Mg, Unk		Not Reported
	Atarax			S	Oral	25 Mg, Unk		Not Reported
	Rohypnol			S	Unknown	Unk		Not Reported
	Imovane			S	Oral	7.5 Mg, Unk		Not Reported
	Cipralext			S	Oral	10 Mg, Unk		Not Reported

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Vallergan			S	Oral	10 Mg, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14685991	DIRECT	Y				61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Muscle Spasms	Escitalopram			S	Oral			Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14073495	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1757190US		47 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Off Label Use; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Seropram Konzentrat Zur Infusionsbereitung			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported	
	Alprazolam			S	Unknown	0.5 Mg, Qd		Not Reported	
	Alprazolam			S	Unknown	5 Mg, Qd		Not Reported	
	Temesta (Lorazepam)			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14379229	EXPEDITED (15-DAY)		HO, OT	AT-MACLEODS PHARMACEUTICALS US LTD-MAC2017008317			Unknown	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Macleods	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods	
	Seropram (Citalopram Hydrobromide)			S	Intravenous drip	20 Mg, Qd, (Seropram Concentrate For Infusion Preparation)		Not Reported	

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	Alprazolam		S	Unknown	0.5 Mg, Qd			Not Reported	
	Alprazolam		S	Unknown	1 Mg, Unk			Not Reported	
	Temesta (Lorazepam)		C	Oral	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14455269	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1804113US		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Blood Pressure Decreased; Cardiomyopathy	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14627742	EXPEDITED (15-DAY)		LT, OT	IT-ALLERGAN-1813199US		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Incorrect Dose Administered; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Abilify			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14638704	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R5-165596			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Parkinson'S Disease; Product Administration Error; Tremor	Risperidone			S	Unknown	Half Tablet		Ranbaxy	
	Escitalopram			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Not Reported	
	Akineton			S	Unknown			Not Reported	

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27-Mar-2018	14683009	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-159037		45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Coma; Fall; Rib Fracture	Zolpidem			S	Oral	Unk		Sun	
	Baclofen			S	Oral	Unk		Sun	
	Lexomil Roche			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Valium			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14683417	NON-EXPEDITED			US-PFIZER INC- 2018125856		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depression	Pristiq			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14683944	EXPEDITED (15-DAY)		HO	NO-ALLERGAN- 1815832US			Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14684145	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT- 00016313		70 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Gastrointestinal Tube Insertion; Laryngectomy	Salbutamol Inhaler	C	Unknown	Unknown
	Escitalopram	S	Unknown	Unknown
	Prucalopride	C	Unknown	Unknown
	Morphine Sulphate	C	Unknown	Unknown
	Cald-3	C	Unknown	Unknown
	Bendroflumethaide	C	Unknown	Unknown
	Gabapentin	C	Unknown	Unknown
	Calciferol [Ergocalciferol]	C	Unknown	Unknown
	Tiotropium Inhaler	C	Unknown	Unknown
	Alendronic Acid	C	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14684326	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-2018M1018897			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Condition Aggravated; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Escitalopram			S	Oral	10 Mg, Hs		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Zolpidem			S	Oral	10 Mg, Od		Not Reported
	Zolpidem			S				Not Reported
	Clarithromycin			S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses		Not Reported
	Doxepin			S		Unk		Not Reported
	Doxepin			S	Oral	25 Mg, Od, At Bed Time		Not Reported
	Doxepin			S				Not Reported
	Doxepin			S				Not Reported
	Sertraline			S				Not Reported
	Sertraline			S	Oral	50 Mg, Od, (In The Morning)		Not Reported
	Bisoprolol			S	Oral	Unk		Not Reported

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	Meloxicam	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
	Meloxicam	S		Unk	Not Reported
	Atorvastatin	S	Oral	Unk (Bedtime)	Not Reported
	Tramadol	S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol	S		Unk	Not Reported
	Perindopril	S	Oral	Unk	Not Reported
	Polisen	S	Unknown	10 Mg, Od, At Bed Time	Mylan
	Atoris	S	Unknown	Unk	Mylan
	Concor	S	Unknown	Unk	Mylan
	Trosicam	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14685908	EXPEDITED (15-DAY)		OT	ES-BAYER-2018-013966			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Musculoskeletal Pain; Somnolence; Treatment Noncompliance	Paracetamol			S	Unknown	1 Df, Tid		Bayer
	Aleve			S		1 Df, Bid		Bayer
	Noctamid 2 Mg			S	Unknown	1 Df, Qd		Not Reported
	Omeprazole			S		1 Df, Qd		Not Reported
	Glibenclamida			S		2 Df, Qd		Not Reported
	Temazepam			S		Unk, Qd		Not Reported
	Amitriptyline			S		25 Mg, Qd		Not Reported
	Amitriptyline			S		12.5 Mg, Unk		Not Reported
	Amitriptyline			S		5 Mg, Unk		Not Reported
	Amlodipine			S		1 Df, Qd		Not Reported

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Simvastatin	S		1 Df, Qd	Not Reported
Simvastatin	S		20 Mg, Unk	Not Reported
Escitalopram	S		1 Df, Qd	Not Reported
Topiramate	S		1 Df, Qd	Not Reported
Topiramate	S	Unknown	2 Df, Qd	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Topiramate	S	Unknown	25 Mg, Qd	Not Reported
Topiramate	S	Unknown	12.5 Mg, Qd	Not Reported
Topiramate	S	Unknown	5 Mg, Qd	Not Reported
Topiramate	S	Unknown	1 Df, Tid	Not Reported
Topiramate	S	Unknown	20 Mg, Unk	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Topiramate	S	Unknown	.5 Df, Unk	Not Reported
Topiramate	S	Unknown	.5 Df, Unk	Not Reported
Topiramate	S	Unknown	1 Df, Qd	Not Reported
Enalaprilhydrochlorothiazide	S		1 Df, Unk	Not Reported
Diazepam	S		.5 Dosage Forms Daily; 5 Mg	Not Reported
Tramadol	S	Unknown	3 Df, Qd; 1 Df = 37.5/325 Mg	Not Reported
Metoclopramide	C			Not Reported
Metoclopramide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14685962	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2018M1020948		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Olanzapine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	

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27-Mar-2018	14686686	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2018M1018234		29 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypomania; Mood Altered; Psychotic Symptom	Cabergoline			S	Unknown	0.5 Mg, Qw		Not Reported	
	Escitalopram			S	Unknown	5-10mg Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	13042782	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK186963		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Diclofenac Diethylammonium Salt			S	Unknown	Unk Unk, Qw		Glaxosmithkline	
	Methotrexate			S	Unknown	Unk		Glaxosmithkline	
	Vitamin D3			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk, Qd		Glaxosmithkline	
	Cosentyx			S	Subcutaneous	150 Mg, Qw		Not Reported	
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Not Reported	
	Cosentyx			S	Unknown	Unk		Not Reported	
	Humira			C	Unknown	Unk		Not Reported	
	Enbrel			C	Unknown	Unk		Not Reported	
	Remicade			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	13537421	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1718950US		19 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Qt Prolonged; Intentional	Escitalopram Oxalate Unk			S	Oral	200 Mg, In Total		Allergan	

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Self-Injury; Nausea; Off
Label Use; Tremor

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28-Mar-2018	14326568	EXPEDITED (15-DAY)		DE, OT	FI-MACLEODS PHARMACEUTICALS US LTD- MAC2017007498			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ventricular Fibrillation	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Ciprofloxacin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14444511	EXPEDITED (15-DAY)		HO, LT, OT	GR-MACLEODS PHARMACEUTICALS US LTD- MAC2018008827			Unknown	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported	
	Methylene Blue			S	Intravenous (not otherwise specified)	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14573676	EXPEDITED (15-DAY)		OT	ES-SA-2018SA041186		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Lantus Solostar	S	Subcutaneous	Not Reported
	Solostar	S		Not Reported
	Enalapril	S	Oral	Not Reported
	Carvedilol	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Seguril	S	Oral	Not Reported
	Orvatez	S	Oral	Not Reported
	Lyxumia	C	Subcutaneous	Dose:20 Unit(S) Not Reported
	Toujeo	C	Subcutaneous	Not Reported
	Solostar U300	C		Not Reported
	Novorapid	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14637299	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-866885		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	0-0-1		Teva
	Escitalopram			S	Oral	1-0-0		Ivax
	Irbesartan			S	Oral	1-0-0		Actavis
	Furosemide			S	Oral	1-0-0		Ivax
	Seresta 10 Mg, Comprimé			C	Oral	0-0-1		Not Reported
	Duphalac			C	Oral	1-1-1		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C	Oral	0-1-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14654699	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1805711US		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Balanitis	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan

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Candida; Depression; Gastrointestinal Candidiasis; Type 2 Diabetes Mellitus	Cardiocalm	S	Oral	3 Df, Qd	Not Reported
	Cardiocalm	S	Oral	1 Df, Qd	Not Reported
	Stelara	S	Subcutaneous	90 Mg, 1 Time Every 12 Weeks	Not Reported
	Stelara	S			Not Reported
	Stresam	S	Oral	150 Mg, Qd	Not Reported
	Stresam	S	Oral	50 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14687067	EXPEDITED (15-DAY)		OT	US-ZYDUS-019478		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine/Venlafaxine Hydrochloride			S				Zydu Pharm	
	Escitalopram			S				Zydu Pharm	
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose ; In Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14687373	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US12827			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Invagen	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single Dose; In Total		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688333	EXPEDITED (15-DAY)		OT	US-ACCORD-064819		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt	Escitalopram			S				Not Reported	

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Prolonged	Ondansetron	S	Intravenous (not otherwise specified)	Accord
	Venlafaxine/Venlafaxine Hydrochloride	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688571	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018011944			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine			S	Unknown	Unk		Macleods
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single (4 Mg, Single Dose)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688814	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-010392			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram 20 Mg			S	Oral	20 Milligram, Daily		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688821	EXPEDITED (15-DAY)		HO	PHHY2018CH049405		73 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hyponatraemia	Exforge Hct			S	Oral	1 Df, Qd		Novartis
	Escitalopram Mepha 5 Mg			S	Oral	5 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	1 Df, Qmo		Not Reported
	Nebilet			C	Oral	5 Mg, Qd		Not Reported
	Valdoxan			C	Oral	50 Mg, Qd		Not Reported
	Stilnox			C	Oral	5 Mg, Qd		Not Reported

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Pantozol			C	Oral	20 Mg, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14689063	EXPEDITED (15-DAY)	HO		FR-ROCHE-2090184		25 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Malaise	Rivotril			S	Oral			Not Reported	
	Atarax			S	Oral			Not Reported	
	Marinol (Dronabinol)			S	Oral			Not Reported	
	Acupan			S	Subcutaneous			Not Reported	
	Donormyl (Doxylamine Succinate)			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Levocarnil			C	Unknown	100 Mg/ML		Not Reported	
	Cymbalta			C	Oral			Not Reported	
	Theralene			C	Oral			Not Reported	
	Melatonine			C	Oral			Not Reported	
	Dafalgan Codeine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14689471	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1816059US		2 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Administration Error; Tachycardia	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14689488	EXPEDITED (15-DAY)	CA		NL-TEVA-2018-NL-874587			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Congenital Oral Malformation	Escitalopram Tablet, 10 Mg (Milligram)	S		10 Milligram Daily; 1 Dd 1	Ivax
	Foliumzuur	C	Unknown		Not Reported
	Davitamon	C	Unknown		Not Reported
	Cyklokapron	C	Unknown		Not Reported
	Calciumcarbonaat/Colecalciferol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14690333	EXPEDITED (15-DAY)	CA		NL-MYLANLABS-2018M1018058			Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Oral Malformation	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Foliumzuur			C	Transplacental			Mylan
	Davitamon			C	Transplacental			Mylan
	Cyklokapron			C	Transplacental			Mylan
	Calciumcarbonaat/Colecalciferol			C	Transplacental			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14690811	EXPEDITED (15-DAY)	OT		SG-ALLERGAN-1816318US		69 YR	Female	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Pruritic	Escitalopram Oxalate - Bp			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14691339	EXPEDITED (15-DAY)	OT		SG-ALLERGAN-1816326US		59 YR	Male	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Erythematous	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	13638516	EXPEDITED (15-DAY)	OT		IT-MYLANLABS-		50 YR	Female	ITA

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2017M1034158

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 MI, Total		Not Reported	
	Escitalopram Oxalate			S	Oral	15 MI, Total		Mylan	
	Esomeprazole Sodium			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14297404	EXPEDITED (15-DAY)		OT	IT-CIPLA LTD.- 2017IT26604			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Abuse; Vomiting	Escitalopram			S	Oral	10 Df, Unk In Total		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14692667	NON-EXPEDITED			IN-LUPIN LIMITED- 2017-07845		17 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Galactorrhoea	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Sertraline			S	Unknown	50 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14692700	EXPEDITED (15-DAY)		DE, HO	FR-CIPLA LTD.- 2018FR12799			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Venous Thrombosis	Escitalopram			S	Oral	1 Df, Per Day		Invagen	
	Qizenday			S	Oral	3 Df, Unk		Not Reported	
	Vesicare			S	Oral	1 Df, Unk		Not Reported	
	Dafalgan			S	Oral	Unk		Not Reported	

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Baclofene	S	Oral	45 Mg, Unk	Not Reported
Xatral /00975301/	S	Oral	1 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14692709	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR12715			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disorientation; Hallucination, Visual	Hydroxyzine			S	Oral	25 Mg, Per Day		Invagen
	Escitalopram			S	Oral	15 Mg, Per Day		Invagen
	Vesicare			S	Oral	10 Mg, Per Day		Not Reported
	Artotec			S	Oral	2 Df, Per Day		Not Reported
	Lyrica			S	Oral	75 Mg, Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14692912	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02674		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse	Cocaine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Lupin
	Bupropion			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14693229	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018011876			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Tachycardia	Escitalopram Oral Solution			S	Oral	45 MI, 1 Cycle		Macleods

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Risperdal			C	Oral	1 Mg/ML, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14693480	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180333510		73 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Dysuria; Hyponatraemia; Upper Respiratory Tract Infection	Simponi			S	Subcutaneous			Not Reported	
	Exforge Hct			S	Oral			Not Reported	
	Escitalopram Mepha 5 Mg			S	Oral			Not Reported	
	Nebilet			C	Unknown			Not Reported	
	Valdoxan			C	Unknown			Not Reported	
	Stilnox			C	Unknown			Not Reported	
	Pantozol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14693521	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018052435		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Lansoprazole			S	Unknown	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694348	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown			Hikma	
	Lansoprazole			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694516	EXPEDITED (15-DAY)		HO	LT-ALLERGAN-1816293US		46 YR	Female	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Insomnia; Overdose; Speech Disorder	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Quetiapine			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	Unk		Not Reported	
	Etoricoxib			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14696033	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1816276US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Aplasia	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan	
	Clexane			C	Transplacental	40 Mg, Qd		Not Reported	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14696233	EXPEDITED (15-DAY)		OT	US-SUNOVION-2018SUN001218			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Feeling Abnormal; Suicidal Ideation; Weight Decreased	Latuda			S	Oral			Sunovion	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	11101412	EXPEDITED (15-DAY)		OT	FR-ASTELLAS-2015EU006269		29 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Dizziness	Vesicare			S	Unknown			Astellas
	Seroplex			S	Unknown			Not Reported
	Abilify			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Lexapro /01588501/			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14635820	EXPEDITED (15-DAY)		HO	AT-JNJFOC-20180304736		27 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Mood; Extrapyramidal Disorder; Fluid Retention; Hospitalisation; Hypotension; Lipoma; Memory Impairment; Off Label Use; Product Prescribing Error; Rash; Schizophrenia; Suicidal Ideation; Visual Impairment	Haldol			S	Unknown			Not Reported
	Zyprexa			S	Unknown			Not Reported
	Ciprallex			S	Unknown			Not Reported
	Akineton			S	Unknown			Not Reported
	Prothipendyl			S	Unknown			Not Reported
	Temesta (Lorazepam)			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14651819	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-014350		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Furosemide			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk ()		Not Reported
	Bisoprolol			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk ()		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	20 Mg, Unk		Aurobindo

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698702	NON-EXPEDITED			US-PFIZER INC-2018128151		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Ultracet			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698856	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000543		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Suicide Attempt	Hydrochlorothiazide			S	Unknown	Unk		Ipca	
	Amlodipine			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Amphetamine/Dextroamphetamine			S	Unknown	Unk		Not Reported	
	Buspirone			S	Unknown	Unk		Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698870	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018011909			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram			S	Oral	15 Mg, Unk		Macleods	
	Escitalopram			S	Oral	10 Mg, Unk		Macleods	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14699039	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2018IN13907			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Delusion; Drug Ineffective; Headache; Hypomania; Weight Increased	Escitalopram			S	Unknown	5 To 10 Mg Per Day		Invagen	
	Olanzapine			S	Unknown	10 G, Per Day		Invagen	
	Cabergoline			S	Unknown	0.5 Mg, Once A Week		Not Reported	
	Aripiprazole			S	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14699312	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2017272929		78 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ear Haemorrhage	Amiodarone Hcl			S	Unknown	Unk		Pfizer	
	Ciprallex			S	Oral			Not Reported	
	Coumadin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14699375	EXPEDITED (15-DAY)		HO	FR- GLAXOSMITHKLINE- FR2018049596		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline	
	Esomeprazole			S	Oral	20 Mg, Qd		Glaxosmithkline	
	Valaciclovir			S	Oral	500 Mg, Qd		Glaxosmithkline	
	Ramipril			S	Oral	Unk		Glaxosmithkline	
	Metoclopramide			S	Oral	Unk		Glaxosmithkline	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14699786	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1019085		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Ceftriaxone			S		Unk		Not Reported	
	Risperidone			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14699818	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-874895		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Irritability; Overdose; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Quetiapine			S	Unknown			Teva	
	Quetiapine			S	Oral	Pills		Teva	
	Escitalopram			S	Unknown			Ivax	
	Temazepam			S	Oral	Pills		Actavis	
	Oxazepam			S	Oral	Pills		Not Reported	
	Naloxone			S	Intramuscular	0.8 Mg		Not Reported	
	Citalopram			S	Unknown			Actavis	
	Atorvastatin			C	Unknown			Not Reported	
	Ferrous-Gluconate			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Ramipril			C	Unknown			Not Reported	
	Spironolactone			C	Unknown			Not Reported	
	Fluticasone/Salmeterol			C	Unknown			Not Reported	
	Ipratropium			C	Unknown			Not Reported	
	Salbutamol			C	Respiratory (inhalation)	Metered Dose Inhalers		Not Reported	

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Clopidogrel			C		Unknown			Not Reported	
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30-Mar-2018	14700253	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1816521US		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antipsychotic Drug Level Increased; Seizure; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Clozaril			S	Oral	500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14700294	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816529US		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Escitalopram Oxalate - Bp			S	Oral	27 Df, Single		Allergan	
	Paracetamol			S	Oral	40 G, Single		Not Reported	
	Codeine			S	Oral	6 Df, Single		Not Reported	
	Alprazolam			S	Oral	15 Df, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14700339	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine			S	Oral			Westward	
	Escitalopram			S	Oral			Hikma	
	Hydrochlorothiazide			S	Oral			Hikma	
	Venlafaxine			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Duophet (Amphetamine, Dextroamphetamine)			S	Oral			Not Reported	

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Fluoxetine	S	Oral	Not Reported
Buspirone	S	Oral	Not Reported

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30-Mar-2018	14700776	EXPEDITED (15-DAY)	HO		PHHY2018FR055600		88 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Mg, Qd		Novartis
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14701107	EXPEDITED (15-DAY)		DE, HO, OT	DE-BAUSCH-BL-2018-007866		55 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported
	Cipralext			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Lexapro			S	Unknown			Not Reported
	Tavor [Lorazepam]			S	Oral			Not Reported
	Tavor			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Movicol			C				Not Reported
	Simeticone			C				Not Reported
Eferox			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14719469	DIRECT						Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Reaction	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2018	13890544	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2017-39088		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria; Blindness; Circulatory Collapse; Colour Blindness; Depressed Level Of Consciousness; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Intentional Overdose; Optic Atrophy; Optic Nerve Injury; Pulmonary Oedema; Shock; Tachycardia; Toxicity To Various Agents	Amlodipine			S	Oral	150 Mg, Unk		Aurobindo	
	Escitalopram			S	Oral	60 Mg, Unk		Aurobindo	
	Risperidone			S	Oral	6 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2018	14701879	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-017532		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper; Diarrhoea	Escitalopram			S	Oral	5 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2018	14701896	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-017102		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hyponatraemia	Escitalopram	S	Oral			Aurobindo
	Esomeprazole	S	Oral			Aurobindo
	Esomeprazole	S	Oral			Aurobindo
	Valaciclovir	S	Oral			Aurobindo
	Ramipril	S	Oral	()		Aurobindo
	Ramipril	S	Oral	()		Aurobindo
	Metoclopramide	S	Oral	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2018	14701922	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-017769		44 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole Tablets			S	Oral	5 Mg, Qd		Aurobindo	
	Aripiprazole Tablets			S	Oral	10 Mg, Qd		Aurobindo	
	Escitalopram			S	Oral	10 Mg, Qd		Aurobindo	
	Escitalopram			S	Oral	20 Mg, Qd		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2018	14702070	NON-EXPEDITED			US-MYLANLABS-2018M1015400		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Dyspepsia; Gastrointestinal Disorder; Gastrointestinal Pain; Swollen Tongue; Tongue Discomfort	Escitalopram			S	Oral	Unk		Not Reported	
	Alprazolam			C		25 Mg, Hs		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2018	14702089	NON-EXPEDITED			US-JNJFOC-20180323071		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Pain Upper;	Topamax	S	Oral		Not Reported
Fatigue; Heart Rate	Escitalopram	S	Oral		Not Reported
Increased; Insomnia;	Butalbital, Acetaminophen And	C	Unknown	50/300/40 Mg	Not Reported
Nausea; Palpitations;	Caffeine	C	Unknown		Not Reported
Panic Attack; Thirst	Lorazepam	C	Unknown		Not Reported
	Coconut Oil	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14206693	EXPEDITED (15-DAY)		HO	FR-ROCHE-2025455		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic; Intentional Product Use Issue; Off Label Use	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Belustine			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Solupred (France)			S	Oral			Not Reported
	Silodyx			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14562928	EXPEDITED (15-DAY)		LT, OT	JP-JNJFOC- 20180223737		90 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block Complete; Dysuria; Feeding Disorder; Renal Impairment	Tramcet			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Alfacalcidol			C	Oral			Not Reported
	Nexium			C	Oral			Not Reported
	Spironolactone			C	Oral			Not Reported

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Mecobalamin	C	Oral	Not Reported
Lyrica	C	Oral	Not Reported
Amitiza	C	Oral	Not Reported
Sodium Ferric Citrate	C	Oral	Not Reported
Limaprost Alfadex	C	Oral	Not Reported
Magnesium Oxide	C	Oral	Not Reported
Feburic	C	Oral	Not Reported
Quetiapine	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14599012	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20180238098		47 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Simponi			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Bilaska			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported
	Tramadol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14648538	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1017273		35 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antipsychotic Drug Level Increased; Seizure; Syncope	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	500 Mg, Unk		Mylan
	Ciprallex /01588501/			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14702754	EXPEDITED (15-DAY)		HO, OT	US-STRIDES ARCOLAB LIMITED-			Unknown	USA

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2018SP002305

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Buspirone Hydrochloride			S	Oral	Unk		Strides
	Fluoxetine			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Amphetamine			S	Oral	Unk		Not Reported
	Dextroamphetamine /00016601/			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14703326	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-168776		84 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Esomeprazole			S	Oral	20 Mg, Daily		Sun
	Valaciclovir			S	Oral	500 Mg, Daily		Sun
	Ramipril			S	Oral	Unk		Ranbaxy
	Metoclopramide			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14703328	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-168802		24 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Escitalopram Paracetamol Alprazolam Codeine			S S S S	Oral Oral Oral Oral	Unk Unk Unk Unk	Not Reported Ohm Lab Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14704309	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018011959			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Libido Disorder; Priapism	Escitalopram Oxalate			S	Oral	Unk		Macleods	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14704412	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018011965			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Escitalopram Oxalate Paracetamol Codeine			S S S	Oral Oral Oral	27 Df, Unk 40 G, Unk 6 Df, Unk		Macleods Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14704665	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-017472		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram Loperamide Lansoprazole			S C C	Unknown Unknown Unknown			Aurobindo Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14705249	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1020176		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Not Reported	
	Venlafaxine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14705768	EXPEDITED (15-DAY)		HO, LT, OT	US- ELI_LILLY_AND_COMP ANY-US201803012042		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose	Fluoxetine Hydrochloride			S	Oral	Unk Unk, Unknown		Eli Lilly And Co	
	Amlodipine			S	Oral	Unk Unk, Unknown		Not Reported	
	Venlafaxine			S	Oral	Unk Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk Unk, Unknown		Not Reported	
	Atorvastatin			S	Oral	Unk Unk, Unknown		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk Unk, Unknown		Not Reported	
	Amphetamine			S	Oral	Unk Unk, Unknown		Not Reported	
	Dextroamphetamine /00016601/			S	Unknown	Unk Unk, Unknown		Not Reported	
	Buspirone			S	Oral	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	9733385	EXPEDITED (15-DAY)		DE, LT, OT	NO-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2013- BI-40		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Intentional Self-Injury;	Catapresan			S	Unknown	50 Mg, Unk		Boehringer Ingelheim	

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Medication Error; Overdose; Sedation; Unevaluable Event	Sobril	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Oxynorm	S	Unknown		Not Reported
	Pinex Forte	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown	Unk	Not Reported
	Sarotex	S	Unknown	Unk	Not Reported
	Vival	S	Unknown	Unk	Not Reported
	Imovane	S	Oral	Unk	Not Reported
	Orfiril	S	Unknown	1200 Mg, Unk	Not Reported
	Cipralex	S	Unknown	Unk	Not Reported
	Lamictal	S	Unknown	100 Mg, Unk	Not Reported
	Nozinan	S	Unknown	Unk	Not Reported
	Remeron	S	Unknown	Unk	Not Reported
	Atarax	S	Unknown	Unk	Not Reported
	Truxal	S	Unknown	Unk	Not Reported
	Nobligan	S	Unknown	200 Mg, Unk	Not Reported
	Seroquel	S	Unknown	Unk	Not Reported
	Cipramil [Citalopram Hydrobromide]	S	Unknown	Unk	Not Reported
	Cyanocobalamin	C	Unknown	Unk	Not Reported
	Diamorphine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14145390	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2017M1055962		30 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Escitalopram			S	Oral	10 Mg, Bid		Not Reported
Asthenia; Decreased	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
Appetite; Dizziness;	Escitalopram			S		7.5 Mg, Qd		Not Reported
Fatigue; Galactorrhoea;	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
Headache; Nightmare;								
Orgasm Abnormal; Sexual								

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Dysfunction; Sleep
Disorder; Suicidal
Ideation; Tremor; Wound

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03-Apr-2018	14491260	EXPEDITED (15-DAY)		HO, OT	PHHY2017AT199893		57 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Increased Appetite; Prescribed Overdose; Weight Increased	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	200 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Quetiapine			S	Unknown	500 Mg, Qd		Novartis
	Quetiapine			S	Unknown	450 Mg, Qd		Novartis
	Quetiapine			S	Unknown	500 Mg, Qd		Novartis
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis
	Quetiapine			S	Unknown	300 Mg, Qd		Novartis
	Quetiapine			S	Unknown	200 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Quetiapine			S	Unknown	50 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Cipralext			S	Oral	10 Mg, Qd		Not Reported
Cipralext			S	Oral	15 Mg, Qd		Not Reported	
Cipralext			S	Oral	20 Mg, Qd		Not Reported	

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Ciprallex	S	Oral	30 Mg, Qd	Not Reported
Pregabalin	S	Unknown	150 Mg, Unk	Not Reported
Pregabalin	S	Oral	300 Mg, Unk	Not Reported
Pregabalin	S	Unknown	450 Mg, Unk	Not Reported
Seroquel	S	Oral	50 Mg, Unk	Not Reported
Seroquel	S	Oral	400 Mg, Unk	Not Reported
Seroquel	S	Oral	500 Mg, Unk	Not Reported
Seroquel	S	Oral	450 Mg, Unk	Not Reported
Seroquel	S	Oral	300 Mg, Unk	Not Reported
Seroquel	S	Oral	100 Mg, Unk	Not Reported
Seroquel	S	Oral	100 Mg, Unk	Not Reported
Seroquel	S	Oral	200 Mg, Unk	Not Reported
Seroquel	S	Oral	50 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	1.25 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	2.5 Mg, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C	Unknown	1 Df, Unk	Not Reported
Molaxole	C		2 Df, Unk	Not Reported
Molaxole	C		3 Df, Unk	Not Reported
Rivotril	C	Unknown	1 Mg, Unk	Not Reported
Rivotril	C	Oral	Unk	Not Reported

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	Cymbalta	C	Unknown	30 Mg, Unk	Not Reported
	Cymbalta	C	Unknown	30 Mg, Unk	Not Reported
	Combithyrex	C	Unknown	1 Df, Unk	Not Reported
	Quetiapin	C	Unknown	50 Mg, Unk	Not Reported
	Quetiapin	C	Unknown	50 Mg, Unk	Not Reported
	Lamotrigin	C	Unknown	50 Mg, Unk	Not Reported
	Lamotrigin	C	Unknown	50 Mg, Unk	Not Reported
	Thyrex	C	Oral	50 Ug, Unk	Not Reported
	Zyprexa	C		5 Mg, Unk	Not Reported
	Zyprexa	C		10 Mg, Unk	Not Reported
	Zyprexa	C	Unknown	15 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14681641	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018117792		83 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Thrombocytopenia	Aldactone			S	Oral	25mg, 1x/Day		Pfizer
	Pantoprazol Sandoz			S	Oral	20mg, 1x/Day		Not Reported
	Aspirin Cardio			S	Oral	100mg, 1x/Day		Not Reported
	Calcimagon /00751501/			S	Oral	500mg/800 E Once Daily		Not Reported
	Cipralelex /01588501/			S	Oral	5mg, 1x/Day		Not Reported
	Remeron			S	Oral	15mg, 1x/Day		Not Reported
	Risperdal			S	Oral	1mg, 1x/Day		Not Reported
	Xarelto			S	Oral	10mg, 1x/Day		Not Reported
	Dafalgan			S	Oral	500mg, 4x/Day		Not Reported
	Torem /01036501/			S	Oral	"X5 Mg 4-2-0"		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14704901	EXPEDITED (15-DAY)		OT	PHHY2018TH054307		69 YR	Male	THA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Ganglia Infarction;	Entacapone			S	Oral	1 Df, Tid		Novartis
Bradykinesia; Cerebral	Escitalopram			S	Oral	1 Df, Qd		Not Reported
Atrophy; Cerebral	Levodopa Benserazide			C	Oral	0.75 Df, Tid		Not Reported
Disorder; Cognitive	Pramipexole			C	Oral	1 Df, Qd		Not Reported
Disorder; Cogwheel	Quetiapine			C	Oral	0.5 Df, Qhs		Not Reported
Rigidity; Lymphocyte	Omeprazole			C	Oral	1 Df, Qd		Not Reported
Count Decreased; Mean	Sennoside			C	Oral	2 Df, Qd		Not Reported
Cell Volume Decreased;	Fenoterol Hydrobromide			C	Unknown	2 Df, Bid		Not Reported
Movement Disorder;	Procaterol			C	Oral	1 Df, Bid		Not Reported
Parkinsonian Gait;	Theophylline			C	Oral	1 Df, Bid		Not Reported
Periventricular	Manidipine			C	Oral	1 Df, Qd		Not Reported
Leukomalacia; Posture								
Abnormal; Red Cell								
Distribution Width								
Increased; Reduced Facial								
Expression; Resting								
Tremor; Retention Cyst								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707162	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-18_00003298		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic	Buspirone			S	Oral			Not Reported
Shock; Electrocardiogram	Fluoxetine			S	Oral			Not Reported
Qrs Complex Prolonged;	Amlodipine			S	Oral			Not Reported
Intentional Overdose;	Venlafaxine			S	Oral			Not Reported
Muscle Necrosis;	Escitalopram			S	Oral			Not Reported
Rhabdomyolysis; Seizure	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Amphetamine-Dexamphetamine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707249	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US14446			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Feeling Jittery; Paraesthesia; Product Dose Omission	Sertraline			S	Oral	25 Mg, Qd		Invagen
	Escitalopram			S	Unknown	Unknown		Invagen
	Ritalin			C	Unknown	5 Mg, Tid		Not Reported
	Klonopin			C	Unknown	1 Mg, A Quarter Tablet A Day		Not Reported
	Plaquenil			C	Unknown	400 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707848	EXPEDITED (15-DAY)		OT	PHHY2018GB057617		69 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Stalevo			S	Unknown	Unk		Novartis
	Entacapone			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported
	Rivastigmine			C	Transdermal	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Macrogol			C	Unknown	Unk		Not Reported
	Co-Beneldopa			C	Unknown	50/12.5 Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707856	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD- MAC2018011966			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14708818	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2018-017893		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Irritability; Overdose; Sinus Tachycardia; Somnolence; Toxicity To Various Agents	Quetiapine			S	Unknown			Aurobindo	
	Topiramate			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Citalopram			S	Unknown			Aurobindo	
	Temazepam			S	Unknown			Not Reported	
	Oxazepam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14709065	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-017224		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Alprazolam			S	Oral			Aurobindo	
	Escitalopram			S	Oral			Aurobindo	
	Paracetamol			S	Oral			Aurobindo	
	Codeine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14709304	EXPEDITED (15-DAY)		HO	US-OTSUKA-DJ20091276		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dysarthria; Hypertension; Hypokalaemia; Mental Status Changes; Multiple Drug Therapy	Abilify			S	Unknown	15 Mg, Bid		Otsuka
	Desvenlafaxine Succinate			S	Oral	Unk, Qd		Not Reported
	Ibuprofen			S	Unknown	800 Mg, Tid		Not Reported
	Loratadine			S	Unknown	10 Mg, Qd		Not Reported
	Ambien			S	Oral	10 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	1 Mg, Bid		Not Reported
	Fluticasone			S	Unknown	1 Df, Qd (1 Dosage Form = 2 Sprays)		Not Reported
	Lexapro			S	Unknown	20 Mg, Qd		Not Reported
	Lyrica			S	Unknown	75 Mg, Qd		Not Reported
	Methocarbamol			S	Unknown	750 Mg, Tid		Not Reported
	Vicodin			S	Transdermal	1 Df, Unk (1 Dosage Form = 5/500 Units Not Specified), Prn		Not Reported
	Vivelle			S	Transdermal	0.10 Mg, Unk		Not Reported
	Zestoretic			S	Unknown	1 Df, Qd (1 Dosage Form = 20/12.5 (Units) Not Specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14710871	EXPEDITED (15-DAY)		DE	US-TARO PHARMACEUTICALS USA.,INC- 2018SUN00193		19 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Taro
	Olanzapine			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14711508	EXPEDITED (15-DAY)		OT	DE-TEVA-802971GER		30 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14732983	DIRECT		HO			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Panic Reaction; Skin Burning Sensation	Escitalopram 5mg Tablets Cipla			S	Oral	Quantity:1 Tablet(S);	2 DAY	Cipla	
	Symbicort			C				Not Reported	
	Alprazolam			C				Not Reported	
	Spiriva Respimat			C				Not Reported	
	Fluticasone Nasal Spray			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713100	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-065230		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine			S	Oral			Accord	
	Escitalopram			S	Oral			Not Reported	
	Hydrochlorothiazide			S	Oral			Not Reported	
	Buspirone			S	Oral			Not Reported	
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported	

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Atorvastatin	S	Oral	Not Reported
Amphetamine/Dexamphetamine	S	Oral	Not Reported
Fluoxetine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14714385	EXPEDITED (15-DAY)		HO	CA-SCIENGEN PHARMACEUTICALS INC-2018SCILIT00169		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Quetiapine			S	Unknown	Unk,		Sciegen
	Temazepam			S	Unknown	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14714902	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1816939US		40 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Libido Disorder; Priapism	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14714903	EXPEDITED (15-DAY)		OT	NO-ALLERGAN- 1816938US		19 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rectal Haemorrhage; Vaginal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cerazette (Desogestrel)			C	Oral	1 Df (75 Mcg), Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14715637	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2018-		26 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Venlafaxine Hydrochloride			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14715978	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1816945US		33 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14716356	EXPEDITED (15-DAY)		HO	PHHY2018FR058753		91 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10 Mg, Unk		Not Reported	
	Lansoprazole			S	Oral	30 Mg, Unk		Novartis	
	Gliclazide			S	Oral	60 Mg, Unk		Not Reported	
	Stilnox			S	Oral	1 Df, Unk		Not Reported	
	Efferalgan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14716376	EXPEDITED (15-DAY)		OT	PHHY2016CA172003		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract	Voltaren			S	Unknown	Unk		Not Reported	
	Voltaren			S	Unknown	Unk, Qw		Not Reported	

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Infection Viral; Malaise;	Methotrexate	S	Unknown	Unk	Novartis
Mouth Ulceration;	Escitalopram	S	Unknown	Unk, Qd	Not Reported
Musculoskeletal Stiffness;	Cosentyx	S	Subcutaneous	150 Mg, Qw	Not Reported
Nasopharyngitis; Nausea;	Cosentyx	S	Subcutaneous	150 Mg, Qmo	Not Reported
Pain; Swollen Tongue;	Cosentyx	S	Unknown	Unk	Not Reported
Tonsillar Ulcer; Tonsillitis;	Vitamin D3	S	Unknown	Unk	Not Reported
Vomiting	Mouth Wash (Eucalyptol\	S	Unknown		Not Reported
	Menthol\Methyl				
	Salicylate\Thymol)				
	Humira	C	Unknown	Unk	Not Reported
	Enbrel	C	Unknown		Not Reported
	Remicade	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	13383671	EXPEDITED (15-DAY)		HO	PHHY2017IT043382		43 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Sopor	Escitalopram			S	Oral	270 Mg, Once/Single (Total)		Not Reported
	Quetiapine			S	Oral	Unk		Novartis
	Carbolithium			S	Oral	1500 Mg, Once/Single (Total)		Not Reported
	Etiltox			S	Oral	1800 Mg, Once/Single (Total)		Not Reported
	Ethyl Alcohol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14218267	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1767215US		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

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Avastin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Belustine	S	Oral	40 Mg, Cyclical	Not Reported
Solupred (Prednisolone)	S	Oral	40 Mg, Qd	Not Reported
Xanax	C		Unk	Not Reported
Silodyx	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14378336	EXPEDITED (15-DAY)	HO		AT-ALLERGAN-1000074347		19 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parkinsonism	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd		Allergan
	Aripiprazole			S	Oral	2.5 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Atarax			C	Oral	Unk (25-50 Mg), Qd		Not Reported
	Atarax			C	Oral	25 Mg, Qd		Not Reported
	Atarax			C	Oral	50 Mg, Qd		Not Reported
	Atarax			C	Oral	25 Mg, Qd		Not Reported
	Seroquel			C	Unknown	50 Mg, Qd		Not Reported
	Seroquel			C	Unknown	75 Mg, Qd		Not Reported
	Sertraline Hydrochloride			C	Unknown	25 Mg, Qd		Not Reported
	Sertraline Hydrochloride			C	Unknown	50 Mg, Qd		Not Reported
	Probiotics			C	Unknown	1 Df, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Mexalen			C	Oral	500 Mg, Qd		Not Reported
	Praxiten			C	Oral	15 Mg, Qd		Not Reported
	Praxiten			C	Oral	7.5 Mg, Qd		Not Reported

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	Praxiten	C	Oral	15 Mg, Unk	Not Reported
	Methylprednisolone	C		Unk	Not Reported
	Zoldem	C	Oral	10 Mg, Qd	Not Reported
	Zoldem	C	Oral	5 Mg, Qd	Not Reported
	Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd	Not Reported
	Hova	C	Unknown	1 Df, Unk	Not Reported
	Aerius (Ebastine)	C	Unknown	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14718610	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-877840		25 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Ivax	
	Levonelle			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14718676	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-878480		50 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Hypotension; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Ivax	
	Valsartan			S	Oral			Teva	
	Bromazepam			S	Oral			Not Reported	
	Prazepam			S	Oral			Not Reported	
	Xeroquel			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14719438	EXPEDITED (15-DAY)		OT	DE-CIPLA LTD.-2018DE13815			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Abdomen; Drug	Escitalopram			S	Unknown	5 Df, (5-0-0)		Invagen	

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Interaction	Seroquel	S	Unknown	125 Df, (50-25-50)	Not Reported
	Leponex	C	Unknown	100-0-75	Not Reported
	Levomepromazin /00038601/	C	Unknown	25 Df, (25-25-25)	Not Reported
	Eisensulfat	C	Unknown	1 Df, (1-0-0)	Not Reported
	Kalinor /00031402/	C	Unknown	Unk (1-0-0)	Not Reported
	Delix /00885601/	C	Unknown	5 Df, (5-0-0)	Not Reported
	Pantoprazol Abz Protect	C	Unknown	20 Df, (20-0-0)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14719889	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2018IN14297			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Escitalopram			S	Unknown	60 Mg, Unk		Invagen
	Sertraline			S	Unknown	100 Mg, Unk		Invagen
	Fluoxetine			S	Unknown	50 Mg, Unk		Not Reported
	Fluvoxamine			S	Unknown	50 Mg, Unk		Not Reported
	Clomipramine			S	Unknown	200 Mg, Unk		Not Reported
	Buspirone			S	Unknown	15 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14719893	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2018IN13985			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Acneiform	Escitalopram			S	Unknown	Unk		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14720015	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US13971			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Escitalopram			S	Unknown	Unk		Invagen

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Drug Ineffective; Lethargy; Suicidal Ideation; Weight Increased	Risperidone	S	Unknown	Unk	Cipla
	Risperidone	S	Unknown	Unk	Cipla
	Gabapentin	S	Unknown	Unk	Invagen
	Lorazepam	S	Unknown	Unk	Not Reported
	Aripiprazole	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14720284	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2018-009877		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome	Dexamethasone			S	Oral			Valeant	
	Escitalopram			S	Oral			Not Reported	
	Hidroaltesona			S	Oral	Compress 10 Tablets		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14720672	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1021268		93 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma	Escitalopram Mylan			S	Oral	1 Df, Qd		Mylan	
	Eliquis			S	Oral	2 Df, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14723027	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1817198US		23 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Paraesthesia	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14723075	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1816951US		94 YR	Female	FRA

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Pruritus; Skin Reaction	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Esomeprazole			C	Oral			Not Reported	
	Ventoline			C	Respiratory (inhalation)			Not Reported	
	Lasilix Special			C	Oral			Not Reported	
	Renitec [Enalapril Maleate]			C	Oral			Not Reported	
	Flixotide			C	Respiratory (inhalation)			Not Reported	
	Molsidomine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14723077	EXPEDITED (15-DAY)		DS, HO, OT	FR-ALLERGAN-1816535US		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Major Depression	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14744825	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro Paxil			S				Not Reported	
				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	10930214	NON-EXPEDITED			US-PFIZER INC-2015096821		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	

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Dilantin	S	Unk	Pfizer
Oxycodone	S	Unk	Not Reported
Toradol	S	Unk	Not Reported
Metformin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Stadol	S	Unk	Not Reported
Methadone	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Terbinafine	S	Unk	Not Reported
Triamterene/Hctz	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14155030	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US02137			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk, Generic		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14366071	EXPEDITED (15-DAY)		HO	AT-MACLEODS PHARMACEUTICALS US LTD- MAC2017008190			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Parkinsonism	Escitalopram Tablet			S	Oral	5 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	10 Mg, Unk		Macleods
	Escitalopram Tablet			S	Oral	15 Mg, Unk		Macleods
	Aripiprazole Tablet			S	Oral	2.5 Mg, Qd		Macleods

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Aripiprazole Tablet	S	Oral	5 Mg, Qd	Macleods
Cipralex	S	Oral	5 Mg, Qd	Not Reported
Cipralex	S	Oral	10 Mg, Qd	Not Reported
Cipralex	S	Oral	15 Mg, Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Aerius (Desloratadine)	C	Unknown	Unk	Not Reported
Atarax	C	Unknown	Unk	Not Reported
Atarax	C	Oral	25 Mg, Unk	Not Reported
Atarax	C	Oral	20-25 Mg	Not Reported
Atarax	C	Oral	50 Mg, Unk	Not Reported
Atarax	C	Unknown	25 Mg, Unk	Not Reported
Hova	C	Unknown	Unk	Not Reported
Proboptics	C	Unknown	1 Df, Qd	Not Reported
Mexalen	C	Oral	500 Mg, Unk	Not Reported
Mexalen	C	Oral	500 Mg, Unk	Not Reported
Mexalen	C	Oral	500 Unk, Unk	Not Reported
Praxiten	C	Unknown	Unk	Not Reported
Praxiten	C	Oral	15 Mg, Unk	Not Reported
Praxiten	C	Oral	7.5 Mg, Unk	Not Reported
Praxiten	C	Oral	15 Mg, Qd	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	75 Mg, Qd	Not Reported
Sertraline Hydrochloride	C	Unknown	Unk	Not Reported
Sertraline Hydrochloride	C	Oral	50 Mg, Qd, Tablet	Not Reported
Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd	Not Reported
Zolpidem	C	Oral	10 Mg, Unk	Not Reported
Zoldem	C	Unknown	Unk	Not Reported
Zoldem	C	Oral	5 Mg, Unk	Not Reported
Lactobacillus Acidophilus, Bifidobacterium Longum,	C	Unknown	Unk, Qd	Not Reported

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Lactobacillus Rhamn

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06-Apr-2018	14576149	EXPEDITED (15-DAY)		HO	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R3-163891			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Ternelin			C	Oral	1 Mg, Qd		Not Reported	
	Wypax			C	Oral	0.5 Mg, Tid		Not Reported	
	Depakene-R			C	Oral	400 Mg, Qd		Not Reported	
	Myslee			C	Oral	5 Mg, Qd		Not Reported	
	Rivotril			C	Oral	0.5 Mg, Qd		Not Reported	
	Silece			C	Oral	2 Mg, Qd		Not Reported	
	Depas (Etizolam)			C	Oral	0.5 Mg, Prn		Not Reported	
	Daikenchuto			C	Oral	2.5 Mg, Tid		Not Reported	
	Magnesium Oxide			C	Oral	250 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14726169	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA- 878234		33 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Chromaturia; Oedema Peripheral	Teva-Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14726204	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA- 878239		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Hypertension	Escitalopram			S	Oral			Ivax	

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Escitalopram			S		Oral			Ivax	
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06-Apr-2018	14726205	EXPEDITED (15-DAY)		LT	CA-TEVA-2018-CA-878261		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14726249	EXPEDITED (15-DAY)		DE	US-ZYDUS-019636		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram			S	Unknown			Zydus Pharm	
	Olanzapine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14726868	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00005995		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Amlodipine			S	Oral	Unknown		Unknown	
	Venlafaxine Hydrochloride			S	Oral	Unknown		Unknown	
	Escitalopram Oxalate			S	Oral	Unknown		Unknown	
	Atorvastatin Calcium			S	Oral	Unknown		Unknown	
	Hydrochlorothiazide			S	Oral	Unknown		Unknown	
	Dextroamphetamine			S	Oral	Unknown		Unknown	
	Fluoxetine			S	Oral	Unknown		Unknown	
	Buspirone Hydrochloride			S	Oral			Unknown	

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06-Apr-2018	14727213	EXPEDITED (15-DAY)		OT	US-LPDUSPRD-20180497		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection (4420-01)			S	Intravenous (not otherwise specified)	Single Dose Of 4 Mg		Luitpold	
	Escitalopram			S	Unknown	Unknown		Not Reported	
	Venlafaxine			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14730573	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1819531US		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ataxia; Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Eliquis			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14731007	EXPEDITED (15-DAY)		OT	US-XIROMED, LLC-XIRO20180188		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Colitis Microscopic; Diarrhoea; Rectal Tenesmus; Rectal Ulcer	Lansoprazole			S	Unknown	Unknown		Not Reported	
	Escitalopram			S	Unknown	Unknown		Not Reported	
	Losartan			C	Unknown	Unknown		Not Reported	
	Fluticasone/Salmeterol			C	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2018	14731375	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2018012201			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bradycardia; Cardiogenic Shock; Condition Aggravated;	Escitalopram Oxalate	S	Oral	Unk, Overdose	Macleods
Electrocardiogram Qrs Complex Prolonged;	Amlodipine Besylate	S	Oral	Unk, Overdose	Macleods
Intentional Overdose; Seizure	Venlafaxine	S	Oral	Unk, Overdose	Macleods
	Atorvastatin	S	Oral	Unk, Overdose	Not Reported
	Fluoxetine	S	Oral	Unk, Overdose	Not Reported
	Hydrochlorothiazide	S	Oral	Unk, Overdose	Not Reported
	Amphetamine, Dextroamphetamine	S	Oral	Unk, Overdose	Not Reported
	Buspirone	S	Oral	Unk, Overdose	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2018	14731576	NON-EXPEDITED			US-TORRENT-00002671		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram (Escitalopram Oxalate)			S				Torrent	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14701951	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-017470		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Diarrhoea; Rectal Ulcer	Escitalopram			S	Unknown			Aurobindo	
	Escitalopram			S		()		Aurobindo	
	Lansoprazole			S	Unknown	Unk		Not Reported	
	Lansoprazole			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14732265	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US14775			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Invagen	

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Lansoprazole			S		Unknown		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
09-Apr-2018	14732471	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2018IN14486			Unknown	IND	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Condition Aggravated; Drug Ineffective; Extrapyramidal Disorder	Escitalopram			S	Unknown	20 Mg, Unk		Invagen		
	Olanzapine			S	Unknown	20 Mg, Unk		Invagen		
	Lorazepam			S	Unknown	8 Mg, Unk		Not Reported		
	Aripiprazole			S	Unknown	Unk		Not Reported		
	Aripiprazole			S	Unknown	20 Mg, Unk		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
09-Apr-2018	14733007	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001656		29 YR	Female	IND	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Akathisia; Drug Ineffective; Headache; Hypomania; Weight Increased	Olanzapine			S		Unknown		Unknown		
	Cabergoline			C		Unknown		Unknown		
	Lorazepam			C		Unknown		Unknown		
	Escitalopram Oxalate			S		5-10 Mg/Day		Unknown		
	Aripiprazole			S		Unknown		Unknown		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
09-Apr-2018	14733009	EXPEDITED (15-DAY)		OT	US-TORRENT- 00005998		67 YR	Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Colitis Microscopic; Rectal Ulcer	Escitalopram			S		Unknown		Unknown		
	Lansoprazole			S		Unknown		Unknown		
	Imodium			C		Unknown		Unknown		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14733039	EXPEDITED (15-DAY)		OT	US-ACCORD-065402		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S				Not Reported	
	Lansoprazole			S				Not Reported	
	Fluticasone/Salmeterol			S				Not Reported	
	Losartan			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14733170	EXPEDITED (15-DAY)		HO, OT	PHHY2018US054003		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Therapy Non-Responder	Hydrochlorothiazide			S	Oral			Not Reported	
	Amphetamine+Dextroamphetamine			S	Oral			Novartis	
	Fluoxetine			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Calcium			S	Unknown			Not Reported	
	Calcium			S				Not Reported	
	Venlafaxine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Buspirone			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Atropine			S	Unknown			Not Reported	
	Atropine			S				Not Reported	
	Glucagon			S	Unknown			Not Reported	
	Glucagon			S				Not Reported	
	Intralipid			S	Unknown			Not Reported	
	Intralipid			S				Not Reported	
	Bicarbonate (Sodium Bicarbonate)			S	Intravenous drip			Not Reported	
	Bicarbonate (Sodium Bicarbonate)			S				Not Reported	

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Bicarbonate)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14733538	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-02735		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Lupin	
	Lansoprazole			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14733801	EXPEDITED (15-DAY)		OT	TH-ORION CORPORATION ORION PHARMA-ENT 2018- 0040		69 YR	Male	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acalculia; Affective Disorder; Aggression; Anger; Bradykinesia; Cerebral Atrophy; Cerebral Disorder; Cognitive Disorder; Cogwheel Rigidity; Illusion; Irritability; Lacunar Infarction; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Memory Impairment; Movement Disorder; Nightmare; Parkinsonian Gait; Periventricular Leukomalacia; Posture Abnormal; Red Cell Distribution Width Increased; Reduced Facial Expression; Resting Tremor; Retention Cyst; Sleep Talking; Somnolence	Entacapone (Trade Name Unknown) Escitalopram Oxalate Levodopa Benserazide Pramipexole Quetiapine Omeprazole Sennoside Fenoterol Procaterol Theophylline Manidipine			S S C C C C C C C C C	Oral Oral Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Strength: 200 Mg Strength: 10 Mg Strength: 200/50 Strength: 0.25 Mg Strength: 25 Mg Strength: 20 Mg Strength: 25 Ug Strength: 200 Mg Strength: 10 Mg		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14737681	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1819569US		38 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	1 Df, Bid		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Monocrixo			S	Unknown	150 Mg, Qhs		Not Reported	
	Lyrica			S	Unknown	5 Df, Daily (2 Df In The Morning And 3 Df In The Evening)		Not Reported	
	Lyrica			S	Unknown	1000 Mg, Qd		Not Reported	
	Urbanyl			S	Unknown	0.5 Df, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14737760	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1819604US		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Malaise	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Gilenya			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14738053	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018138744		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Hyponatraemia	Lyrica			S	Oral	25 Mg, 1x/Day		Pfizer	
	Lyrica			S	Oral	50 Mg, 1x/Day		Pfizer	
	Seresta			S	Oral	Unk		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported	
	Mianserine			S	Oral	30 Mg, 1x/Day		Not Reported	

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09-Apr-2018	14832867	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Intolerance	Escitalopram Oxalate			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	12537713	NON-EXPEDITED		OT	PHEH2016US016797		6 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mood Altered; Mouth Ulceration; Mouth Ulceration; Peripheral Swelling; Seizure	Afinitor			S	Oral	3 Mg, Qd		Novartis
	Afinitor			S	Oral	2.5 Mg, Qd		Novartis
	Afinitor			S	Oral	5 Mg, Qod (5mg Alternating Every Other Day With 7.5 Mg)		Novartis
	Afinitor			S	Oral	7.5 Mg (5mg Alternating Every Other Day With 7.5 Mg)		Novartis
	Lexapro			S	Unknown			Not Reported
	Carnitor			C	Unknown	Unk		Not Reported
	Zyrtec			C	Unknown	Prn (As Needed)		Not Reported
	Onfi			C	Unknown			Not Reported
	Risperdal			C	Unknown	Prn (As Needed)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14120971	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20171016049		14 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Intentional Overdose; Intentional Self-Injury; Poisoning	Haldol			S	Oral	Dose Was 15 MI In Total		Not Reported
	Xanax			S	Oral			Not Reported

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Deliberate; Sluggishness; Sopor	Ciprallex	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14421864	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE- HET2018DE00047		42 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd		Hetero	
	Escitalopram			S	Oral	40 Mg, Qd		Hetero	
	Pangrol /00014701/			C	Unknown	Unk, Bid		Not Reported	
	Lorazepam A			C	Unknown	0.5 Mg		Not Reported	
	Olanzapine Accord			C	Unknown	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14572595	EXPEDITED (15-DAY)		LT	JP-ALLERGAN- 1809963US		90 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Complete	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Tramcet			C	Oral	1 Df, Qd		Not Reported	
	Furosemide			C	Oral	40 Mg, Qd		Not Reported	
	Furosemide			C	Oral	10 Mg, Qd		Not Reported	
	Alfacalcidol			C	Oral	0.5 Mg, Unk		Not Reported	
	Nexium			C	Oral	20 Mg, Unk		Not Reported	
	Spironolactone			C	Oral	25 Mg, Unk		Not Reported	
	Mecobalamin			C	Oral	0.5 Mg, Bid		Not Reported	
	Lyrica			C	Oral	25 Mg, Bid		Not Reported	
	Amitiza			C	Oral	24 Mg, Bid		Not Reported	
	Sodium Ferrous Citrate			C	Oral	50 Mg, Bid		Not Reported	
	Limaprost Alfadex			C	Oral	5 Mg, Bid		Not Reported	

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		Magnesium Oxide	C	Oral	330 Mg, Tid		Not Reported		
		Feburic	C	Oral	20 Mg, Unk		Not Reported		
		Quetiapine	C	Oral	25 Mg		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14730558	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1819419US		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Lansoprazole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14738998	EXPEDITED (15-DAY)		HO	NO-CIPLA LTD.-2018NO14236			Unknown	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	15 Mg, Daily		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14739266	EXPEDITED (15-DAY)		DS	SE-CIPLA LTD.-2018SE14195			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hyperhidrosis; Influenza Like Illness; Muscle Spasms; Paraesthesia; Pyrexia	Escitalopram			S	Unknown	Unk		Invagen	
	Oxascand			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14739297	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-ENTC2018-0126		69 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Stalevo			S	Unknown			Not Reported
	Trimethoprim			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Septrin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Carbidopa Levodopa			S	Unknown			Not Reported
	Entacapone (Trade Name Unknown)			S	Unknown			Not Reported
	Cabergoline			S	Unknown			Not Reported
	Co-Beneldopa			C	Unknown	Strength: 25/100 Mg		Not Reported
	Co-Beneldopa			C	Unknown	Strength: 50/12.5 Mg		Not Reported
	Co-Beneldopa			C	Unknown	Strength: 25/100 Mg, Mr		Not Reported
	Macrogol			C	Unknown			Not Reported
	Duloxetine			C	Unknown			Not Reported
	Adcal D3			C	Unknown			Not Reported
	Rivastigmine			C	Transdermal	Strength: 4.6 Mg		Not Reported
	Quetiapine			C	Unknown	Strength: 25 Mg		Not Reported
	Paracetamol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14740286	EXPEDITED (15-DAY)		HO	PHHY2018FR062063		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis	Risperidone			S	Unknown	Unk		Novartis
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14740307	EXPEDITED (15-DAY)		OT	IT-VIIV HEALTHCARE LIMITED-IT2018057129		41 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Kivexa			S	Unknown	In Total		Viiv	
	Tavor [Lorazepam]			S	Unknown	In Total		Glaxosmithkline	
	Escitalopram			S	Oral	In Total		Glaxosmithkline	
	Ethanol			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline	
	Lyrica			S	Oral	150 Mg, Unk		Not Reported	
	Rezolsta			S	Oral	Unk		Not Reported	
	Minias			S	Unknown	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14740480	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2018012509			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Lansoprazole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14740856	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE- IT2018057129		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Kivexa			S	Unknown	In Total		Viiv	
	Tavor [Lorazepam]			S	Unknown	In Total		Glaxosmithkline	
	Escitalopram			S	Oral	In Total		Glaxosmithkline	
	Ethanol			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline	
	Lyrica			S	Oral	150 Mg, Unk		Not Reported	
	Rezolsta			S	Oral	Unk		Not Reported	
	Minias			S	Unknown	In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14741452	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC- 2018SUN00162		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Taro	
	Venlafaxine			S	Unknown			Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14741841	EXPEDITED (15-DAY)		DE, OT	US-DRREDDYS- USA/USA/18/0097605		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Toxicity To Various Agents	Olanzapine Film-Coated Tablet			S	Unknown			Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14741858	EXPEDITED (15-DAY)		HO	DE-ALLERGAN- 1819620US		67 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Life Threatening Event; Arrhythmia; Blood Creatine Phosphokinase Abnormal; Coordination Abnormal; Ear Infection; Gustometry Abnormal; Hyperactive Pharyngeal Reflex; Impaired Self- Care; Intentional Self- Injury; Off Label Use; Pharyngitis; Pyrexia; Sepsis; Skin Disorder; Staphylococcal Infection;	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Unk		Allergan	
	Truxal			C	Unknown	Unk		Not Reported	
	Pk Merz			C	Unknown			Not Reported	
	Trileptal			C	Unknown			Not Reported	
	Seroquel			C	Unknown			Not Reported	
	Haldol			C	Unknown			Not Reported	
	Risperdal			C	Unknown			Not Reported	
	Taxilan			C	Unknown			Not Reported	
	Taxilan			C	Unknown			Not Reported	

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Throat Irritation; Thrombosis; Tooth Loss; Tremor; Urinary Incontinence; Withdrawal Syndrome	Metoprolol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14742843	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1820161US			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Escitalopram Oxalate - Bp			S	Oral			Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14768539	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S				Not Reported
	Escitalopram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	13649332	EXPEDITED (15-DAY)		OT	PHHY2017IT082145		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Self-Injury; Sopor; Suicide Attempt	Alprazolam			S	Oral	10 MI, Total		Novartis
	Escitalopram			S	Oral	15 MI, Total		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14665602	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-872986		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown			Ivax

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Lansoprazole			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14744589	EXPEDITED (15-DAY)		HO	LT-CIPLA LTD.- 2018LT14658			Unknown	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Insomnia; Speech Disorder	Zolpidem Tartrate			S	Oral	Unk		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
	Quetiapine			S	Oral	Unk		Not Reported	
	Etoricoxib			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14745720	EXPEDITED (15-DAY)		OT	PHHY2018ES062716		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Mg, Qd (1-0-0)		Novartis	
	Heipram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14745997	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN- 1819884US		74 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Cerebrovascular Accident; Memory Impairment; Myocardial Infarction; Personality Disorder	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14746114	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1819871US		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Glucose Abnormal; Depression; Diabetic Neuropathy;	Escitalopram Oxalate - Bp	S	Oral	1 Df, Unk	Allergan
Hyperglycaemia;	Enalapril	S	Oral	2 Df, Qd	Not Reported
Hypoglycaemia; Influenza;	Seguril	S	Oral	1 Df, Qd	Not Reported
Myocardial Infarction;	Carvedilol	S	Oral	1 Df, Qd	Not Reported
Nephrectomy; Off Label Use	Lantus Solostar	S	Subcutaneous	30 lu, Qd	Not Reported
	Metformin	S	Unknown	0-1-0	Not Reported
	Adiro	S	Unknown	1-0-0	Not Reported
	Lixisenatide	C	Subcutaneous	Dose:20 Unit(S)	Not Reported
	Insulin Glargine	C	Subcutaneous		Not Reported
	Novorapid	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14746488	EXPEDITED (15-DAY)		OT	ES-GLENMARK PHARMACEUTICALS- 2018GMK034098			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Abnormal; Depression; Diabetic Neuropathy;	Escitalopram			S	Oral	1 Df, Od		Not Reported
Hyperglycaemia;	Carvedilol			S	Oral	1 Df, Od		Glenmark
Hypoglycaemia; Influenza;	Lantus			S	Subcutaneous	30 lu, Unk		Not Reported
Myocardial Infarction;	Enalapril			S	Oral	Q2 Df, Od		Not Reported
Nephrectomy	Seguril			S	Oral	1 Df, Od		Not Reported
	Orvatez			S	Oral	1 Df, Od		Not Reported
	Lyxumia			C	Subcutaneous	20 Ut, Od		Not Reported
	Toujeo			C	Subcutaneous	32 lu, Unk		Not Reported
	Novorapid			C	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14747156	EXPEDITED (15-DAY)		HO	AT- ELI_LILLY_AND_COMP ANY-AT201804002014		27 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depressed Mood;	Zyprexa	S	Unknown	30 Mg, Unknown	Eli Lilly And Co
Extrapyramidal Disorder;	Haldol /00027401/	S	Unknown	40 Mg, Daily	Not Reported
Fluid Retention;	Akineton /00079501/	S	Unknown	20 Mg, Unknown	Not Reported
Hospitalisation;	Temesta /00273201/	S	Unknown	Unk Unk, Unknown	Not Reported
Hypotension; Lipoma;	Cipralext /01588501/	S	Unknown	20 Mg, Unknown	Not Reported
Memory Impairment; Off	Prothipendyl	S	Unknown	1 Mg, Unknown	Not Reported
Label Use; Product					
Prescribing Error; Rash;					
Schizophrenia; Suicidal					
Ideation; Visual					
Impairment					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14747445	EXPEDITED (15-DAY)		HO, OT	US-INCYTE CORPORATION-2018IN003295			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chorea; Dementia;	Jakafi			S	Unknown	20 Mg, Bid		Incyte
Serotonin Syndrome	Lexapro			S		Unk		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Prolia			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Tolterodine			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14747689	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1022495		25 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bursitis;	Escitalopram			S	Oral	5 Mg, Unk		Not Reported
Nasopharyngitis; Skin	Levonelle /00318901/			C		Unk		Mylan
Warm								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14748245	EXPEDITED (15-DAY)		OT	SE-ANIPHARMA-2018-IT-000034		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrapyramidal Disorder; Hypokalaemia; Hyponatraemia	Candesartan Hct			S	Oral	1 Dosage Form Daily		Ani	
	Entact(Escitalopram Oxalate)			S	Oral	1 Df Daily		Not Reported	
	Vasexten(Barnidipine Hydrochloride)			C	Oral	20 Mg Capsule		Not Reported	
	(Nebivolol)			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14770074	DIRECT		DS			56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fear; Feeling Abnormal; Gait Disturbance	Abilify			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Levothyroxine			C				Not Reported	
	Ambien			C				Not Reported	
	Glucerna Drinks			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14773955	DIRECT	Y				41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Temperature Intolerance	Escitalopram			S	Oral			Cipla	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14102002	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1759243US			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral			Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14604376	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1015466		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma; Sinus Bradycardia; Suicide Attempt	Bisoce			S	Oral	300 Mg, Qd		Mylan	
	Escitalopram			S	Oral	1120 Mg, Unk		Not Reported	
	Zopiclone			S	Oral	315 Mg, Unk		Not Reported	
	Plavix			S	Oral	2250 Mg, Qd		Mylan	
	Coveram			S	Oral	60 Df, Unk		Mylan	
	Seresta			S	Oral	1000 Mg, Unk		Mylan	
	Aldactazine			S	Oral	30 Df, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14750048	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hypotension; Myasthenia Gravis; Overdose; Presyncope	Amlodipine			S	Unknown			Westward	
	Amlodipine			S	Unknown			Westward	
	Codeine			S	Unknown			Westward	
	Escitalopram			S	Unknown			Hikma	
	Losartan			S	Unknown			Westward	
	Clopidogrel			C	Unknown			Not Reported	
	Aspirin			C	Unknown			Not Reported	
	Carvedilol			C	Unknown			Not Reported	
	Hydralazine			C	Unknown			Not Reported	
	Olmesartan			C	Unknown			Not Reported	
	Finasteride			C	Unknown			Not Reported	
	Niacin			C	Unknown			Not Reported	

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Mirtazapine	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Simvastatin	C	Unknown	Not Reported
Nitroglycerin	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14751328	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018012559			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram Oxalate			S	Oral	7 Df, Total		Macleods	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14751547	EXPEDITED (15-DAY)		DE, OT	SK-ALLERGAN- 1820042US		72 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage Intracranial	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Pradaxa			S	Oral	300 Mg, Qd		Not Reported	
	Pradaxa			S				Not Reported	
	Cynt			C	Unknown	0.4 Mg, Qd		Not Reported	
	Valsacor			C	Unknown	320 Mg, Qd		Not Reported	
	Detralex			C	Unknown	Unk		Not Reported	
	Aricept			C	Unknown	5 Mg, Qd		Not Reported	
	Siofor			C	Unknown	500 Mg, Qd		Not Reported	
	Helidac			C	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	10 Mg, Qd		Not Reported	
	Predictal			C	Unknown	Unk		Not Reported	
	Carvedilol			C	Unknown	12.5 Mg, Qd		Not Reported	
	Vitacalcin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14751948	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-020063		42 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram			S	Oral	In Total		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14751954	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-019392		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Escitalopram Film-Coated Tablets			S	Oral	In Total		Aurobindo	
	Ethanol			S	Unknown	Dosage Form: Unspecified ()		Not Reported	
	Lyrica			S	Oral	()		Not Reported	
	Rezolsta			S	Oral	()		Not Reported	
	Tavor /00273201/			S	Unknown	In Total		Not Reported	
	Minias			S	Unknown	In Total		Not Reported	
	Kivexa			S	Unknown	In Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14751993	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2018-019734		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Dexametasona /00016001/			S	Oral			Not Reported	
	Hidroaltesona			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14753589	EXPEDITED (15-DAY)		DE, LT, OT	US-TEVA-2018-US-879660		19 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Olanzapine			S	Unknown			Teva	
	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14753850	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1820179US		21 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	15 - 20 Tablets		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14779955	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Lexapro			S				Not Reported	
	Remeron			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	13156332	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1702903US		30 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Anxiety; Completed Suicide; Depression; Insomnia; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Ativan			C	Unknown	4 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14234886	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SYNTHON BV-NL01PV17_45405			Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal	Levocetirizine Dihydrochloride			S	Transplacental	5 Mg, Qd (Tablet)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malformation; Trisomy 18	Levocetirizine Dihydrochloride	S	Transplacental	5 Mg, Qd (Film-Coated Tablet)	Not Reported
	Avamys	S	Transplacental	2 Unk, Qd	Not Reported
	D-Cure	S	Transplacental	25 Kiu, Unk	Not Reported
	Flixotide	S	Transplacental	500 Mg, Qd	Not Reported
	Nucala	S	Transplacental	100 Mg, Unk	Not Reported
	Pantomed /01263204/	S	Transplacental	Unk	Not Reported
	Relvar Ellipta	S	Transplacental	1 Unk, Qd	Not Reported
	Sipralexa	S	Transplacental	10 Mg, Unk	Not Reported
	Ventolin /00139502/	S	Transplacental	100 Mg, Unk	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd	Not Reported
	Seretide	S	Transplacental	Unk	Not Reported
	Fluticasone Furoate	S	Transplacental	1 Unk, Qd	Not Reported
	Pantoprazole Sodium Sesquihydrate	S		Unk	Not Reported
	Theophylline	S		Unk	Not Reported
	Vilanterol Trifenatate	S	Transplacental	1 Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14323642	EXPEDITED (15-DAY)		DE, LT, OT	NO-CONCORDIA PHARMACEUTICALS INC.-E2B_00009040		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Clonidine			S	Unknown	Strength 25 Mg, 50 Mg		Concordia
	Atarax			S	Unknown	Unk		Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	600 To 1200mg		Not Reported
	Truxal			S				Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Vival			S				Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk, Strength:5 To 10mg		Not Reported

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Oxynorm	S			Not Reported
Nozinan	S	Unknown	Unk	Not Reported
Cipramil [Citalopram Hydrobromide]	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg, 25,50,100mg	Not Reported
Orfiril	S	Unknown		Not Reported
Remeron	S	Unknown	Unk	Not Reported
Tramadol Hydrochloride	S	Unknown	Unk	Not Reported
Nobligan	S	Unknown	200 Mg, Unk,	Not Reported
Nobligan	S	Unknown	50, 200mg	Not Reported
Cipralex	S	Unknown	Unk	Not Reported
Rivotril	S	Unknown	Unk	Not Reported
Sarotex	S	Unknown	Unk	Not Reported
Imovane	S	Oral	Unk	Not Reported
Cyanocobalamin	C	Unknown	Unk	Not Reported
Diamorphine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14342222	EXPEDITED (15-DAY)		DS, HO	BE-SYNTHON BV-NL01PV17_45655		41 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Exposure During Pregnancy	Levocetirizine Dihydrochloride			S		5 Mg, Qd		Not Reported
	Avamys			S	Unknown	2 Df, Unk		Not Reported
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Flixotide			S	Unknown	500 Mg, Qd		Not Reported
	Nucala			S	Subcutaneous	100 Mg, Unk		Not Reported
	Nucala			S				Not Reported

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Pantomed /01263204/	S	Unknown	20 Mg, Qd	Not Reported
Relvar Ellipta	S		1 Df, Qd (Inhalation Powder)	Not Reported
Sipralexa	S	Unknown	10 Mg, Unk	Not Reported
Seretide	S	Unknown	Unk	Not Reported
Ventolin /00139501/	S		100 Mg, Unk	Not Reported
Xanthium (Theophylline)	S	Unknown	200 Mg, Qd	Not Reported
Vilanterol Trifenatate	S	Unknown	1 Df, Qd	Not Reported
Xyzal	S		5 Mg, Qd	Not Reported
Fluticasone Furoate	S		Unk (Inhalation Powder)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14544700	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-007545		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg, Once/Single ; In Total		Aurobindo	
	Entact			S	Oral	20 Mg, Once/Single ; In Total		Not Reported	
	Entact			S				Not Reported	
	Clozapine			S	Oral	100 Mg, Once/Single ; In Total		Not Reported	
	Clozapine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14611335	EXPEDITED (15-DAY)		DE, HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018010833			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia;	Sildenafil			S	Unknown	Unk		Macleods	
	Exodus (Escitalopram Oxalate)			S	Unknown	Unk		Not Reported	

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Respiratory Failure	Phenobarbital	S	Unknown	Unk	Not Reported
	Spironolactone	S	Unknown	Unk	Not Reported
	Synagis	S	Intramuscular	150 Mg, Unk	Not Reported
	Topiramate	S	Unknown	Unk	Not Reported
	Varivax	S	Intramuscular	1 Df, Unk, Lotno And Exp Dates: M026438 - 30-Apr- 2018	Not Reported
	Water	C	Unknown	4 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14755501	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-019880		14 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Dosage Form Units In Total		Aurobindo
	Haldol /00027401/			S	Oral	15 Milliliter In Total		Not Reported
	Xanax			S	Oral	12 Dosage Form Units In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14755623	EXPEDITED (15-DAY)		CA	DE-CIPLA LTD.- 2018DE14932			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Renal Aplasia	Escitalopram			S	Transplacental	Unk		Invagen
	Clexane			C	Transplacental	Unk		Not Reported
	Femibion /01597501/			C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14755979	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-SE-ALKEM- 2017-01918			Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During Pregnancy	Citalopram	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Duloxetine	S	Unknown	Unk	Not Reported
	Lamotrigine	S	Unknown	Unk	Alkem
	Olanzapine	S	Unknown	Unk	Alkem
	Risperidone	S	Unknown	Unk	Not Reported
	Quetiapine Fumarate	S	Unknown	Unk	Alkem

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756067	EXPEDITED (15-DAY)		OT	ES-ALKEM LABORATORIES LIMITED-ES-ALKEM- 2017-00470			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Quetiapine Fumarate			S	Unknown	50 Mg, Qd		Alkem
	Olanzapine			S	Unknown	5 Mg, Qd		Alkem
	Olanzapine			S	Unknown	10 Mg, Qd		Alkem
	Olanzapine			S	Unknown	15 Mg, Qd		Alkem
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	Unknown		Not Reported
	Mirtazapine			S	Unknown	60 Mg, Qd		Not Reported
	Fluvoxamine			S	Unknown	Unknown		Not Reported
	Carbamazepine			C	Unknown	1200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756290	EXPEDITED (15-DAY)		HO	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM- 2017-01377		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test	Quetiapine Fumarate			S	Oral	150 Mg, Qd		Alkem

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Increased	Quetiapine Fumarate	S	Oral	50 Mg, Qd	Alkem
	Lorazepam	S	Oral	0.25 Mg, Unk	Not Reported
	Lorazepam	S	Oral	1 Mg, Qd	Not Reported
	Lorazepam	S	Oral	1.5 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Escitalopram	S	Oral	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756494	EXPEDITED (15-DAY)		OT	NL-MACLEODS PHARMACEUTICALS US LTD- MAC2018012560			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma	Escitalopram Tablet			S	Oral	15 Mg, Qd, (1x Per Day 1 Piece)		Macleods	
	Levocetirizine Dihydrochloride			C	Unknown	Unk		Macleods	
	Lorazepam			C	Unknown	1 Mg, Qd, (1mg 1x Per Day)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756819	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-020083		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Abnormal;	Carvedilol			S	Oral			Aurobindo	
Depression; Diabetic	Escitalopram			S	Oral			Aurobindo	
Neuropathy;	Lantus			S	Subcutaneous			Not Reported	
Hyperglycaemia;	Enalapril			S	Oral			Not Reported	
Hypoglycaemia; Influenza;	Orvatez			S	Oral			Not Reported	
Myocardial Infarction;	Seguril			S	Oral			Not Reported	
Nephrectomy	Lyxumia			C	Subcutaneous	Dose:20 Unit(S) (1)		Not Reported	
	Toujeo			C	Subcutaneous			Not Reported	

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Novorapid			C	Subcutaneous	()	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756877	EXPEDITED (15-DAY)		HO	PHHY2018ES064406		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Amiodarone Hydrochloride			S	Oral			Novartis	
	Escitalopram Oxalate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14757462	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-019337		67 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma	Escitalopram Tablets			S	Unknown	1x Per Dag 1 Stuk		Aurobindo	
	Lorazepam			C	Unknown	1mg 1x Per Dag		Not Reported	
	Levocetirizine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14757474	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018151508		48 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Tract Infection	Celebrex			S		200 Mg, Unk		Pfizer	
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer	
	Euthyrox			S		100 Ug, Unk		Not Reported	
	Lipanthyl			S		200 Mg, Unk		Not Reported	
	Storwin			S		10 Mg, Unk		Not Reported	
	Glucophage Xr			S		500 Mg, Unk		Not Reported	
	CipraleX /01588501/			S		10 Mg, Unk		Not Reported	
	Zopiclone Sandoz			S		7.5 Mg, Unk		Not Reported	
	Be-Tabs Prednisone			S		5 Mg, Unk		Not Reported	

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Be-Tabs Folic Acid

S

5 Mg, Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14758147	EXPEDITED (15-DAY)		LT	FR-LUNDBECK-DKLU2046569		38 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Tolerance; Prescribed Overdose; Somnolence	Seroplex Film-Coated Tablets			S		2 Df, Daily 1 Tablet In The Morning And In The Evening For 1 Month		Not Reported
	Seroplex Film-Coated Tablets			S		1 Df, Daily (Pharmacist Dispensed Escitalopram 20 Mg At 1 Tablet Daily As A Maximal Daily Dose)		Not Reported
	Urbanyl			S	Unknown	0.5 Df, 3x/Day (Half A Tablet In The Morning, At Noon And In The Evening For 1 Month)		Lundbeck
	Monocrixo			S	Unknown	150 Mg, 1x/Day (One Hard Capsule At Bedtime For One Month)		Not Reported
	Lyrica			S	Unknown	5 Df, Daily (2 Df In The Morning And 3 Df In The Evening) For One Month		Not Reported
	Lyrica			S	Unknown	1000 Mg, Daily For 5 Months		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14759048	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1022858			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer;	Escitalopram			S	Unknown	Unk		Not Reported

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Insomnia; Nausea; Panic
Attack; Vertigo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14760138	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC- 2018-IPXL-01162		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Bundle Branch Block Left; Chest Discomfort; Confusional State; Dizziness; Electrocardiogram Qt Prolonged; Generalised Tonic-Clonic Seizure; Hypotension; Intentional Overdose; Myoclonus; Sinus Tachycardia; Unresponsive To Stimuli	Bupropion Hydrochloride Sr			S	Oral	22 Tablets Of 300 Mg		Impax
	Escitalopram			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2018	14760379	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2018012583			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cushing'S Syndrome; Drug Interaction	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Dexamethasone			S	Oral	Qq		Not Reported
	Hydroaltesone			S	Oral	20 Mg, Qd, 10 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2018	14760402	EXPEDITED (15-DAY)		OT	ES-009507513- 1804ESP005247		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Abnormal; Depression; Diabetic	Orvatez 10 Mg/10 Mg Comprimidos Recubiertos Con			S	Oral	1 Df, Qd		Merck

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Neuropathy;	Película								
Hyperglycaemia;	Carvedilol	S	Oral	1 Df, Qd				Not Reported	
Hypoglycaemia; Influenza;	Lantus	S	Subcutaneous	30 lu, Qd				Not Reported	
Myocardial Infarction;	Enalapril	S	Oral	2 Df, Qd				Not Reported	
Nephrectomy	Escitalopram	S	Oral	1 Df, Qd				Not Reported	
	Seguril	S	Oral	1 Df, Qd				Not Reported	
	Lyxumia	C	Subcutaneous	Dose:20 Unit(S)				Not Reported	
	Toujeo	C	Subcutaneous	32 lu, Qd				Not Reported	
	Novorapid	C	Subcutaneous					Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2018	14760523	NON-EXPEDITED			US-TEVA-2018-US-867015			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Interaction;	Oxytrol			S	Transdermal			Not Reported
Fatigue; Nervousness	Lexapro			S				Not Reported
	Vitamin D2			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2018	14760584	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018012474			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2018	14144902	EXPEDITED (15-DAY)		OT	PHHY2017FR157595		77 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt	Bisoprolol			S	Unknown			Not Reported
Prolonged	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14248863	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-PFIZER INC-2017514075		7 DAY	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Pantomed (Pantoprazole)			S	Transplacental	Unk		Pfizer
	Pantoprazole			S	Unknown	Unk		Pfizer
	Levocetirizine Dihydrochloride			S	Transplacental	5 Mg, Qd		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported
	Relvar Ellipta			S	Transplacental	Unk Unk, Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Unk		Not Reported
	Avamys			S	Transplacental	Unk, Bid		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Mg, Qd		Not Reported
	Cholecalciferol			S	Unknown	25 Kiu, Unk		Not Reported
	Theophylline			S	Unknown	Unk		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, 1x/Day		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14514402	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1000074473			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Foetal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
Exposure During Pregnancy; Hypotonia;	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan

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Neonatal Oversedation;	Meilax	S	Oral	1 Mg, Qpm	Not Reported
Respiratory Disorder	Meilax	S	Transplacental	1 Mg, Qd	Not Reported
Neonatal	Sodium Raberprazole	C	Oral	10 Mg, Qd	Not Reported
	Sodium Raberprazole	C	Transplacental	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14719877	NON-EXPEDITED		OT	US-TEVA-2018-US-877192		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective	Lexapro Generic			S		10 Milligram Daily; 10 Mg Tablet Once Daily By Mouth In The Morning		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14741144	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0097471		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Lansoprazole Delayed-Release Capsules			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14762501	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-019862		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14763801	NON-EXPEDITED			US-TEVA-2018-US-882479			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective	Escitalopram	S	Unknown		Ivax				
	Prempro	S	Unknown		Not Reported				
	Xanax	S	Unknown		Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14764999	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2018061951		30 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Lamictal			S	Oral	2 Df, Unk		Glaxosmithkline	
	Seroplex			S	Oral	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14765429	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1820670US		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14804197	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14833181	DIRECT		OT			54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia	Escitalopram			S	Oral	Quantity:30 Tablet(S); At Bedtime Oral		Walgreen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	12729606	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ20071458		< 1 DAY	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Abilify			S	Transplacental	15 Mg, Qd		Otsuka	
	Lexapro			S	Transplacental	10 Mg, Qd		Not Reported	
	Seroplex			S	Transplacental	10 Mg, Qd		Not Reported	
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported	
	Seresta			S	Transplacental	Unk		Not Reported	
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	13565376	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1720795US		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Increased Appetite; Inhibitory Drug Interaction; Nausea; Suicidal Ideation	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan	
	Orkambi			S	Oral	Unk, Q12h		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14326720	EXPEDITED (15-DAY)		OT	BE-UCBSA-2017052230		41 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Exposure During Pregnancy	Xyzall			S		5 Mg, Once Daily (Qd)		Ucb	
	D-Cure			S		25 Kiu, Unk		Not Reported	
	Seretide			S		Unk		Not Reported	
	Sipralexa			S		10 Mg, Z, Tablet		Not Reported	
	Vilanterol Trifenatate			S		Unk , Once Daily (Qd)		Not Reported	
	Fluticasone Furoate			S		Unk, Once Daily (Qd)		Not Reported	
	Flixotide			S		250 Mg, 2x/Day (Bid)		Not Reported	

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Xanthium (Theophylline)	S	20 Mg, Once Daily (Qd)	Not Reported
Pantomed (Pantoprazole Sodium Sesquihydrate)	S	20 Mg, Once Daily (Qd)	Not Reported
Ventolin	S	100 Mg, Unk	Not Reported
Avamys	S	Unk, 2x/Day (Bid)	Not Reported
Mepolizumab	S	Subcutaneous 100 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14536469	EXPEDITED (15-DAY)		OT	ES-SA-2018SA026783			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Omeprazole			S	Unknown	Dose: 1		Not Reported
	Tramadol Hydrochloride/Paracetamol			S	Oral	Df = 37.5/325 Mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Glibenclamide			S	Unknown			Not Reported
	Simvastatin			S	Unknown	Dose 1		Not Reported
	Simvastatin			S	Unknown	Dose; 1		Not Reported
	Topiramate			S	Unknown	Dose 1		Not Reported
	Topiramate			S	Unknown			Not Reported
	Diazepam			S	Unknown	Dose 1		Not Reported
	Diazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown	Dose; 1		Not Reported
	Diazepam/Sulpiride			S	Unknown	Dose; 1		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Amlodipine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported

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Lormetazepam	S	Unknown		Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14586720	EXPEDITED (15-DAY)	HO		IT-ALLERGAN-1811297US		75 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gingival Bleeding	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Xarelto			S	Unknown			Not Reported
	Cardioaspirin			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Cardura			C	Unknown			Not Reported
	Lasix Fiale			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14607464	EXPEDITED (15-DAY)		DE, HO, OT	DE-JNJFOC-20180235094		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence;	Topiramate			S	Oral			Not Reported
Immobile; Lung Infiltration;	Phenobarbital			S	Unknown			Not Reported
Off Label Use; Oxygen	Sildenafil Citrate			S	Unknown			Not Reported
Saturation Decreased;	Varivax li			S	Intramuscular			Not Reported
Pain; Pneumonia; Product	Spironolactone			S	Unknown			Not Reported
Use Issue; Respiratory	Synagis			S	Intramuscular			Not Reported
Failure	Escitalopram Oxalate			S	Unknown			Not Reported
	Nutrini			C	Other			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14652383	NON-EXPEDITED			US-MYLANLABS-2018M1013400			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Drug Interaction	Clonazepam			S	Oral	Unk		Not Reported	
	Lexapro			S		10 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14654589	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-PFIZER INC- 2006063621		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Product Use Issue; Respiratory Arrest	Cytotec			S	Vaginal	400 Ug, 2x/Day(Twice Two Tablets At 200 Mg)		Pfizer	
	Tiapridal			S	Oral	100 Mg, 1x/Day		Not Reported	
	Lexapro			S	Oral	15 Mg, 1x/Day		Not Reported	
	Abilify			S	Oral	15 Mg, 1x/Day		Not Reported	
	Seroplex			S	Oral	15 Mg, Daily		Not Reported	
	Lysanxia			C	Unknown	10 Mg To 40 Mg		Not Reported	
	Imovane			C	Unknown	7 Mg, Unk		Not Reported	
	Mifegyne			C	Oral	600 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14681717	EXPEDITED (15-DAY)		HO, LT, OT	CZ-TEVA-2018-CZ- 870872			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Loss Of Consciousness; Poisoning	Escitalopram			S	Oral			Ivax	
	Olanzapine			S	Oral			Teva	
	Metoclopramide			S	Oral			Not Reported	
	Venlafaxine			S	Oral			Teva	
	Levopromazine			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Melperone			S	Oral			Not Reported	

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Ibuprofen			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14767728	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR15308			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Libido Disorder; Priapism	Escitalopram			S	Oral	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14767814	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1820704US		77 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Confusional State; Depression	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Trittico			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14767871	EXPEDITED (15-DAY)		OT	FR-CIPLA LTD.- 2018FR15350			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Skin Reaction	Escitalopram			S	Oral	Unk		Invagen	
	Esomeprazole			C	Oral	Unk		Not Reported	
	Ventoline /00139501/			C		Unk		Not Reported	
	Lasilix /00032601/			C	Oral	Unk		Not Reported	
	Renitec /00574902/			C	Oral	Unk		Not Reported	
	Molsidomine			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14767879	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR15358			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depressed Level Of Consciousness;	Escitalopram	S	Oral	27 Df, Unk	Invagen
Disturbance In Attention;	Paracetamol	S	Oral	40 G, Unk	Not Reported
Poisoning Deliberate	Codeine	S	Oral	6 Df, Unk	Not Reported
	Alprazolam	S	Oral	15 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14768505	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018010950			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Intentional Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df, Total,		Macleods	
	Xanax			S	Oral	12 Df, Totalal, (0.25 Mg Tablets)		Not Reported	
	Haldol			S	Oral	15 MI, Total, (2 Mg / MI Oral Drops, Solution)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14770718	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-032915			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage Urinary Tract	Eliquis			S	Oral	5 Mg, Bid		Bristol Myers Squibb	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14771826	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1820565US		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bronchitis; Cutaneous Lupus Erythematosus; General Physical Health Deterioration; Weight	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	

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Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	12830868	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1671250US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Abilify			S	Transplacental	15 Mg, Qd		Not Reported	
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported	
	Seresta			S	Transplacental	Unk		Not Reported	
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	12841971	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1672057US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Abilify			S	Transplacental	15 Mg, Qd		Not Reported	
	Depamide			S	Transplacental	1200 Mg, Qd		Not Reported	
	Seresta			S	Transplacental	Unk		Not Reported	
	Largactil			S	Transplacental	50 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14240164	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1768118US		39 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Abuse; Overdose; Sopor; Tremor	Escitalopram Oxalate Unk			S	Oral	560 Mg, Unk		Allergan	
	Bromazepam			S	Oral	40 MI, Unk		Not Reported	

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18-Apr-2018	14491803	EXPEDITED (15-DAY)		OT	PHJP2017JP009846		73 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety;	Tegretol			S	Oral	1 Df, Qd		Novartis	
Asthenia; Depression;	Tegretol			S	Oral	200 Mg, Qd		Novartis	
Dizziness; Dyspepsia;	Tegretol			S	Oral	3 Df, Qd (2 Tablets In The		Novartis	
Feeling Abnormal; Gait						Early Evening And 1			
Inability;						Tablet At Bedtime)			
Gastrooesophageal Reflux	Tegretol			S	Oral	600 Mg, Qd		Novartis	
Disease; Heart Rate	Tegretol			S	Oral	400 Mg, Qd		Novartis	
Increased;	Tegretol			S	Oral	3 Df, Qd		Novartis	
Hyperventilation; Initial	Tegretol			S	Oral	600 Mg, Bid		Novartis	
Insomnia; Malaise; Mania;	Tegretol			S	Oral	600 Mg, Unk		Novartis	
Mental Disorder; Muscle	Tegretol			S	Oral			Novartis	
Twitching; Nausea; Pain	Tegretol			S	Oral			Novartis	
Of Skin; Phobia Of	Tegretol			S	Oral			Novartis	
Driving; Pollakiuria;	Ternelin			S	Oral			Not Reported	
Restlessness; Sedation;	Goodmin			S	Oral	0.25 Mg, Qd		Not Reported	
Somnolence; Suicidal	Goodmin			S	Oral	Unk, Qhs (Before		Not Reported	
Ideation						Bedtime)			
	Goodmin			S	Oral	1 Df, Unk		Not Reported	
	Lexapro			S	Oral	5 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S	Oral	20 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Unk		Not Reported	
	Depas (Etizolam)			S	Oral	6 Mg, Unk		Not Reported	
	Depas			S	Oral	1.5 Mg, Qd (In 3 Divided		Not Reported	
						Doses)			
	Depas			S	Oral	2 Mg, Unk		Not Reported	
	Depas			S	Oral	2 Df, Qd		Not Reported	
	Depas			S	Oral	2 Mg, Unk		Not Reported	

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Valproate Sodium			C	Unknown	200 Mg, Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14586718	EXPEDITED (15-DAY)	CA		AU-ALLERGAN-1811010US			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum Disorder	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14720805	EXPEDITED (15-DAY)	OT		US-TEVA-2018-US-877405		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Teva	
	Venlafaxine			S	Unknown			Teva	
	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14731395	EXPEDITED (15-DAY)	OT		NL-MACLEODS PHARMACEUTICALS US LTD-MAC2018012212			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Hypertension; Tachycardia; Wrong Technique In Product Usage Process	Quetiapine Tablet			S	Oral	12.5 Mg, Qd, Half A Tablet For The Night, Film Coated Tablet		Macleods	
	Quetiapine Tablet			S				Macleods	
	Escitalopram Oxalate 20mg Tablet			S	Oral	20 Mg, Qd, 1x Daily 2 Tablets		Macleods	
	Colecalciferol			C	Unknown	800 Iu, Qd, 1x1		Not Reported	
	Melatonin			C	Unknown	1 Mg, Qd, 1 Mg 1x1		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772375	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.- 2018FR15336			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Daily		Invagen	
	Esomeprazole			S	Oral	20 Mg, Daily		Not Reported	
	Valacyclovir			S	Oral	500 Mg, Daily		Cipla	
	Ramipril			S	Oral	Unk		Invagen	
	Metoclopramide			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772700	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE- HET2018US00315		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Intentional Product Misuse; Seizure; Suicide Attempt	Escitalopram			S	Unknown			Hetero	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Amphetamine Sulfate W/Dexamphetamine			S	Unknown			Not Reported	
	Buspirone /00803202/			S	Unknown	Unk		Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide			S	Unknown			Not Reported	
	Amlodipine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772737	EXPEDITED (15-DAY)		DE	IT-ROCHE-2108919			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Rivotril			S	Unknown			Not Reported	

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Cipralex	S	Unknown	Not Reported
Zarelis	S	Unknown	Not Reported
Sonirem	S	Unknown	Not Reported
Xanax	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773144	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2018-009787		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction; Nephrectomy	Enalapril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Lantus Solostar			S	Subcutaneous			Not Reported
	Seguril			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Orvatez			S	Oral			Not Reported
	Lyxumia			C	Subcutaneous	Dose:20 Units 1 Unspecified In 1 Day		Not Reported
	Toujeo			C	Subcutaneous			Not Reported
	Novorapid			C	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773215	NON-EXPEDITED			US-TEVA-815182ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dissociation; Feeling Abnormal; Tremor	Escitalopram			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773222	NON-EXPEDITED			US-TEVA-763085ACC			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Adverse Event; Panic Attack		Escitalopram		S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773223	NON-EXPEDITED		DE	US-TEVA-781002USA		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Unknown			Ivax	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773224	NON-EXPEDITED			US-TEVA-793417ACC		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773225	NON-EXPEDITED		OT	US-TEVA-821573USA			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Nervous System Disorder; Product Quality Issue; Suicidal Ideation	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773226	NON-EXPEDITED			US-TEVA-429550USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Drug Ineffective	Escitalopram			S				Ivax	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773227	NON-EXPEDITED			US-TEVA-796516ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Drug Reaction; Drug Ineffective	Escitalopram			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773228	NON-EXPEDITED			US-TEVA-793140ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Akathisia	Escitalopram			S				Ivax	
	Abilify Maintena			S				Not Reported	
	Abilify Maintena			S				Not Reported	
	Abilify Maintena			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773245	NON-EXPEDITED			US-TEVA-818651ACC		35 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Decreased Appetite; Insomnia; Mood Swings; Product Substitution Issue	Escitalopram			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773246	NON-EXPEDITED			US-TEVA-786572ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Balance Disorder; Decreased Appetite; Dizziness	Escitalopram			S	Unknown			Ivax	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773247	NON-EXPEDITED			US-TEVA-429766USA		29 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash	Escitalopram			S		5 Milligram Daily;		Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773248	NON-EXPEDITED			US-TEVA-770158ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Escitalopram			S				Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773249	NON-EXPEDITED			US-TEVA-778758ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective; Weight Increased	Escitalopram			S				Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773250	NON-EXPEDITED			US-TEVA-765860USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Hyperhidrosis	Escitalopram			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773251	NON-EXPEDITED			US-TEVA-795777ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Abnormal Behaviour	Escitalopram	S	Unknown	Ivax					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773252	NON-EXPEDITED			US-TEVA-2017-US-835787			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Hyperhidrosis; Product Size Issue	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773253	NON-EXPEDITED			US-TEVA-766157ACC		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Hyperhidrosis	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773254	NON-EXPEDITED			US-TEVA-816990USA			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773258	NON-EXPEDITED			US-TEVA-777223ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Drug Ineffective	Escitalopram			S	Unknown			Ivax	
	Clonazepam			S	Unknown			Teva	
	Bupropion			S	Unknown			Teva	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773259	NON-EXPEDITED			US-TEVA-747107USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Feeling Abnormal; Product Substitution Issue	Escitalopram			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773260	NON-EXPEDITED			US-TEVA-2017-US-827191			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Escitalopram Fondaparinux Sodium			S C				Ivax Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773261	NON-EXPEDITED			US-TEVA-784174ACC		35 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773262	NON-EXPEDITED		OT	US-TEVA-763231USA		54 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Suicidal Ideation	Escitalopram			S	Unknown			Ivax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773263	NON-EXPEDITED			US-TEVA-376531USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Anxiety; Depression; Drug Ineffective		Escitalopram	S						Ivax
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773265	NON-EXPEDITED			US-TEVA-782498ACC		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Escitalopram			S		20 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773271	NON-EXPEDITED			US-TEVA-772465ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depression; Intentional Product Misuse; Paraesthesia; Product Prescribing Error; Stress; Withdrawal Syndrome	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773272	NON-EXPEDITED			US-TEVA-763087ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Escitalopram			S		10 Or 20 Mg Daily		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14774976	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00203		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram	Escitalopram			S	Unknown	Unk		Taro	

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Qrs Complex Prolonged;	Venlafaxine	S	Unknown	Unk	Not Reported
Muscle Necrosis;	Amphetamine/Dextroamphetamine	S	Unknown	Unk	Not Reported
Overdose;	Buspirone	S	Unknown	Unk	Not Reported
Rhabdomyolysis; Seizure	Fluoxetine	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Atorvastatin	S	Unknown	Unk	Not Reported
	Amlodipine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14776086	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1816295US		82 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiac Failure; Cardiac Valve Disease; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Pantoprazol Sandoz			S	Oral	20 Mg, Qd		Not Reported
	Remeron			S	Oral	15 Mg, Qd		Not Reported
	Risperdal			S	Oral	1 Mg, Qd		Not Reported
	Xarelto			S	Oral	10 Mg, Qd		Not Reported
	Dafalgan			S	Oral	500 Mg, Qid		Not Reported
	Torem			S	Oral	30 Mg, Qd		Not Reported
	Aldactone			S	Oral	25 Mg, Qd		Not Reported
	Aspirin Cardio			S	Oral	100 Mg, Qd		Not Reported
	Calcimagon			S	Oral	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14355449	NON-EXPEDITED		OT	US-GLAXOSMITHKLINE-US2018GSK000878			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyp2d6 Polymorphism; Drug Metabolising Enzyme Test Abnormal;	Wellbutrin			S		Unk		Glaxosmithkline
	Pamelor			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Dyskinesia; Ill-Defined Disorder; Malaise;	Celexa	S						Not Reported
Nausea; Suicidal Ideation; Tic	Lexapro	S			Unk			Not Reported
	Geodon	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14421183	NON-EXPEDITED			US-NEUROCRINE BIOSCIENCES INC.-2017NBI01798		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Discomfort; Drug Interaction; Malaise; Tremor	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences
	Lexapro			S				Not Reported
	Linzess			C				Not Reported
	Lamictal			C				Not Reported
	Clonazepam			C				Not Reported
	Atorvastatin			C				Not Reported
	Loratadine			C				Not Reported
	Magnesium			C				Not Reported
	Trileptal			C				Not Reported
						300 Mg; Take 150 Mg In The Morning, 1.5 Tablets In The Pm		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14616413	EXPEDITED (15-DAY)		OT	FR-009507513-1802FRA013685		76 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parkinsonism	Mirtazapine			S	Unknown	Unk		Merck
	Norset			S	Oral	Unk		Merck
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Irbesartan	C	Oral	Unk	Not Reported
Inipomp	C	Unknown	Unk	Not Reported
Aprovel	C	Unknown	Unk	Not Reported
Irbesartan	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14715004	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-019551		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Shock; Suicide Attempt	Amlodipine			S	Oral			Zydus Pharm
	Buspirone			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Zydus Pharm
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm
	Dextroamphetamine/Amphetamine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14776887	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018012649			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Macleods
	Haldol			S	Oral	20 Drp, Qd, (Oral Solution Drops)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14778659	EXPEDITED (15-DAY)		HO, OT	US-ALEMBIC PHARMACEUTICALS LIMITED-			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2018SCAL000274

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Seizure	Venlafaxine Hydrochloride			S	Oral	Unk		Alembic
	Fluoxetine Hydrochloride			S	Oral	Unk		Alembic
	Hydrochlorothiazide			S	Oral	Unk		Alembic
	Amlodipine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14779506	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1023984		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Suicide Attempt	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Amfetamine/Dexamfetamine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14780469	EXPEDITED (15-DAY)		HO	CZ-BAUSCH-BL-2018-010621			Male	CZE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Venlafaxine			S	Unknown			Not Reported
	Metoclopramide			S	Unknown			Valeant
	Ibuprofen			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Melperon			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Levomepromazine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14780662	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2018M1026056		70 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Salbutamol			C	Unknown			Mylan
	Prucalopride			C	Unknown			Mylan
	Morphine Sulphate			C	Unknown			Mylan
	Cal-D			C	Unknown			Mylan
	Bendroflumethiazide			C	Unknown			Mylan
	Gabapentin			C	Unknown			Mylan
	Calciferol /00107901/			C	Unknown			Mylan
	Tiotropium			C	Unknown			Mylan
	Alendronic Acid			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14781483	EXPEDITED (15-DAY)		HO	PHHY2018US065141		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Overdose; Seizure	Atorvastatin	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide Sandoz	S	Unknown	Unk	Not Reported
	Venlafaxine	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown		Not Reported
	Dextroamphetamine	S	Unknown		Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Amphetamine	S	Unknown	Unk	Not Reported
	Fluoxetine	S	Unknown	Unk	Not Reported
	Amlodipine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14423876	EXPEDITED (15-DAY)			ES-AUROBINDO-AUR-APL-2018-002290		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Escitalopram			S	Unknown	()		Aurobindo
	Ondansetron			S	Unknown	()		Not Reported
	Ondansetron			S		()		Not Reported
	Dexamethasone			C		()		Not Reported
	Dexamethasone			C		()		Not Reported
	Levetiracetam			C		()		Not Reported
	Levetiracetam			C		()		Not Reported
	Temozolomide			C		()		Not Reported
	Temozolomide			C		()		Not Reported
	Cipraxel			S	Oral	10 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14538119	NON-EXPEDITED			US-TEVA-2018-US-852125			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14712377	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2018US14043			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Rash Pruritic; Skin Reaction; Suicidal Ideation; Therapy Non- Responder	Lamotrigine			S	Unknown	25 Mg, Daily		Cipla	
	Lamotrigine			S	Unknown	50 Mg, Daily		Cipla	
	Lamotrigine			S	Unknown	200 Mg, Daily		Cipla	
	Lamotrigine			S	Unknown	50 Mg, Daily		Cipla	
	Sertraline			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	10 Mg, Daily		Invagen	
	Escitalopram			S		10 Mg, Unk		Invagen	
	Bupropion			S	Unknown	Unk		Invagen	
	Vilazodone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14781750	EXPEDITED (15-DAY)		LT	FR-CIPLA LTD.- 2018FR15839			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ataxia; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Mg, Per Day		Invagen	
	Eliquis			S	Oral	10 Mg, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14783917	EXPEDITED (15-DAY)		HO, LT, OT	TR-MACLEODS PHARMACEUTICALS US LTD- MAC2016002889			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hot Flush; Hyperhidrosis; Loss Of Consciousness; Muscle Rigidity; Mydriasis; Nervousness; Nystagmus;	Escitalopram Oxalate			S	Unknown	1400 Mg, Single		Macleods	
	Escitalopram Oxalate			S				Macleods	
	Moclobemide			S	Unknown	6000 Mg, Total		Not Reported	
	Moclobemide			S				Not Reported	

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Overdose; Pupillary Reflex
Impaired; Restlessness;
Rhabdomyolysis;
Serotonin Syndrome;
Tachycardia; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14784414	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1821251US		31 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Fatigue; Feeling Abnormal; Hypoglycaemia; Insomnia; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 60 Milligram Daily		Allergan	
	Desvenlafaxine			S	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14784450	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1821860US		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Alcohol Interaction; Coma; Drug Abuse; Electrocardiogram Qt Prolonged; Mydriasis; Overdose	Escitalopram Oxalate Unk			S	Oral	Overdose: 590 Milligram In Total		Allergan	
	Delorazepam			S	Oral	Overdose: 6.5 Milligram In Total		Not Reported	
	Mutabon			S	Oral	Form Strength: 2 Mg + 25 Mg; Overdose: 26 Dosage Forms In Total		Not Reported	
	Depamide			C	Unknown			Not Reported	
	Gabapentin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14785098	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018159943		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anaphylactic Shock	Venlafaxine Hcl	S	Unknown					Pfizer	
	Escitalopram Oxalate	S	Unknown		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14785587	EXPEDITED (15-DAY)		DS	AT-TEVA-2018-AT-882475		25 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14785794	EXPEDITED (15-DAY)		DE	CA-ALLERGAN-1822236US		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14785796	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1822352US		49 YR	Female	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14786820	NON-EXPEDITED			JP-ALLERGAN-1822063US		73 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	

FDA Adverse Event Reporting System

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Detailed Report

Tegretol	S	Oral	Unk	Not Reported
Depas (Etizolam)	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2018	14731548	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-018455		16 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Blood Pressure Increased;	Quetiapine Film-Coated Tablet			S	Unknown	Voor De Nacht Een Halve Tablet		Aurobindo
Diarrhoea; Diarrhoea Haemorrhagic;	Escitalopram Tablets			S	Unknown	1x Daags 2 Tabletten		Aurobindo
Haematochezia; Heart Rate Increased;	Cholecalciferol			C	Intracardiac	800 International Unit, 1 X 1		Not Reported
Hypertension; Tachycardia	Melatonin			C	Unknown	1 Mg 1 X 1		Not Reported
	Melatonin			C		1 Mg 1 X 1		Not Reported
	Melatonin			C		1 Mg 1 X 1		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2018	14787261	EXPEDITED (15-DAY)		LT	CZ-ROCHE-2111027			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea;	Clonazepam			S	Unknown			Not Reported
Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness;	Metoclopramide			S	Unknown			Not Reported
Toxicity To Various Agents	Venlafaxine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Levopromazine			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Melperone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

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22-Apr-2018	13144997	EXPEDITED (15-DAY)		HO, OT	NO-APOTEX-2017AP005985		20 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour;	Seroxat			S	Unknown	Unk		Apotex
Aggression; Aggression;	Seroxat			S	Unknown	20 Mg, Qd		Apotex
Agitation; Anxiety; Balance	Efexor			S	Unknown	Unk		Not Reported
Disorder; Bipolar Disorder;	Cipralext /01588501/			S	Unknown	Unk		Not Reported
Depression; Derealisation;	Cipramil /00582602/			S	Unknown	10-60 Mg Daily		Not Reported
Disturbance In Attention;	Lamictal			S	Unknown	Unk		Not Reported
Disturbance In Social	Lamictal			S	Unknown	Unk		Not Reported
Behaviour; Dizziness;	Seroquel			S	Unknown	Unk		Not Reported
Drug Abuse; Drug	Seroquel			S	Unknown	Unk		Not Reported
Ineffective; Feeling	Seroquel			S	Unknown	Unk		Not Reported
Abnormal; Head Injury;	Seroquel			S	Unknown	Unk		Not Reported
Hyperhidrosis;	Zyprexa			S	Unknown	Unk		Not Reported
Hypomania; Hypomania;	Zyprexa			S	Unknown	Unk		Not Reported
Impaired Work Ability;	Zyprexa			S	Unknown	Unk		Not Reported
Impulse-Control Disorder;	Orfiril			S	Unknown	Unk		Not Reported
Irritability; Judgement	Orfiril			S	Unknown	Unk		Not Reported
Impaired; Logorrhoea;	Sobril			S	Unknown	Unk, Prn		Not Reported
Malaise; Mania; Mania;	Lithionit			S	Unknown	Unk		Not Reported
Memory Impairment;	Lithium			C		Unk		Not Reported
Personality Disorder;								
Psychotic Disorder;								
Quality Of Life Decreased;								
Restlessness; Speech								
Disorder; Stress; Suicidal								
Ideation								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14468181	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2018AP005879		48 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Chronic	Alendronate			S	Unknown			Apotex
	Levetiracetam			S	Unknown	Unk		Apotex

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	Cholecalciferol	S	Unknown	Unk	Not Reported
	Valproic Acid	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Fenofibrate	S	Unknown	Unk	Not Reported
	Emtricitabine W/Tenofovir	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14473169	NON-EXPEDITED			US-APOTEX-2017AP013585		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Paxil Cr Tablets			S	Unknown			Apotex	
	Lexapro			S	Unknown			Not Reported	
	Prozac			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14478548	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006110		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Hypertension	Escitalopram			S	Oral	20 Mg, Qd		Apotex	
	Escitalopram			S	Oral	10 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14479030	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP006120		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Suicide Attempt	Escitalopram			S	Oral	20 Mg, Qd		Apotex	
	Bupropion			C	Unknown	Unk		Not Reported	
	Cetirizine			C	Unknown	Unk		Not Reported	
	Duloxetine			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14479387	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006126			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anxiety; Confusional State; Insomnia; Pain In Jaw; Somnolence; Speech Disorder; Vision Blurred	Escitalopram			S	Unknown	10 Mg, Unk		Apotex	
	Lorazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14479388	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006091		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram			S	Oral	20 Mg, Qd		Apotex	
	Escitalopram			S				Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14524479	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP006699		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Abnormal; Condition Aggravated; Drug Ineffective; Mania; Rash; Sluggishness; Suicidal Ideation	Sertraline			S	Unknown	Unk		Apotex	
	Oxcarbazepine			S	Unknown	Unk		Apotex	
	Carbamazepine			S	Unknown	Unk		Apotex	
	Risperidone			S	Unknown	Unk		Apotex	
	Quetiapine			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Paroxetine			S	Unknown	Unk		Apotex	
	Duloxetine			S	Unknown	60 Mg, Daily		Apotex	
	Fluoxetine			S	Unknown	Unk		Apotex	

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Lamotrigine	S	Unknown	Unk	Apotex
Alprazolam	S	Unknown	Unk	Apotex
Venlafaxine	S	Unknown	Unk	Not Reported
Nortriptyline	S	Unknown	Unk	Not Reported
Lorazepam	S	Unknown	Unk	Not Reported
Thioridazine	S	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown	Unk	Not Reported
Chlorpromazine	C	Unknown	100 Mg, Q.H.S.	Not Reported
Gabapentin	C	Unknown	300 Mg, Bid	Not Reported
Gabapentin	C	Unknown	600 Mg, Q.H.S.	Not Reported
Acamprosate	C	Unknown	666 Mg, Tid	Not Reported
Baclofen	C	Unknown	10 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14530485	NON-EXPEDITED			US-APOTEX-2017AP022227		6 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Precocious Puberty; Therapeutic Product Effect Incomplete; Weight Increased	Risperidone			S	Unknown	Unk		Apotex
	Risperidone			S				Apotex
	Aripiprazole Tablets			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Ziprasidone Hcl			S	Unknown	Unk		Apotex
	Buspirone Hydrochloride Tablets Usp			S	Unknown	Unk		Apotex
	Quetiapine Fumarate			S	Unknown	Unk		Apotex
	Guanfacine			S	Unknown	Unk		Not Reported
	Methylphenidate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14581705	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006913		56 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Inflammation; Rash Macular; Skin Lesion	Atorvastatin			S	Oral	20 Mg, Qd		Apotex	
	Escitalopram Sandoz			S	Oral	10 Mg, Qd		Not Reported	
	Reactine /00884302/			C	Unknown	Unk, Qd		Not Reported	
	Singulair			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14655288	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX- 2018AP007881		66 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Tachycardia	Escitalopram			S	Unknown	10 Mg, Daily		Apotex	
	Perindopril			C	Unknown	Unk		Not Reported	
	Atenolol			C	Unknown	Unk		Not Reported	
	Rosuvastatin			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Lercanidipine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14667926	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2018AP008687		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Apotex	
	Ondansetron Injection Usp			S	Unknown	4 Mg, Single		Apotex	
	Venlafaxine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14668760	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP006129		32 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Depression;	Escitalopram	S	Oral	10 Mg, Qd	Apotex
Depression Suicidal;	Bupropion	S	Oral	150 Mg, Qd	Not Reported
Dizziness	Bupropion	S	Oral	300 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14672526	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008286		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Escitalopram			S				Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14672972	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2018AP008290		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram			S	Oral	Unk Unk, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14674647	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008074			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14694095	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP009166		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Drug Abuse;	Escitalopram			S	Unknown	Unk		Apotex	

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Electrocardiogram Qrs Complex Prolonged;	Buspirone	S	Unknown	Unk	Apotex
Muscle Necrosis;	Fluoxetine	S	Unknown	Unk	Apotex
Overdose;	Hydrochlorothiazide	S	Unknown	Unk	Apotex
Rhabdomyolysis; Seizure;	Atorvastatin	S	Unknown	Unk	Apotex
Suicide Attempt	Amlodipine	S	Unknown	Unk	Apotex
	Venlafaxine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14713383	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP009543		16 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lethargy; Psychotic Disorder; Suicidal Ideation; Weight Increased	Risperidone			S	Unknown	Unk		Apotex
	Risperidone			S				Apotex
	Aripiprazole			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Gabapentin			S	Unknown	Unk		Apotex
	Sertraline			S	Unknown	Unk		Apotex
	Bupropion			S	Unknown	Unk		Apotex
	Buspirone			S	Unknown	Unk		Apotex
	Trazodone			S	Unknown	Unk		Apotex
	Lurasidone			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14713621	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP009602		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Microscopic	Escitalopram			S	Unknown	Unk		Apotex
	Lansoprazole			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14728179	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP009041		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Fatigue; Headache; Hypersensitivity; Rash; Rash Pruritic; Skin Reaction; Therapeutic Product Effect Incomplete	Bupropion			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex	
	Sertraline			S	Unknown	Unk		Apotex	
	Lamotrigine			S	Unknown	25 Mg, Daily		Apotex	
	Lamotrigine			S	Unknown	50 Mg, Daily		Apotex	
	Lamotrigine			S	Unknown	200 Mg, Daily		Apotex	
	Lamotrigine			S	Unknown	50 Mg, Daily		Apotex	
	Divalproex			S	Oral	250 Mg, Bid		Apotex	
	Divalproex Vilazodone			S	Unknown	Unk		Apotex Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14769037	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP010715		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Alprazolam			S	Unknown	27 Unk, Unk		Apotex	
	Alprazolam			S				Apotex	
	Lithium Carbonate			S	Unknown			Apotex	
	Lithium Carbonate			S	Unknown	300 Mg, Daily		Apotex	
	Escitalopram			S	Unknown			Apotex	
	Sertraline			S	Unknown			Apotex	
	Bupropion			S	Unknown			Apotex	
	Risperidone			S	Unknown			Apotex	
	Quetiapine			S	Unknown			Apotex	

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Aripiprazole		S	Unknown		10 Mg, Daily		Apotex		
Aripiprazole		S					Apotex		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	13180139	EXPEDITED (15-DAY)		HO, LT, OT	TR-LUPIN PHARMACEUTICALS INC.-2016-04137		29 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram			S	Unknown	20 Mg, Qd		Lupin	
Overdose;	Escitalopram			S	Unknown	1400 Mg, Qd		Lupin	
Rhabdomyolysis;	Moclobemide			S	Unknown	300 Mg, Unk		Not Reported	
Serotonin Syndrome;	Moclobemide			S	Unknown	6400 Mg, Qd		Not Reported	
Suicide Attempt									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14013361	EXPEDITED (15-DAY)		HO	PHHY2017IT130203		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Abuse; Coma;	Alprazolam			S	Oral	20 Drp, Unk		Novartis	
Drug Abuse; Hypotension;	Cipralax			S	Oral	15 Drp, Unk		Not Reported	
Intentional Self-Injury	Halcion			S	Oral	10 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14348642	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-UCBSA-2017052565			Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Xyzall			S	Transplacental	5 Mg, Once Daily (Qd)		Ucb	
	Avamys			S	Transplacental	2x/Day (Bid)		Not Reported	
	Seretide			S	Transplacental	Unk		Not Reported	
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported	
	Vilanterol Trifenatate			S	Transplacental	1 Df, Once Daily (Qd)		Not Reported	
	Fluticasone Furoate			S	Transplacental	1 Df, Once Daily (Qd)		Not Reported	

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	Flixotide	S	Transplacental	250 Mg, 2x/Day (Bid)	Not Reported
	D-Cure	S	Transplacental	25 Kiu, Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S	Transplacental	Unk	Not Reported
	Ventolin	S		100 Mg, Unk	Not Reported
	Mepolizumab	S	Transplacental	100 Mg, Unk	Not Reported
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14425792	EXPEDITED (15-DAY)	HO		PHHY2018FR009059		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Sedation	Escitalopram			S	Oral	10 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	0.13 Df, Unk (0,25 1/2 Cp/J)		Novartis	
	Risperdal			S	Oral	1.5 G, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14769491	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1820676US		68 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Height Decreased; Carotid Artery Stenosis; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Aas			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14788428	EXPEDITED (15-DAY)	HO		DE-UCBSA-2018017745		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dyspepsia	Neupro			S	Transdermal	14 Mg, Once Daily (Qd)		Ucb	
	Escitalopram			S		20 Mg, Once Daily (Qd)		Not Reported	

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Ibuprofen	S	Unk	Not Reported
Bornaprine Hydrochloride	S	4 Mg, 1-0.5-1-0	Not Reported
Benserazide Hydrochloride W/Levodopa	C	100 25 Mg, 0-0-0-1	Not Reported
Amantadin	C	100 Mg, 2x/Day (Bid)	Not Reported
Amitriptylin	C	75 Mg, Once Daily (Qd)	Not Reported
Madopar	C	1.5 Df, 4x/Day (Qid)	Not Reported
Madopar Lt	C	25 Mg, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14788457	EXPEDITED (15-DAY)		HO, LT, OT	ES-HETERO CORPORATE- HET2018ES00344		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown			Hetero	
	Haloperidol			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14790098	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1822348US		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Haldol			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14790102	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1822359US		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

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Coversyl	S	Oral	10 Mg, Qd	Not Reported
Fycompa	C	Oral	16 Mg, Qd	Not Reported
Bisoce	C	Oral	10 Mg, Qd	Not Reported
Mysoline	C	Oral	750 Mg, Qd	Not Reported
Amlor	C	Oral	10 Mg, Qd	Not Reported
Esidrex	C	Oral	25 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14790108	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-182223US		95 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Faecal Vomiting; Faecaloma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Antarene Codeine			S	Oral			Not Reported	
	Lyrica			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14790408	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1805527US		38 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Autonomic Nervous System Imbalance; Cognitive Disorder; Hyperhidrosis; Hyperreflexia; Labelled Drug-Drug Interaction Medication Error; Restlessness; Serotonin Syndrome; Tachypnoea; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Doubled Dosage		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14794248	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-882530			Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14794551	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS- 2018M1025034		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest;	Haloperidol			S	Unknown			Not Reported	
Condition Aggravated;	Escitalopram			S	Unknown			Not Reported	
Hypomagnesaemia;	Pantoprazole			S	Unknown			Not Reported	
Mental Disorder; Torsade De Pointes									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	12554651	EXPEDITED (15-DAY)		HO, LT, OT	TR-FRI-1000086063		29 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram Oxalate - Bp			S	Unknown	1400 Mg, In Total		Allergan	
Overdose;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
Rhabdomyolysis;	Escitalopram Oxalate - Bp			S				Allergan	
Serotonin Syndrome;	Moclobemide			S	Unknown	6000 Mg, In Total		Not Reported	
Suicide Attempt	Moclobemide			S	Unknown	300 Mg, Qd		Not Reported	
	Moclobemide			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	12572931	EXPEDITED (15-DAY)		HO, LT, OT	TR-ACCORD-042453		29 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction;	Escitalopram	S	1400 Mg (Total Dose)	Not Reported
Overdose;	Moclobemide	S	6000 Mg (Total Dose)	Not Reported
Rhabdomyolysis;				
Serotonin Syndrome;				
Suicide Attempt				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14705752	NON-EXPEDITED		OT	JP-EISAI MEDICAL RESEARCH-EC-2018- 037570		77 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Aricept			S	Oral	Unknown		Not Reported
	Escitalopram Oxalate			S	Unknown	Unknown		Not Reported
	Risperidone			S	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14721242	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018- 008812		84 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Metoclopramide			S	Oral			Valeant
	Ramipril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14746115	EXPEDITED (15-DAY)		OT	NL-ALLERGAN- 1819886US		16 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Blood Pressure Increased;	Escitalopram Oxalate - Bp			S	Unknown	2 Tablets At Once, Once A Day		Allergan
Diarrhoea; Haematochezia; Heart	Escitalopram Oxalate - Bp			S		Unk		Allergan

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Rate Increased; Product Administered To Patient Of Inappropriate Age	Quetiapine	S	Unknown	Before Going To Bed ½ Tablet	Not Reported
	Quetiapine	S			Not Reported
	Cholecalciferol	C	Unknown	800 Iu, Qd	Not Reported
	Melatonin	C	Unknown	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14778591	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180414314		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Urinary Retention	Haldol			S	Oral				Not Reported
	Escitalopram			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14797709	EXPEDITED (15-DAY)		HO	PT-ACCORD-065972		29 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelination; Depression; Gait Disturbance; Headache; Vision Blurred	Escitalopram			S		10 Mg Qd			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14798197	EXPEDITED (15-DAY)		LT, OT	CZ-BAUSCH-BL-2018-010302			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness; Toxicity To Various Agents	Metoclopramide			S	Unknown				Valeant
	Venlafaxine			S	Unknown				Not Reported
	Ibuprofen			S	Unknown				Not Reported
	Clonazepam			S	Unknown				Not Reported
	Olanzapine			S	Unknown				Not Reported
	Levopromazine			S	Unknown				Not Reported

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	Melperone		S	Unknown					Not Reported
	Escitalopram		S	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14798530	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-885092			Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis	Aviomarin			S	Unknown			Not Reported	
	Dextromethorphan			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Ivax	
	Thiocodin (Codeine Phosphate\Sulfogaiacol)			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol		Not Reported	
	Thiocodin (Codeine Phosphate\Sulfogaiacol)			S		1 Dosage Text = Codeine + Sulfogluacol		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14798668	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1822367US		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Binge Eating; Gastrectomy; Hyperphagia; Insomnia; Off Label Use; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Taxilan (Perazine Dimalonate)			S	Oral	250 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14799528	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2018LAN000638		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Lansoprazole			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14801040	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-884884		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral	20 Milligram Daily;		Ivax	
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Xarelto			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14801178	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1024968		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Mg, Qd		Not Reported	
	Bevacizumab			S	Intravenous (not otherwise specified)	Unk		Mylan	
	Lomustine			S	Oral	40 Mg, Unk		Mylan	
	Seroplex			S	Oral	5 Mg, Qd		Mylan	
	Silodyx			C	Unknown	Unk		Mylan	
	Xanax			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14802510	EXPEDITED (15-DAY)		OT	CH-GLAXOSMITHKLINE-CH2018066283		< 1 DAY	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Lamotrigine			S	Transplacental	150 Mg, Unk		Glaxosmithkline	
	Wellbutrin			S	Transplacental	Unk		Glaxosmithkline	
	Trittico			S	Transplacental	50 Mg, Unk		Not Reported	
	Cipralext			S	Transplacental	40 Mg, Unk		Not Reported	
	Benocten			S	Transplacental	50 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14802699	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018162059		80 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Dementia Alzheimer'S Type	Neurontin			S		300 Mg, Unk		Pfizer	
	Seroquel			S		25 Mg, Unk		Not Reported	
	Urbanol			S		10 Mg, Unk		Not Reported	
	Donecept			S		10 Mg, Unk		Not Reported	
	Trustan			S		40 Mg, Unk		Not Reported	
	Sinemet			S		25/100 Mg		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
	Azilect			S		1 Mg, Unk		Not Reported	
	Adco-Simvastatin			S		20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14802739	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018162223		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Disturbance In Attention; Intentional Overdose; Poisoning Deliberate	Alprazolam			S	Oral	15 Df, Single		Pfizer	
	Paracetamol			S	Oral	40 G, Unk		Not Reported	
	Escitalopram			S	Oral	27 Df, Unk		Not Reported	
	Codeine			S	Oral	6 Df, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14871197	DIRECT		DS			31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sleep Disorder; Tinnitus	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Torrent	
	Ativan			C				Not Reported	
	Prilosec			C				Not Reported	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14871244	DIRECT	Y				60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nausea; Vomiting	Generic Lexapro			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14141521	EXPEDITED (15-DAY)		OT	PHHY2017FR157601		84 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14312397	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-ALLERGAN-1772916US			Male	BEL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Foetal Exposure During Pregnancy; Foetal Malformation; Premature Baby; Trisomy 18	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Unk		Allergan	
	Mepolizumab			S	Transplacental	100 Mg, Unk		Not Reported	
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Not Reported	
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported	
	Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Not Reported	
	Seretide			S	Transplacental	Unk		Not Reported	
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental	Unk		Not Reported	
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported	
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported	
	Levocetirizine			S	Transplacental	5 Mg, Qd		Not Reported	
	Avamys			S	Transplacental	Unk, Bid		Not Reported	
	Pantoprazole Sodium			S	Transplacental	Unk		Not Reported	

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Sesquihydrate D-Cure	S	Transplacental	25 Kiu, Unk	Not Reported
Xyzall	S	Transplacental	5 Mg, Qd	Not Reported
Theophylline	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14329331	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2017-034443		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Metformine			S	Oral			Santarus
	Dafalgan			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Nefopam Hydrochloride			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Bisoprolol Hemifumarate			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Irbesartan			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14698865	EXPEDITED (15-DAY)		HO, OT	CH-ASTELLAS-2018US015385		88 YR	Male	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Delirium; Infection; Inflammation	Xtandi			S	Oral			Astellas
	Escitalopram			S	Unknown	Unk, Unknown Freq.		Not Reported
	Fragmin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Pantozol /01263204/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Co Diovan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Targin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Oxynorm			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Torasemid			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Pregabalin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14702570	NON-EXPEDITED			US-JNJFOC-20180323177		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tooth Socket Haemorrhage	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported
	Evoxac			S	Unknown			Not Reported
	Biotin			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Calcium Vitamin D			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Calcifediol			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Bystolic			C	Unknown			Not Reported
	Prilosec			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

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Topamax	C	Oral	Not Reported
Ferrous Sulfate	C	Unknown	Not Reported
Hydrodiuril	C	Unknown	Not Reported
Xiidra	C	Unknown	Not Reported
Hctz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14803553	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-170847		76 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parkinsonism	Aripiprazole			S	Oral	Unk ()		Not Reported
	Mirtazapine			S	Unknown	()		Sun
	Seroplex			S	Unknown	Unk ()		Not Reported
	Seroplex			S	Oral	Unk ()		Not Reported
	Norset			S	Oral	Unk ()		Not Reported
	Aprovel			C	Unknown	Unk ()		Not Reported
	Inipomp			C	Unknown	Unk ()		Not Reported
	Irbesartan			C	Oral	()		Not Reported
	Kardegic			C	Unknown	Unk ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14803935	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00007125		30 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep	Escitalopram			S	Oral	Daily Dose: 15 Mg Milligram(S) Every Day		Unknown

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Disorder; Suicidal
Ideation; Tremor; Wound

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25-Apr-2018	14806430	EXPEDITED (15-DAY)		HO	FR-SA-2018SA110424			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Furosemide			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Terbutaline			S		Respiratory (Inhalation)		Not Reported
	Pantoprazole			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Nefopam			S	Oral			Not Reported
	Colchicine Opocalcium			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14807385	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1822504US		19 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram Oxalate - Bp	S	Unknown	Allergan

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25-Apr-2018	14807398	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1815648US		64 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Abdomen; Drug Interaction	Escitalopram Oxalate - Bp			S	Unknown	5-0-0		Allergan	
	Seroquel			S	Unknown	50-25-50		Not Reported	
	Leponex			C	Unknown	100-0-75		Not Reported	
	Levomepromazine			C	Unknown	25-25-25		Not Reported	
	Eisensulfat			C	Unknown	1-0-0		Not Reported	
	Kalinor (Potassium Bicarbonate\Potassium Citrate)			C	Unknown	1-0-0		Not Reported	
	Delix (Ramipril)			C	Unknown	5-0-0		Not Reported	
	Pantoprazol Abz			C	Unknown	20-0-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14808795	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-885180		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Condition Aggravated; Hypomagnesaemia; Mental Disorder; Torsade De Pointes	Haloperidol			S	Unknown	2 Milligram Daily;		Actavis	
	Haloperidol			S				Actavis	
	Escitalopram			S	Unknown	15 Milligram Daily;		Ivax	
	Escitalopram			S				Ivax	
	Pantoprazole			S	Unknown			Teva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14138225	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1761119US		83 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	8 Gtt, Qd		Allergan	
	Ramipril + Hydrochlorothiazide			S	Oral	30 Mg, Qd		Not Reported	
	Avodart			C	Oral			Not Reported	
	Cardirene			C	Oral			Not Reported	
	Sivastin			C	Oral			Not Reported	
	Vertisec			C	Oral			Not Reported	
	Metformine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14707218	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.- 2018AU13541			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Immune Thrombocytopenic Purpura; Neuropathy Peripheral; Steroid Diabetes	Escitalopram			S	Oral	Daily, Unk		Invagen	
	Hydroxychloroquine			C	Oral	200 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14813136	NON-EXPEDITED			US-MALLINCKRODT- T201701853			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hypersomnia; Lethargy	Temazepam			S	Unknown	Unk, Unk		Mallinckrodt	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14813288	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.- 2018AU16596			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Fatigue; Pain In Extremity;	Escitalopram			S	Unknown	Unk		Invagen	

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Withdrawal Syndrome		Escitalopram		S		Invagen			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14814101	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-066141		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest;	Escitalopram			S				Not Reported	
Condition Aggravated;	Pantoprazole			S				Not Reported	
Electrocardiogram Qt	Haloperidol			S				Not Reported	
Prolonged;									
Hypomagnesaemia;									
Myocardial Ischaemia;									
Tachycardia; Torsade De									
Pointes									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14814934	EXPEDITED (15-DAY)		HO, LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2018012774			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest;	Escitalopram Oxalate			S	Unknown	15 Milligram, Qd		Macleods	
Electrocardiogram Qt	Haloperidol			S	Unknown	2 Milligram, Qd		Not Reported	
Prolonged; Myocardial									
Ischaemia; Tachycardia;									
Torsade De Pointes									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14815425	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US- 884938		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic	Venlafaxine			S	Oral			Teva	
Shock; Electrocardiogram	Escitalopram			S	Oral			Ivax	
Qrs Complex Prolonged;	Amphetamine			S	Oral			Barr	
Intentional Overdose;	W/Dextroamphetamine								
Muscle Necrosis;	Bupropion			S	Oral			Teva	
Rhabdomyolysis; Seizure									

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Fluoxetine	S	Oral	Barr
Hydrochlorothiazide	S	Oral	Ivax
Atorvastatin	S	Oral	Teva
Amlodipine	S	Oral	Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14815845	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180431684		89 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extradural Haematoma;	Rivaroxaban			S	Oral			Not Reported
Hypotension;	Rivaroxaban			S	Oral			Not Reported
Hypovolaemia; Paralysis	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14816457	NON-EXPEDITED			US-TEVA-2018-US-872462		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Autophobia; Decreased Appetite; Depressed Mood; Drug Tolerance; Eye Pain; Feeling Abnormal; Formication; Hypersomnia; Impatience; Irritability; Mental Disorder; Ocular Discomfort; Paraesthesia; Screaming; Social Avoidant Behaviour; Thinking Abnormal	Escitalopram			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14895588	DIRECT		DS, HO, LT, OT			16 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Concussion; Educational Problem; Fall; Head Injury; Headache; Hypotension; Malaise; Physical Assault; Suicidal Ideation; Upper Limb Fracture	Lexapro			S				Unknown
	Generic Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	12479115	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2016-014302		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Nystagmus; Poisoning; Psychomotor Skills Impaired; Suicidal Ideation; Toxicity To Various Agents	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bromazepam			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14336898	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-47644		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral	Bid ()		Not Reported
	Furosemide			S		Unk		Not Reported
	Furosemide			S	Oral	2 Unk, Qd ()		Not Reported
	Amlodipine Capsules			S	Oral	10 Mg, Once Daily (Qd)		Aurobindo
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Aurobindo

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Terbutaline	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Terbutaline	S			Not Reported
Irbesartan	S	Oral	300 Mg, Once Daily (Qd)	Aurobindo
Alprazolam	S	Oral	0.25 Mg, 3x/Day (Tid)	Aurobindo
Diazepam Tablet	S	Oral	10 Mg, 3x/Day (Tid)	Not Reported
Bisoprolol	S	Oral	1.25 Mg, Qd	Aurobindo
Metformin Film-Coated Tablet	S	Oral	500 Mg, Bid	Aurobindo
Pantoprazole	S	Oral	20 Mg, Once Daily (Qd)	Aurobindo
Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Tavanic	S			Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
Nefopam	S		1 Df, Tid	Not Reported
Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
Diffu-K	S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14703101	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/18/0097358		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure	Amlodipine Besylate			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Fluoxetine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Hydrochlorothiazide			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amphetamine	S	Oral	Not Reported
Buspirone	S	Oral	Not Reported
Dextroamphetamine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14817692	EXPEDITED (15-DAY)		DE, DS, LT, OT	BE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-170975			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Pantoprazole			S	Unknown	Unk ()		Sun
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk		Not Reported
	Fluticasone Furoate Inhalation Powder			S	Transplacental	Unk Unk, Qd ()		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Vilanterol Trifenatate Inhalation Powder			S	Transplacental	1 Df, Qd		Not Reported
	Seretide			S	Transplacental	Unk ()		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk ()		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Ventolin			S	Transplacental	100 Ug, Unk		Not Reported
	Levocetirizine Tablets			S	Transplacental	5 Mg, Qd		Not Reported
	Avamys Nasal Spray			S	Transplacental	Bid		Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	1 Df, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Xyzall Film-Coated Tablet			S	Transplacental	5 Mg, Qd		Not Reported
	Theophylline			S	Unknown	Unk ()		Not Reported
	Sipralexa Tablet			S	Transplacental	10 Mg,		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818262	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-886960		91 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Lansoprazole			S	Oral	30 Milligram Daily;		Teva	
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported	
	Gliclazide			S	Oral	60 Milligram Daily;		Not Reported	
	Stilnox 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Efferalgan			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818643	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-665329USA		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia; Hyponatraemia; Lactic Acidosis	Metformin			S	Unknown	Initial Dose Not Stated, Eventually The Dose Was Increased To 1gram Twice A Day		Not Reported	
	Insulin			S	Unknown			Not Reported	
	Gliclazide			S	Unknown			Not Reported	
	Hydrochlorothiazide			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Telmisartan			C	Unknown			Not Reported	
	Levothyroxine Sodium			C	Unknown			Not Reported	
	Trazodone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818757	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-019848		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged;	Escitalopram			S	Unknown			Zydus Pharm	
	Pantoprazole			S	Unknown			Not Reported	
	Haloperidol			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hypomagnesaemia;
Mental Disorder;
Myocardial Ischaemia;
Torsade De Pointes

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14819037	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2017DE00170		30 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	15 Mg, Qd		Hetero
	Escitalopram			S	Unknown	7.5 Mg Qd		Hetero
	Escitalopram			S		20 Mg Qd		Hetero

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14819297	EXPEDITED (15-DAY)		HO	DE-BAYER-2018- 075287		65 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Dizziness; Dyspnoea; Haematochezia; Pain	Acetylsalicylic Acid(<=100 Mg)			S		100 Mg, Qd		Bayer
	Ciprallex			S		10 Mg, Qd		Not Reported
	Simvastatin			C		20 Mg, Qd		Not Reported
	Ramipril			C		25 Mg, Qd		Not Reported
	Spiriva			C		18 Mg, Qd		Not Reported
	Pantoprazole			C		40 Mg, Qd		Not Reported
	Euthyrox			C		50 Mg, Qd		Not Reported
	Allopurinol			C		0.5 Df, Qd		Not Reported
	Metamizol			C		15 Gtt, Tid		Not Reported
	Metoprolol			C		47.5 Mg, Bid		Not Reported

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	Alna	C		4 Mg, Qd		Not Reported
	Torasemid	C		10 Mg, Qd		Not Reported
	Tramal Long	C		Unk, Prn		Not Reported
	Symbicort	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14819384	NON-EXPEDITED			US-TEVA-2018-US-873443			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Eye Pain; Sexual Dysfunction	Hydrochlorothiazide			S				Ivax	
	Aspirin			S		81 Milligram Daily;		Not Reported	
	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14820136	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-022329		20 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S	Unknown	15 Mg, Nk		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14820201	EXPEDITED (15-DAY)		HO, LT, OT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00242		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Muscle Necrosis; Overdose; Rhabdomyolysis; Seizure	Hydrochlorothiazide Tablets			S	Unknown	Unk		Sciegen	
	Fluoxetine Capsules, Usp			S	Unknown	Unk		Sciegen	
	Atorvastatin Calcium			S	Unknown	Unk		Sciegen	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Amphetamine/Dextroamphetamine			S	Unknown	Unk		Not Reported	

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ne									
Buspirone	S	Unknown	Unk						Not Reported
Amlodipine	S	Unknown	Unk						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14820282	EXPEDITED (15-DAY)		HO	PHHY2017FR202566		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Mg, Qd		Novartis
	Bevacizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lomustine			S	Oral	40 Mg, Unk		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Silodyx			C	Unknown	Unk		Not Reported
	Xanax			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14820572	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1822986US			Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Escitalopram Oxalate - Bp			S	Transplacental	40 Mg, Unknown		Allergan
	Lamotrigine			S	Transplacental	150 Mg, Unknown		Not Reported
	Wellbutrin			S	Transplacental	150 Mg, Unknown		Not Reported
	Wellbutrin			S	Transplacental	300 Mg, Unknown		Not Reported
	Trittico			S	Transplacental	50 Mg, Unknown		Not Reported
	Benocten			S	Transplacental	50 Mg, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14821890	EXPEDITED (15-DAY)		HO	US-ARBOR PHARMACEUTICALS, LLC-US-2018ARB000503		17 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure; Suicide Attempt	Amphetamine Sulfate			S		Unk		Arbor	
	Venlafaxine			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Dextroamphetamine /00016601/			S		Unk		Not Reported	
	Buspirone			S		Unk		Not Reported	
	Fluoxetine			S		Unk		Not Reported	
	Hydrochlorothiazide			S		Unk		Not Reported	
	Atorvastatin			S		Unk		Not Reported	
	Amlodipine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14822675	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1823116US		85 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Communication Disorder; Loss Of Personal Independence In Daily Activities; Memory Impairment; Sluggishness	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14822901	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-SA-2018SA109223			Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Xyzall			S	Transplacental			Not Reported	
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported	
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental			Not Reported	
	Nucala			S	Transplacental			Not Reported	
	Fluticasone Furoate			S	Transplacental	Inhalation Powder		Not Reported	

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	Xanthium (Theophylline)	S	Transplacental		Not Reported
	Vilanterol Trifenatate	S	Transplacental		Not Reported
	Seretide	S	Transplacental		Not Reported
	Flixotide	S	Transplacental		Not Reported
	Ventolin	S	Transplacental		Not Reported
	Levocetirizine	S	Transplacental		Not Reported
	Avamys	S	Transplacental	Nasal Spray	Not Reported
	Relvar Ellipta	S	Transplacental		Not Reported
	D-Cure	S	Transplacental		Not Reported
	Theophylline	S	Transplacental		Not Reported
	Sipralexa	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2018	14824080	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018012796			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram Oxalate			S	Unknown	15 Milligram, Medication Errors		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14151884	EXPEDITED (15-DAY)		OT	PHHY2017FR157552		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Galantamine			S	Unknown	Unk		Not Reported
	Irbesartan			S	Unknown	Unk		Novartis
	Paracetamol			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14345827	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007501		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Accidental Overdose; Disinhibition; Drug Interaction; Mental Disorder; Product Use Issue	Cipralex			S	Oral	Daily Dose: 5 Gtt Drop(S) Every Day		Unknown	
	Aripiprazole			S	Unknown			Unknown	
	Calcium + Vitamin D			C	Unknown			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14488371	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1805752US		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Hypertension	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14506098	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1805926US		20 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Decreased; Syncope	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14605169	EXPEDITED (15-DAY)		HO, LT, OT	CA-ALLERGAN-1812266US		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	

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Ibuprofen	C	Unknown	Unk	Not Reported
Bupropion	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown	Unk	Not Reported
Duloxetine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14699180	EXPEDITED (15-DAY)		HO	CH-TEVA-2018-CH-874485		45 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Escitalopram			S	Unknown	20 Milligram Daily; 20 Mg/Day		Ivax	
	Escitalopram			S	Unknown	10 Milligram Daily; 10 Mg/Day		Ivax	
	Emtricitabine			C	Unknown			Not Reported	
	Tenofovir			C	Unknown			Not Reported	
	Dolutegravir			C	Unknown			Not Reported	
	Quetiapine			C	Unknown	50 Milligram Daily; 50 Mg/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14740283	EXPEDITED (15-DAY)		HO, OT	PHHY2017IT071807		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram			S	Oral	140 Mg, Once/Single		Not Reported	
	Lorazepam			S	Oral	20 Mg, Once/Single		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14825260	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-171224		29 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Emotional Disorder;	Venlafaxine	S	Unknown	150 Mg, Unk	Sun
Hyperhidrosis; Libido	Venlafaxine	S	Unknown	Up To 225 Mg	Sun
Decreased; Off Label Use;	Escitalopram	S	Endocervical	30 Mg, Unk	Not Reported
Sexual Dysfunction;	Escitalopram	S	Unknown	20 Mg, Daily	Not Reported
Therapeutic Product Effect	Quetiapine	S	Unknown	12.5 Mg, Unk	Sun
Incomplete; Weight	Bupropion	S	Unknown	150 Mg, Daily	Not Reported
Increased	Bupropion	S	Unknown	Up To 300 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14827416	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2018M1028493			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Clozaril			S	Oral	250 Mg, Unk		Mylan
Hypersomnia; Malaise;	Clozaril			S	Oral	Unk		Mylan
Neutropenia;	Clozaril			S	Oral	275 Mg, Unk		Mylan
Schizophrenia; Self-Medication	Clozaril			S	Oral	200 Mg, Unk		Mylan
	Clozaril			S	Oral	225 Unk, Unk		Mylan
	Clozaril			S	Oral	212.5 Mg, Unk		Mylan
	Clozaril			S	Oral	225 Mg, Pm		Mylan
	Aripiprazole			S		Unk		Not Reported
	Aripiprazole			S		10 Mg, Am		Not Reported
	Aripiprazole			S	Oral	5 Mg, Unk		Not Reported
	Escitalopram			S		10 Mg, Unk		Not Reported
	Escitalopram			S		20 Mg, Unk		Not Reported
	Escitalopram			S		10 Mg, Unk		Not Reported
	Brexpiprazole			S		0.5 Mg, Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14273115	EXPEDITED (15-DAY)		OT	FR-OTSUKA-DJ201404328		20 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section;	Abilify			S	Oral	5 Mg, Qd		Otsuka
Communication Disorder;	Abilify			S	Oral	10 Mg, Qd		Otsuka
Gestational Diabetes;	Seroplex			S	Oral	10 Mg, Qd		Not Reported
Maternal Exposure During Pregnancy; Normal Newborn; Personality Disorder; Pregnancy On Contraceptive; Product Use In Unapproved Indication	Lexomil			S	Oral	Unk (Half Tab To Three Quarts Tab In The Eve)		Not Reported
	Lexapro			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14831541	EXPEDITED (15-DAY)		HO, LT, OT	CZ-MACLEODS PHARMACEUTICALS US LTD- MAC2018012823			Unknown	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea;	Escitalopram Tablet			S	Oral	Unk		Macleods
Electrocardiogram Qt Prolonged;	Olanzapine Tablet			S	Oral	Unk		Macleods
Electrocardiogram Qt Shortened; Epilepsy;	Venlafaxine			S	Oral	Unk, Tablet		Macleods
Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Clonazepam			S	Oral	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Not Reported
	Melperone			S	Oral	Unk		Not Reported
	Metoclopramide			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14833205	EXPEDITED (15-DAY)		HO, OT	FR- GLAXOSMITHKLINE- FR2018071441		82 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebellar Syndrome;	Lexomil			S	Oral	0.5 Gbq, Unk		Glaxosmithkline
Cognitive Disorder; Fall	Bactrim			S	Oral	Unk		Glaxosmithkline

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	Dexamethasone	S	Oral	Unk	Glaxosmithkline
	Zelitrex	S	Oral	Unk	Glaxosmithkline
	Seroplex	S	Oral	Unk	Glaxosmithkline
	Revlimid	S	Oral	Unk	Not Reported
	Imovane	C	Oral	1 Df, Unk	Glaxosmithkline
	Spironolactone	C	Oral	Unk	Glaxosmithkline
	Lasilix	C	Oral	Unk	Glaxosmithkline
	Nebivolol	C	Oral	5 Mg, Unk	Glaxosmithkline
	Kardegic	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14834230	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1823524US		55 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cytomegalovirus Chorioretinitis; Dry Eye; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	Unk, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	11587511	EXPEDITED (15-DAY)		OT	US-FRI-1000079855		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Torticollis	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	
	Clonazepam			C	Unknown	0.5 Mg, Prn (At Bedtime)		Not Reported	
	Clonazepam			C		0.25 Mg, Qd (At Bedtime)		Not Reported	
	Clonazepam			C				Not Reported	
	Amlodipine			C		Unk		Not Reported	
	Celecoxib			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Unknown	Unk		Not Reported	

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Tamsulosin	C	Unknown	Unk	Not Reported
Omeprazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14204688	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-GLAXOSMITHKLINE-BE2017GSK177076			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Nucala			S	Transplacental	100 Mg, Unk		Glaxosmithkline
	Relvar Ellipta			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Sipralexa			S	Transplacental	10 Mg, Z		Glaxosmithkline
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Glaxosmithkline
	Levocetirizine			S	Transplacental	5 Mg, Qd		Glaxosmithkline
	Avamys			S	Transplacental	Unk Unk, Bid		Glaxosmithkline
	Flixotide			S	Transplacental	250 ?G, 2x/Day (Bid)		Glaxosmithkline
	Ventolin			S	Unknown	100 Ug, Unk		Glaxosmithkline
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Glaxosmithkline
	Seretide			S	Transplacental	Unk		Glaxosmithkline
	Theophylline			S		Unk		Glaxosmithkline
	Vilanterol Trifenatate			S	Transplacental	Unk Unk, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14676103	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ELI_LILLY_AND_COMP ANY-CZ201803010170			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Diarrhoea;	Olanzapine	S	Oral	Unk Unk, Unknown	Eli Lilly And Co
Electrocardiogram Qt	Clonazepam	S	Oral	Unk Unk, Unknown	Not Reported
Prolonged;	Levopromazin	S	Oral	Unk Unk, Unknown	Not Reported
Electrocardiogram Qt	Metoclopramide	S	Oral	Unk Unk, Unknown	Not Reported
Shortened; Epilepsy;	Ibuprofen	S	Unknown	Unk Unk, Unknown	Not Reported
Gastrointestinal	Venlafaxine	S	Oral	Unk Unk, Unknown	Not Reported
Hypermotility; Loss Of	Escitalopram	S	Oral	Unk Unk, Unknown	Not Reported
Consciousness; Poisoning	Melperone	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14765202	EXPEDITED (15-DAY)		HO, LT, OT	ES-JNJFOC-20180414902		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest;	Haloperidol			S	Unknown			Not Reported	
Electrocardiogram Qt	Escitalopram			S	Unknown			Not Reported	
Prolonged; Myocardial									
Ischaemia; Torsade De									
Pointes									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14835950	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018012838			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Contusion; Fall;	Escitalopram			S	Unknown	Unk		Macleods	
Syncope	Metoprolol			C	Unknown	47.5 Milligram, 1-0-0-0		Not Reported	
	Pantoprazole			C	Unknown	20 Milligram, 1-0-0-0		Macleods	
	Valsartan 80 Mg			C	Unknown	80 Milligram, 0.5-0-0-1		Macleods	
	Ass 100			C	Unknown	100 Milligram, 0-1-0-0		Not Reported	
	Eferox			C	Unknown	50 Microgram, 1-0-0-0		Not Reported	
	Hct			C	Unknown	12.5 Milligram, 1-0-0-0		Not Reported	

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Metamizole	C	Unknown	500 Milligram, 1-1-1-0	Not Reported
Simvastatin	C	Unknown	40 Milligram, 0-0-0-1	Not Reported
Ventolair	C	Unknown	250 Microgram, 2-0-0-2	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14835988	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-BAUSCH-BL-2018-012172			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Theophylline			S	Transplacental			Not Reported
	Levocetirizine			S	Transplacental	5 Mg, Qd		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)			S	Transplacental			Not Reported
	Fluticasone Furoate			S	Transplacental	Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported
	Nucala			S	Transplacental	100 Mg,		Not Reported
	Relvar Ellipta			S	Transplacental	Qd		Not Reported
	Seretide			S	Transplacental			Not Reported
	D-Cure			S	Transplacental	25 Kiu		Not Reported
	Avamys			S	Transplacental	Bid		Not Reported
	Vilanterol Trifenatate			S	Transplacental	Qd		Not Reported
	Ventolin			S	Transplacental	100 Ug		Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14836559	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1823527US		20 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram Oxalate - Bp	S	Unknown	15 Mg, Unknown	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14836822	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-023050		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	20 Mg, 1-0-0		Aurobindo	
	Ibuprofen			S	Unknown	Nk		Aurobindo	
	Bornaprine Hydrochloride			S	Unknown	4 Mg, 1-0.5-1-0		Not Reported	
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported	
	Madopar Depot			C	Unknown	100 25 Mg, 0-0-0-1		Not Reported	
	Amantadin /00055902/			C	Unknown	100 Milligram, Two Times A Day, (1-1-0-0)		Not Reported	
	Amitriptylin			C	Unknown	75 Mg, 0-0-0-1		Not Reported	
	Madopar			C	Unknown	100 25 Mg, 1.5-1.5-1.5-1.5		Not Reported	
	Madopar Lt			C	Unknown	100 25 Mg, 1-0-0-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14836937	EXPEDITED (15-DAY)		DS	AT-MYLANLABS-2018M1027264		25 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Decreased; Emotional Poverty; Loss Of Libido; Male Sexual Dysfunction; Urinary Retention; Vision Blurred	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14837467	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2018M1027341		55 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Lorazepam			S	Oral	6 Mg, Qd		Not Reported	
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported	
	Abilify			S	Oral	20 Mg, Unk		Mylan	
	Abilify			S	Oral	15 Mg, Unknown		Mylan	
	Cipralex /01588501/			S	Oral	10 Mg, Unk		Mylan	
	Lexapro			S	Oral	10 Mg, Qd		Mylan	
	Lexapro			S				Mylan	
	Tavor /00273201/			S	Oral	2 Mg, Unk		Mylan	
	Tavor /00273201/			S	Oral	6 Mg, Unk		Mylan	
	Seroquel			S	Oral	200 Mg, Unk		Mylan	
	Movicol			C	Unknown	Unk		Mylan	
	Simeticone			C	Unknown	Unk		Mylan	
	Eferox			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14837505	EXPEDITED (15-DAY)		HO	PHHY2016FR186709		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose	Zolpidem			S	Oral	30 Df		Novartis	
	Lexapro			S	Oral	15 Df,		Not Reported	
	Seroplex			S	Oral	15 Df,		Not Reported	
	Stilnox			S	Oral	30 Df,		Not Reported	
	Theralene			S	Oral	50 Df,		Not Reported	
	Theralene			S	Oral	1 Df		Not Reported	
	Seresta			S	Oral	80 Df,		Not Reported	
	Abilify			S	Oral	7 Df,		Not Reported	
	Valium			S	Oral	1 Df		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14918150	DIRECT		DS, HO, LT, OT			16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Head Injury; Hypotension; Intentional Overdose; Poverty Of Thought Content; Product Prescribing Issue; School Refusal; Suicidal Ideation; Upper Limb Fracture	Current Lexapro But Other Ssri Has The Same Effects				S	Oral	Quantity:30 Tablet(S);		Unknown
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14919559	DIRECT		DS, OT			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erectile Dysfunction; Impaired Quality Of Life; Orgasmic Sensation Decreased; Sexual Dysfunction	Escitalopram Oxalate				S	Oral	Quantity:30 Tablet(S);		Unknown
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14920148	DIRECT	Y					Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Night Sweats	Escitalopram 10mg				S	Oral			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	13180102	EXPEDITED (15-DAY)		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2016-02723		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clonus; Confusional State;	Escitalopram				S	Oral	840 Mg, Unk		Lupin

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Electrocardiogram Qt Prolonged;	Venlafaxine	S	Oral	7875 Mg, Unk	Not Reported
Hypoglycaemia;	Bromazepam	S	Oral	180 Mg, Single	Not Reported
Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicidal Ideation; Toxicity To Various Agents	Lormetazepam	S	Oral	14 Mg, Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14337790	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1773751US		65 YR	Female	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Energy Increased; Euphoric Mood; Impulsive Behaviour; Insomnia; Major Depression; Mania; Pressure Of Speech; Tachyphrenia; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Venlafaxine			S	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported
	Metformin			C	Unknown	500 Mg, Q8hr		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840170	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-886830		40 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thyroid Mass	Escitalopram (2858a)			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840223	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-023143		77 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk ()		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eferox	C	Unknown	50 Microgram, Once A Day	Not Reported
Hct	C	Unknown	12.5 Milligram, Once A Day	Not Reported
Metoprolol	C	Unknown	47.5 Milligram, Once A Day	Not Reported
Ventolair	C	Unknown	250 Microgram,2-0-0-2	Not Reported
Metamizole	C	Unknown	500 Milligram	Not Reported
Valsartan	C	Unknown	80 Milligram,0.5-0-0-1	Not Reported
Ass	C	Unknown	100 Milligram, Once A Day	Not Reported
Simvastatin	C	Unknown	40 Milligram, Once A Day	Not Reported
Pantoprazol /01263201/	C	Unknown	20 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840507	EXPEDITED (15-DAY)		HO, LT	DE-WEST-WARD PHARMACEUTICALS CORP.-DE-H14001-18-03		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Westward
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Ivabradin			C	Unknown	Daily Dose: 15 Mg Milligram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown			Not Reported
	Scopolamin			C	Unknown	()		Not Reported
	Baclofen			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Lorazepam			C	Unknown	Daily Dose: 1 Mg Milligram(S) Every Days		Not Reported

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L-Thyroxin	C	Unknown		Not Reported
Esomeprazole	S	Unknown		Not Reported
Escitalopram	S	Unknown	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840769	NON-EXPEDITED			US-PFIZER INC-2018177180		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Latuda			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Risperidone			S		Unk		Not Reported
	Lithium			C		Unk		Not Reported
	Rexulti			C		Unk		Not Reported
	Mirtazapine			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14841133	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-889625			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basedow'S Disease; Dermatitis; Dry Skin; Gingival Atrophy; Gingivitis; Prostatomegaly;	Escitalopram			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pruritus; Squamous Cell
Carcinoma; Toothache;
Urethral Stricture
Postoperative

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14841151	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163- 2340501-00		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral	On Saturday		Not Reported	
	Methotrexate			S	Oral	Dose Decreased		Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Progesterone			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Cymbalta			S	Unknown			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Remeron			S	Oral	Before Bed		Not Reported	
	Atorvastatin			C	Oral	At Bedtime And Taking For At Least 6 Months		Not Reported	
	Cardiazem			C	Oral	Taking For At Least 6 Months		Not Reported	
	Cardiazem			C				Not Reported	
	Carvedilol			C	Oral			Not Reported	
	Cozaar			C	Oral			Not Reported	
	Potassium			C	Oral			Not Reported	
	Potassium			C	Oral			Not Reported	
	Pantoprazole			C	Oral			Not Reported	
	Folic Acid			C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two		Not Reported	

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Aldactone	C	Oral		Not Reported
Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily	Not Reported
Tramadol	C			Not Reported
Bumex	C	Oral		Not Reported
Gabapentin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14841324	EXPEDITED (15-DAY)		LT, OT	IN-TORRENT-00001709		53 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Suicidal Ideation; Suicide Attempt	Escitalopram Oxalate			S		Unknown		Unknown
	Amitriptyline Hydrochloride			S		Unknown		Unknown
	Mirtazapine			S		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14842772	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2010DE101573		55 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hyperhidrosis; Restlessness; Schizoaffective Disorder	Quetiapine			S	Oral	200 Mg, Qd		Novartis
	Lorazepam			S	Oral	6 Mg, Qd		Not Reported
	Abilify			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Oral	15 Mg, Unk		Not Reported
	Cipralext			S	Oral	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Tavor [Lorazepam]			S	Oral	2 Mg, Unk		Not Reported
	Tavor			S	Oral	6 Mg, Unk		Not Reported
	Seroquel			S	Oral	200 Mg, Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported

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	Simeticone	C	Unknown	Unk				Not Reported	
	Eferox	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14842789	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-012293		82 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Cognitive Disorder; Fall	Dexamethasone			S	Oral			Valeant	
	Seroplex			S	Oral	Divisible Coated Tablet		Not Reported	
	Revlimid			S	Oral	21 Days On 28		Not Reported	
	Zelitrex			S	Oral			Not Reported	
	Bactrim			S	Oral			Not Reported	
	Lexomil			S	Oral	Compressed		Not Reported	
	Imovane			C	Oral	Coated Tablet		Not Reported	
	Spironolactone			C	Oral			Not Reported	
	Lasilix			C	Oral	Tablet Breackable		Not Reported	
	Kardegic			C	Oral	Dose		Not Reported	
	Nebivolol			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843146	EXPEDITED (15-DAY)		HO	DE-JNJFOC-20180427891		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dyspepsia	Ibuprofen		Y	S	Unknown			Not Reported	
	Ibuprofen			S	Unknown	Nk		Not Reported	
	Neupro			S	Transdermal	1-0-0-0		Not Reported	
	Escitalopram			S	Unknown	1-0-0		Not Reported	
	Bornaprine Hydrochloride			S	Unknown	1-0.5-1-0		Not Reported	
	Amantadine			C	Unknown	1-1-0-0		Not Reported	
	Amitriptyline			C	Unknown	0-0-0-1		Not Reported	

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	Madopar	C	Unknown	100/25 Mg 0-0-0-1	Not Reported
	Madopar	C	Unknown	100/25 Mg, 1.5-1.5-1.5-1.5	Not Reported
	Madopar	C	Unknown	100 25 Mg, 1-0-0-0	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843357	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-888011		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Ceftriaxone Sodique			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Pliva	
	Escitalopram			S	Unknown			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843464	EXPEDITED (15-DAY)		LT, OT	IT-MYLANLABS-2018M1027921		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Prescribed Underdose	Escitalopram			S	Oral	5 Mg, Qd		Not Reported	
	Abilify			S	Oral	10 Mg, Qd		Mylan	
	Cipralex /01588501/			S	Oral	5 Mg, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843770	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1028844		7 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Headache; Medication Error; Myalgia; Wrong Product Administered	Aciclovir			S		Unk		Not Reported	
	Seroplex			S	Oral	1 Df, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843949	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018176104		41 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Lyrica			S	Oral	Unk		Pfizer	
	Tavor [Lorazepam]			S	Unknown	3 Df, Single		Pfizer	
	Ethanol			S	Unknown	Unk		Not Reported	
	Rezolsta			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	3 Df, Single		Not Reported	
	Minias			S	Unknown	40 Gtt, Single		Not Reported	
	Kivexa			S	Unknown	4 Df, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14844325	EXPEDITED (15-DAY)		OT	PHHY2014BR056233			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Arthropathy; Cardiac Disorder; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea; Fear; Flatulence; Gastritis; Headache; Hypoaesthesia; Malaise; Nightmare; Pain; Panic Disorder; Restlessness; Sleep Disorder; Tremor; Weight Decreased; Weight Increased; Wrong Technique In Product Usage Process	Olcadil			S	Oral	2 Df, A Day		Not Reported	
	Olcadil			S	Oral	3 Df, A Day		Not Reported	
	Olcadil			S	Oral	1 To Go Out And 1 At Night		Not Reported	
	Cloxazolam			S	Oral	4 Mg And 2 Mg 3 Times A Day		Not Reported	
	Cloxazolam			S				Not Reported	
	Cloxazolam			S				Not Reported	
	Citalopram			S	Oral	1 Df, Qd		Not Reported	
	Fluoxetine			S	Oral	1 Df, A Day		Novartis	
	Denyl//Citalopram Hydrobromide			S	Oral	1 Df, A Day		Not Reported	
	Escitalopram			S	Oral	1 Df, A Day		Not Reported	
	Valium			S	Unknown			Not Reported	
	Frontal			S	Unknown			Not Reported	
	Dorflex			C	Unknown	At Night		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	13339676	EXPEDITED (15-DAY)		HO	PHHY2017IT035607		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral	100 Mg, Unk (Total)		Not Reported	
	Clozapine			S				Not Reported	
	Lorazepam			S	Oral	1 mg, Unk (Total)		Novartis	
	Lorazepam			S				Novartis	
	Entact			S	Oral	20 Mg, Unk (Total)		Not Reported	
	Entact			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14281465	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2017M1077181			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Depression; Dysmenorrhoea; Hypomenorrhoea; Menorrhagia	Escitalopram			S		20 Mg, Qd		Not Reported	
	Valdoxan			S	Oral	25 Mg, Qd		Mylan	
	Zoely			S	Oral	1 Dosage Forms Daily One Df Contains 2.5 Mg Nomegestrel And 1.5mg Estradiol		Mylan	
	Estradiol			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14290936	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2017M1078175		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported	
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported	
	Candesartan			S	Oral	16 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported	

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	Escitalopram	S	Oral	20 Mg, Qd	Not Reported
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Risperdal	C		1.5 Mg, Qd	Mylan
	Risperdal	C		2 Mg, Unk (For Nights)	Mylan
	Risperdal	C	Unknown	2 Mg, Qd	Mylan
	L-Thyroxin	C	Oral	100 Mg, Qd	Mylan
	L-Thyroxin	C	Oral	100 G, Unk	Mylan
	Amisulpride	C	Unknown	200 Mg, Qd	Mylan
	Metformin	C	Oral	1500 Mg, Qd	Mylan
	Atorvastatin	C	Oral	20 Mg, Qd	Mylan
	Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14803485	EXPEDITED (15-DAY)		OT	CA-ROCHE-2070850			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety Disorder; Decreased Appetite; Diarrhoea; Frequent Bowel Movements; Nasopharyngitis; Weight Decreased	Tecentriq			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose On 18/Apr/2018		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Tamoxifen			S	Unknown			Not Reported
	Mistletoe			C				Not Reported
	Gabapentin			C				Not Reported
	Ativan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2018	14285863	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT- 00007377		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Quetiapine Fumarate			S	Oral			Unknown
	Escitalopram			S	Oral			Unknown

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Lorazepam			S		Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2018	14354607	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2018-000227		42 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 40 Mg		Aurobindo	
	Escitalopram Film-Coated Tablets			S	Oral	30 Milligram, Once A Day		Aurobindo	
	Lorazepam			C	Unknown	0.5 Mg,		Not Reported	
	Lorazepam			C	Unknown	0.5 Mg, Unk		Not Reported	
	Pangrol /00014701/			C	Unknown	1 Dosage Form		Not Reported	
	Olanzapine			C	Unknown	10 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2018	14813489	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2018-020931		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Mental Disorder; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Milligram, Once A Day		Aurobindo	
	Pantoprazole			S	Unknown	()		Aurobindo	
	Haloperidol			S	Unknown	2 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2018	14850183	EXPEDITED (15-DAY)		HO	LT-TEVA-2018-LT- 887365		46 YR	Female	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dizziness; Insomnia; Speech	Escitalopram			S	Oral			Ivax	

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Disorder	Zolpidem	S	Oral	Not Reported
	Quetiapine	S	Oral	Not Reported
	Etoricoxib	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	6430818	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2007079081		56 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Interaction; Hypomania; Serotonin Syndrome	Phenytoin Sodium			S		300 Mg, 1x/Day		Pfizer
	Sertraline			S		100 Mg, 1x/Day		Pfizer
	Trazodone Hydrochloride			S		100 Mg, 1x/Day		Not Reported
	Lithium Carbonate			S		750 Mg, 1x/Day		Not Reported
	Escitalopram			S		10 Mg, 1x/Day		Not Reported
	Amlodipine			C		10 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	10896249	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2015-01685		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Joint Range Of Motion Decreased; Musculoskeletal Stiffness; Neck Pain; Nuchal Rigidity; Torticollis	Escitalopram			S	Unknown	5 Mg, Daily		Aurobindo
	Escitalopram			S	Unknown	10 Mg, Daily		Aurobindo
	Escitalopram			S	Unknown	15 Mg, Daily		Aurobindo
	Clonazepam			C	Unknown	0.25 Mg, At Bedtime		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, At Bedtime As Needed		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime As Needed		Not Reported
	Clonazepam			C		At Bedtime		Not Reported
	Clonazepam			C		At Bedtime		Not Reported

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Clonazepam	C		.25 Milligram	Not Reported
Clonazepam	C		At Bedtime As Needed	Not Reported
Clonazepam	C		At Bedtime	Not Reported
Clonazepam	C		At Bedtime	Not Reported
Clonazepam	C		At Bedtime	Not Reported
Clonazepam	C		At Bedtime As Needed	Not Reported
Clonazepam	C		()	Not Reported
Clonazepam	C		At Bedtime	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Ibuprofen	C		()	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Amlodipine	C		()	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Celecoxib	C		()	Not Reported
Tamsulosin	C	Unknown	Unk	Not Reported
Tamsulosin	C		()	Not Reported
Omeprazole	C	Unknown	Unk	Not Reported
Omeprazole	C		()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14445994	EXPEDITED (15-DAY)	HO		US-ABBVIE-17K-163-2099796-00			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Cardiac Failure; Drug Interaction; Joint Swelling; Pulmonary Embolism; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.5mg Nine Tablets By Mouth On Saturday Once A Week		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported

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Remeron	S	Oral	Before Bed	Not Reported
Cymbalta	S	Unknown		Not Reported
Progesterone	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Atorvastatin	C	Oral	At Bedtime	Not Reported
Cardiazem	C	Oral		Not Reported
Cardiazem	C			Not Reported
Carvedilol	C	Oral		Not Reported
Potassium	C	Oral		Not Reported
Potassium	C	Oral		Not Reported
Pantoprazole	C	Oral		Not Reported
Folic Acid	C	Oral	Six Days A Week	Not Reported
Aldactone	C	Oral		Not Reported
Tramadol	C			Not Reported
Tramadol	C			Not Reported
Bumex	C	Oral		Not Reported
Progesterone	C			Not Reported
Plaquenil	C			Not Reported
Cozaar	C	Oral		Not Reported
Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily	Not Reported
Gabapentin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14652996	EXPEDITED (15-DAY)		OT	IT-ABBVIE-18P-083-2285824-00		52 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Loss Of Consciousness; Malaise	Depakin			S	Oral			Not Reported	
	Carbolithium			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Frontal			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14683945	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1815810US		20 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
Communication Disorder;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
Gestational Diabetes;	Abilify			S	Oral	10 Mg, Qd		Not Reported	
Maternal Exposure During Pregnancy; Normal Newborn; Personality Disorder; Pregnancy On Contraceptive	Abilify			S	Oral	5 Mg, Qd		Not Reported	
	Lexomil			S	Oral	Half Tab To Three Quarts Tab In The Eve, Qpm		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14789951	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-170607		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Ineffective;	Escitalopram			S	Unknown	15 Mg, Daily		Not Reported	
Electrocardiogram Qt Prolonged;	Pantoprazol			S	Unknown	Unk		Sun	
Hypomagnesaemia; Myocardial Ischaemia; Torsade De Pointes	Haloperidol			S	Unknown	2 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14826911	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-023043		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis;	Escitalopram			S	Oral			Aurobindo	
	Escitalopram			S	Oral	()		Aurobindo	
	Venlafaxine			S	Oral			Aurobindo	

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Overdose; Rhabdomyolysis; Seizure; Suicide Attempt	Venlafaxine	S	Oral	()	Aurobindo
	Buspirone Hydrochloride	S	Oral		Aurobindo
	Buspirone Hydrochloride	S	Oral	()	Aurobindo
	Fluoxetine	S	Oral		Aurobindo
	Fluoxetine	S	Oral	()	Aurobindo
	Hydrochlorothiazide	S	Oral		Aurobindo
	Hydrochlorothiazide	S	Oral	()	Aurobindo
	Amlodipine	S	Oral		Aurobindo
	Amlodipine	S	Oral	()	Aurobindo
	Amphetamine W/Dexamphetamine	S	Oral		Not Reported
	Atorvastatin	S	Oral		Not Reported
	Atorvastatin	S	Oral	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852074	EXPEDITED (15-DAY)		HO	TW-MYLANLABS-2018M1027181		71 YR	Female	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Dyspnoea; Excessive Eye Blinking; Head Titubation; Insomnia; Tremor; Trismus	Quetiapine			S	Unknown	Increased To 100mg/Day		Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown	10-15mg/Day For 6 Months; Increased To 20mg/Day Due To Aggravation		Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852081	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-024339		19 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During	Escitalopram			S	Unknown			Aurobindo

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Pregnancy; Product Use
In Unapproved Indication;
Toxicity To Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14150152	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1762669US		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sepsis; Urticaria	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Temesta (Lorazepam)			S	Oral			Not Reported	
	Topalgic (Tramadol Hydrochloride)			S	Oral			Not Reported	
	Smecta			C	Endocervical	1 Df, Bid		Not Reported	
	Tiorfan			C	Unknown			Not Reported	
	Motilium			C	Unknown			Not Reported	
	Sandostatine			C	Intramuscular			Not Reported	
	Eupantol			C	Unknown			Not Reported	
	Creon			C	Oral			Not Reported	
	Laroxyl			C	Oral			Not Reported	
	Questran			C	Unknown			Not Reported	
	Tardyferon B9 [Ferrous Sulfate;Folic Acid]			C	Unknown			Not Reported	
	Un-Alfa			C	Oral			Not Reported	
	Gaviscon			C	Unknown			Not Reported	
	Lantus			C	Subcutaneous			Not Reported	
	Ornithine Oxoglurate			C	Oral			Not Reported	
	Debridat			C	Unknown			Not Reported	
	Innohep			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14652876	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		67 YR	Female	USA

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2018US-166902

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Microscopic; Rectal Ulcer	Lansoprazole			S	Unknown			Sun
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14858223	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US17054			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Overdose	Escitalopram			S	Unknown	Unk		Invagen
	Sertraline			S	Unknown	Unk		Invagen
	Valproic Acid			S	Unknown	Unk		Not Reported
	Quetiapin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14858511	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.- 2018US17053			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Overdose	Escitalopram			S	Unknown	Unk		Invagen
	Flurazepam			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14860244	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-066519		47 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose; Off Label Use	Clonazepam	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Quetiapine	S	Oral		Not Reported
	Valproic Acid	S	Oral		Not Reported
	Antabus	S	Oral	Strength: 250 Mg 40 Tablets	Not Reported
	Abilify	S	Oral	Strength: 15 Mg 28 Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14860871	EXPEDITED (15-DAY)		DS	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018012994			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pain In Jaw	Escitalopram			S	Oral	5 Milligram		Macleods
	Lansoprazole			C	Unknown	30 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14861213	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20180503239		15 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Extrapyramidal Disorder; Intentional Overdose; Mydriasis; Sinus Tachycardia; Suicide Attempt	Risperidone			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Theralene			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14862138	EXPEDITED (15-DAY)		HO	ES-LANNETT COMPANY, INC.-ES- 2018LAN000670		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate	S	Unknown	15 Mg, Qd	Lannett
	Haloperidol Lactate	S	Unknown	2 Mg, Unk	Lannett

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14949505	DIRECT					73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram 10 Mg Tablet			S	Oral	Quantity:1 Tablet(S);		Lupin	
	Levothyroxine			C				Not Reported	
	Nifedipine			C				Not Reported	
	Calcium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	12544139	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-011570		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clonus; Confusional State; Electrocardiogram Qt Prolonged;	Bromazepam			S	Unknown			Not Reported	
	Escitalopram			S	Oral			Zydus Pharm	
Hypoglycaemia; Intentional Overdose;	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm	
Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Lormetazepam			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14868064	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018- 012951		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine			S	Oral	Unspecified		Not Reported	
	Atarax			S	Oral	Unspecified		Not Reported	
	Zopiclone			S	Oral	Unspecified		Not Reported	

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	Previscan (Fluindione)		S	Oral		Unspecified Tablet Breakable			Not Reported
	Seroplex		S	Oral		Unspecified			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14868576	NON-EXPEDITED			US-MACLEODS PHARMACEUTICALS US LTD- MAC2017006346			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram Oxalate			S	Unknown	5 Mg, Unk		Macleods	
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported	
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported	
	Iron Infusion			C	Unknown	Unk, Infusion As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14869083	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD- MAC2018012995			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Erectile Dysfunction	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited Lithionit			S	Oral	5 Milligram, Qd, (Escitalopram Intensity:10)		Macleods	
				C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14869240	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018013000			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness	Venlafaxine			S	Oral	Unk, (Unspecified)		Macleods	
	Atarax			S	Oral	Unk, (Unspecified)		Not Reported	

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		Zopiclone		S	Oral	Unk (Unspecified)			Not Reported
		Previscan (Fluindione)		S	Oral	Unk, (Unspecified), (Tablet Breakable)			Not Reported
		Seroplex		S	Oral	Unk, (Unspecified)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14869419	EXPEDITED (15-DAY)		HO	SE-MACLEODS PHARMACEUTICALS US LTD- MAC2018013004			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block	Escitalopram Oxalate 5mg Tablet Prescription F 53 = [Aurobindo Pharma Limited Desloratadine			S	Oral	5 Milligram, Qd		Macleods	
				C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14869651	EXPEDITED (15-DAY)		DE	IT-SA-2018SA125273		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Alprazolam			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Zolpidem Tartrate			S	Oral			Not Reported	
	Zolpidem Tartrate			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14870566	NON-EXPEDITED			US-PFIZER INC- 2018190671		26 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Prozac			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Fetzima			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported
	Trintellix			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14870690	EXPEDITED (15-DAY)		HO	AT-PFIZER INC-2018182104		27 YR	Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Mood; Extrapyramidal Disorder; Fluid Retention; Hypotension; Lipoma; Memory Impairment; Off Label Use; Product Prescribing Error; Rash; Schizophrenia; Suicidal Ideation; Visual Impairment	Temesta (Lorazepam)			S		Unk		Pfizer
	Haldol			S		40 Mg, 1x/Day		Not Reported
	Akineton /00079501/			S		20 Mg, Unk		Not Reported
	Ciprallex /01588501/			S		20 Mg, Unk		Not Reported
	Dominal /00018902/			S		1 Mg, Unk		Not Reported
	Zyprexa			S		30 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14871233	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK080988			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Substitution Issue; Suicidal Ideation	Lamotrigine			S				Glaxosmithkline
	Escitalopram			S				Glaxosmithkline

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Lexapro	C	20 Unk, Unk	Not Reported
Nifedipine	C	60 Mg, Unk	Not Reported
Alprazolam	C		Not Reported
Alprazolam	C		Not Reported
Cbd	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14871645	EXPEDITED (15-DAY)		DE	IT-BAUSCH-BL-2018-012897		49 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Cipralex Oral Drops			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported
	Zolpidem Tartrate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	13053480	EXPEDITED (15-DAY)		HO, OT	IT-ROCHE-1869005		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder With Mixed Anxiety And Depressed Mood;	Clonazepam			S	Oral			Not Reported
Anhedonia; Anxiety;	Escitalopram			S	Oral	Total		Not Reported
Depressed Mood; Drug Interaction; Feeling Of Despair; Insomnia;	Venlafaxine			S	Oral	Total		Not Reported
Labelled Drug-Drug Interaction Medication Error; Mood Altered;	Quetiapine			S	Oral	Total		Not Reported
	Alprazolam			S	Oral	Total		Not Reported
	Trazodone Hydrochloride			S	Oral	Total		Not Reported

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Retirement; Suicidal Ideation; Tension; Therapeutic Response Decreased	Trazodone Hydrochloride	S	Unknown			Not Reported
	Valproic Acid	S	Oral	Total		Not Reported
	Valproic Acid	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14329207	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1773536US		42 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Level Decreased;	Escitalopram Oxalate - Bp			S	Oral	Overdose: 40 Mg, Qd		Allergan
Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram Oxalate - Bp			S	Oral	Overdose: 30 Mg, Qd		Allergan
	Olanzapine			C	Unknown	10 Mg, Qd		Not Reported
	Lorazepam			C	Unknown	0.5 Mg		Not Reported
	Pangrol			C	Unknown	2 Ot, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14549524	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1809266US		13 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Overdose; Pancreatitis Acute; Somnolence	Escitalopram Oxalate - Bp			S	Oral	14 Df In Total		Allergan
	Atarax /00058401/			S	Oral	Unknown		Not Reported
	Seresta			S	Oral	15 Df In Total		Not Reported
	Tramadol Biogaran			S	Oral	10 Df, Qd - In Total		Not Reported
	Stresam			S	Oral	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14742650	EXPEDITED (15-DAY)		HO, LT, OT	CZ-BAUSCH-BL-2018-009329			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Electrocardiogram Qt Prolonged;	Venlafaxine			S	Oral			Not Reported
	Metoclopramide			S	Oral			Valeant

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Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal	Ibuprofen	S	Unknown	Not Reported
Hypermotility; Loss Of Consciousness; Poisoning	Clonazepam	S	Oral	Not Reported
	Levopromazine	S	Oral	Not Reported
	Olanzapine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Melperone	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14872926	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-024557			Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Use; Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis; Substance Use	Escitalopram			S	Unknown	Unk		Aurobindo
	Dextromethorphan			S	Unknown	60 Milligram		Not Reported
	Thicodin /01295801/			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol		Not Reported
	Aviomarin			S	Unknown	1 Dosage Form		Not Reported
	Thicodin /01295801/			S	Unknown	1 Dosage Text = Codeine + Sulfogluacol ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873123	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-024720		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Lamotrigine 100mg			S	Unknown	100 Milligram, 3 Day, (1-1-1-0)		Aurobindo
	Mirtazapine 45mg			S	Unknown	45 Milligram, Once A Day,At Night		Aurobindo
	Escitalopram 20 Mg			S	Unknown	20 Milligram, Once A Day, (20mg-0mg-0mg-0mg) In The Morning		Aurobindo
	Mirtazapine 15mg			S	Unknown	15 Milligram, Once A Day,(0-0-1) At Night		Aurobindo

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Milnacipran	S	Oral	200 Milligram, Once A Day	Not Reported
Milnacipran	S	Oral	50 Milligram, Two Times A Day	Not Reported
Levothyroxin	C	Unknown	100 Microgram, Once A Day,(1-0-0-0) In The Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14874402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-024694		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness	Zopiclone			S	Oral	Non Précisée		Not Reported	
	Venlafaxine			S	Oral	Non Précisée		Aurobindo	
	Atarax /00058401/			S	Oral	Non Précisée		Not Reported	
	Previscan /00789001/			S	Oral	Non Précisée		Not Reported	
	Seroplex			S	Oral	Non Précisée		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14874418	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2018-024760		33 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram Tablets			S	Oral	5 Milligram		Aurobindo	
	Lansoprazole			C	Unknown	30 Milligram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14877550	EXPEDITED (15-DAY)		HO	DE-009507513-1805DEU003245		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive	Mirtazapine			S	Unknown	At Night		Merck	
	Mirtazapine			S	Unknown	(0-0-1) At Night		Merck	
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported	

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Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram	S	Unknown	(20mg-0mg-0mg-0mg) In The Morning	Not Reported
	Milnacipran	S	Oral	200 Mg, Qd	Not Reported
	Milnacipran	S	Oral	50 Mg, Qod	Not Reported
	Levothyroxine Sodium	C	Unknown	(1-0-0-0) In The Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	12502088	EXPEDITED (15-DAY)		HO, OT	AU-FRI-1000085500		66 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Orthostatic Hypotension; Poisoning	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Lercanidipine Hcl Unk			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	Unk		Not Reported
	Rosuvastatin			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	12516486	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2016002860			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Overdose; Psychomotor Retardation; Psychomotor Skills Impaired; Suicidal Ideation; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	840 Milligram, (Total)		Macleods
	Escitalopram Oxalate			S				Macleods
	Venlafaxine			S	Oral	7875 Milligram, (Total, Overdose)		Macleods
	Venlafaxine			S				Macleods
	Bromazepam			S	Oral	180 Milligram, (Total, Overdose)		Not Reported
	Bromazepam			S				Not Reported
	Lormetazepam			S	Oral	14 Milligram, (Total, Overdose)		Not Reported

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Lormetazepam			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14480943	EXPEDITED (15-DAY)		HO, OT	NO-ABBVIE-18P-122-2242450-00		21 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Aggression;	Valproate Sodium			S	Oral			Not Reported	
Agitation; Alcohol Abuse;	Valproate Sodium			S	Oral			Not Reported	
Bipolar Disorder;	Cipralext			S	Unknown			Not Reported	
Depression; Derealisation;	Efexor			S	Unknown	Extended Release Capsule		Not Reported	
Disturbance In Attention;	Efexor			S	Unknown	Extended Release Capsule		Not Reported	
Disturbance In Social Behaviour; Dizziness;	Efexor			S	Unknown	Extended Release Capsule		Not Reported	
Drug Abuse; Drug Abuse;	Efexor			S	Unknown	Extended Release Capsule		Not Reported	
Drug Ineffective;	Efexor			S	Unknown	Extended Release Capsule		Not Reported	
Hypomania; Impaired Work Ability; Irritability;	Lamictal			S	Unknown			Not Reported	
Judgement Impaired;	Lamictal			S	Unknown			Not Reported	
Logorrhoea; Malaise;	Seroquel			S	Oral	Film Coated Tablet		Not Reported	
Mania; Mania; Memory Impairment; Personality Disorder; Quality Of Life	Seroquel			S	Oral	Film Coated Tablet		Not Reported	
Decreased; Restlessness	Seroxat			S	Unknown			Not Reported	
	Seroxat			S	Unknown			Not Reported	
	Zyprexa			S	Unknown			Not Reported	
	Cipramil [Citalopram Hydrochloride]			S	Unknown			Not Reported	
	Cipramil			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Orfiril			S	Unknown			Not Reported	
	Lithionit			C				Not Reported	
	Sobril			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14760818	EXPEDITED (15-DAY)		HO	US-JNJFOC-20180402091		88 YR	Male	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial Fibrillation; Biliary Sepsis; Blood Loss Anaemia; Cardiac Failure	Imbruvica			S	Oral			Not Reported
Congestive; Cholecystitis	Imbruvica			S	Oral			Not Reported
Acute; Electrocardiogram	Imbruvica			S	Oral			Not Reported
Qt Prolonged; Escherichia Bacteraemia; Haemobilia; Hypocalcaemia;	Remeron			S				Not Reported
International Normalised Ratio Increased; Lactic Acidosis; Myocardial Ischaemia; Pancytopenia; Pleural Effusion; Pneumonia; Supraventricular Extrasystoles; Thrombocytopenia	Lexapro			S				Not Reported
	Plavix			S	Unknown			Not Reported
	Pacerone			C		1 Tablet Twice Daily Until 3/31, Then Transition To 1 Tablet Once Daily		Not Reported
	Cefdinir			C		1 Capsule (300 Mg Total) By Mouth 2 Times A Day At 6:00 Am And 4:00 Pm For 10 Days		Not Reported
	Flagyl			C	Oral	1 Tablet (500 Mg Total) By Mouth 3 (Three) Times A Day For 8 Days		Not Reported
	Roxicodone			C	Oral			Not Reported
	Zanaflex			C	Oral	1 Tablet (2 Mg Total) By Mouth Every 8 (Eight) Hours As Needed		Not Reported
	Prednisone			C	Oral	1 Tablet (10 Mg Total) By Mouth Daily For 7 Days		Not Reported
	Prednisone			C	Oral	1 Tablet (10 Mg Total) By Mouth Daily For 7 Days		Not Reported
	Zyloprim			C	Oral	300 Mg, Daily With Breakfast		Not Reported
	Folvite			C	Oral			Not Reported
	Synthroid			C	Oral	150 Mcg, Daily At 6:00 Am		Not Reported
	Levothroid			C	Oral	150 Mcg, Daily At 6:00 Am		Not Reported
	Prilosec			C	Oral			Not Reported
	Zocor			C	Oral			Not Reported
	Zofran			C				Not Reported
	Kenalog			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14768046	EXPEDITED (15-DAY)		HO, LT, OT	ES-LUPIN PHARMACEUTICALS INC.-2018-02905		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Myocardial Ischaemia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Qd		Lupin	
	Escitalopram			S				Lupin	
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported	
	Haloperidol			S				Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14878935	EXPEDITED (15-DAY)		DS	GB-CIPLA LTD.- 2018GB17520			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram			S	Oral	5 Mg, Unk		Invagen	
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14880325	EXPEDITED (15-DAY)		HO	TW-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-172540		71 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Disorder; Drug Ineffective; Dyskinesia	Quetiapine			S	Unknown	50 Mg, Daily		Sun	
	Quetiapine			S	Unknown	100 Mg, Daily		Sun	
	Quetiapine			S	Unknown	Tapped Off		Sun	
	Quetiapine			S	Unknown	50 Mg, Daily		Sun	
	Venlafaxine			S	Unknown	Up To 150 Mg/D For 4 Weeks		Sun	
	Mirtazapine			S	Unknown	Up To 45 Mg/D For 4 Weeks		Sun	

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Risperidone	S	Unknown	Up To 1 Mg/Day For 1 Week	Ranbaxy
Escitalopram	S	Unknown	10 To 15 Mg/D For 6 Months	Not Reported
Escitalopram	S	Unknown	20 Mg, Daily	Not Reported
Escitalopram	S	Unknown	10 Mg, Daily	Not Reported
Sertraline	S	Unknown	Up To 80 Mg/D For 3 Weeks	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14880371	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018187392		95 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Faecal Vomiting; Faecaloma	Lyrca			S	Oral	50 Mg, 1x/Day		Pfizer
	Antarene Codeine			S	Oral	3 Df, 1x/Day, [Codeine Phosphate Hemihydrate 400 Mg]/[Ibuprofen 60 Mg]		Not Reported
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14880929	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-025149		15 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	36 Milligram		Aurobindo
	Escitalopram			S	Oral	9 Milligram		Aurobindo
	Theralene			C	Oral	Posologie Non Précisée		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14882860	EXPEDITED (15-DAY)		HO	PH-ALLERGAN-1824843US			Male	PHL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Amoebiasis; Ill-Defined Disorder; Pyrexia; Urinary Tract Infection	Lexapro	S	Unknown	Unk	Allergan
	Lexapro	S			Allergan
	Abilify	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14882881	EXPEDITED (15-DAY)		HO	ES-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00175		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, 1x/Day		Jubilant
	Haloperidol			S	Unknown	2 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14884296	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN00232		90 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Abnormal Dreams; Fall; Feeling Abnormal; Hallucination; Head Injury; Hip Arthroplasty; Humerus Fracture; Illusion; Lower Limb Fracture; Pain; Somnolence; Upper Limb Fracture	Escitalopram			S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical
	Escitalopram			S				Prinston Pharmaceutical
	Hydrocodone Bitartrate And Acetaminophen			S		Unk		Mikart
	Hydrocodone Bitartrate And Acetaminophen			S		0.5 Tablets, Unk		Mikart
	Tramadol			S		Unk		Not Reported
	Carvedilol			C				Not Reported
	Benicar			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14884297	EXPEDITED (15-DAY)		HO	ES-PRINSTON PHARMACEUTICAL INC.-2018PRN00235		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Myocardial Ischaemia; Torsade De Pointes	Escitalopram	S	Unknown	15 Mg, 1x/Day	Princeton Pharmaceutical Not Reported
	Haloperidol	S	Unknown	2 Mg, 1x/Day	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14885044	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-013562		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Partial Responder	Venlafaxine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown	After A Month, Dose Was Doubled		Not Reported
	Clonazepam			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Valproic Acid			S	Unknown	After A Month, Dose Was Doubled		Not Reported
	Quetiapine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14965024	DIRECT	Y	OT			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Loss Of Consciousness	Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14968161	DIRECT	Y	HO			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Dizziness; Dysarthria; Headache; Hypoaesthesia; Muscular Weakness; Nausea; Vomiting	Escitalopram	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	13857722	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-056794		24 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Eosinophilia; Myocarditis; Pericardial Effusion; Pleural Effusion	Clozapine			S				Accord
	Paliperidone/Paliperidone			S				Not Reported
	Palmitate							
	Benzatropine			S				Not Reported
	Valproic Acid			S				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14318162	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1772788US		41 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Dependence; Palpitations; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	5 Or 10 Mg		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14704307	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018011964			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Prescribed Underdose	Tramadol Hydrochloride			S	Oral	Unk		Macleods
	Decapeptyl (Triptorelin)			S	Intramuscular	1 Df, 1 Cycle		Not Reported
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported
	Amlor			S	Oral	Unk		Not Reported

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	Novonorm	S	Oral	Unk	Not Reported
	Esomeprazole	S	Oral	Unk	Not Reported
	Xtandi	S	Oral	120 Mg, Qd	Not Reported
	Xtandi	S	Oral	40 Milligram, Qd	Not Reported
	Lipanthyl	S	Oral	145 Mg, Qd	Not Reported
	Seroplex	S	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14764354	EXPEDITED (15-DAY)		HO, LT, OT	TR-ALLERGAN-1702558US		24 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Drug Abuse; Hypernatraemia; Hypocalcaemia; Intentional Overdose; Leukopenia; Loss Of Consciousness; Respiratory Depression; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Fluoxetine Hcl Unk			S	Oral	Unk		Allergan	
	Olanzapine			S	Oral	Unk		Not Reported	
	Valproic Acid			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14890887	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1825422US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Drug Ineffective; Product Dose Omission	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Citalopram			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14890922	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1825591US		44 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cognitive Disorder; Fatigue; Loss Of Personal Independence In Daily Activities; Muscle Spasms; Pain	Escitalopram Oxalate - Bp	S	Unknown		Allergan
	Diazepam	S	Unknown	Unk	Not Reported
	Gilenya	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Vitamin B Complex	S	Unknown	Unk	Not Reported
	Vitamin D2	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14891590	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1823903US		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gait Disturbance; Muscle Rigidity; Parkinson'S Disease; Tremor	Lexapro			S	Oral	15 Mg, Bid		Allergan
	Lexapro			S				Allergan
	Metformin			C	Unknown	Unk Unk, Unknown		Not Reported
	Glimepiride			C	Oral	2 Mg, Unknown		Not Reported
	Atenolol			C	Unknown	Unk Unk, Unknown		Not Reported
	Valsartan			C	Unknown	Unk Unk, Unknown		Not Reported
	Insulin			C	Unknown	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14895311	EXPEDITED (15-DAY)		HO	ES-ACCORD-066934		81 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram			S	Oral	Strength: 10 Mg 28 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14895474	EXPEDITED (15-DAY)		HO	FR- ELI_LILLY_AND_COMP ANY-FR201805003766		48 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Epilepsy	Zyprexa 10mg	S	Oral	1 Df, Daily	Not Reported
	Seroplex	S	Oral	1 Df, Daily	Not Reported
	Noctamide	S	Oral	2 Df, Daily	Not Reported
	Xanax	S	Oral	3 Df, Daily	Not Reported
	Tercian /00759302/	S	Oral	100 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14895998	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1825577US		82 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebellar Syndrome; Cognitive Disorder; Fall	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Revlimid			S	Oral	21 Days On 28		Not Reported
	Dexamethasone			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	0.5 Gbq, Unk		Not Reported
	Imovane			C	Oral			Not Reported
	Spironolactone			C	Oral	Unk		Not Reported
	Lasilix			C	Oral	Unk		Not Reported
	Kardegic			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14897694	EXPEDITED (15-DAY)	OT		JP-ALLERGAN-1824758US		50 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk, Single		Allergan

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16-May-2018	14701084	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180341436		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis	Tramadol Hydrochloride			S	Oral			Not Reported	
	Decapeptyl [Gonadorelin]			S	Intramuscular			Not Reported	
	Innohep			S	Subcutaneous			Not Reported	
	Amlor			S	Oral			Not Reported	
	Novonorm			S	Oral			Not Reported	
	Esomeprazole			S	Unknown			Not Reported	
	Xtandi			S	Oral			Not Reported	
	Lipanthyl			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14741381	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2018TUS007841		20 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depression; Suicidal Ideation	Trintellix			S	Oral	5 Mg, Qd		Takeda	
	Trintellix			S	Oral	10 Mg, Qd		Takeda	
	Cipralext /01588501/			S	Unknown	20 Mg, Qd		Not Reported	
	Cipralext /01588501/			S	Unknown	15 Mg, Qd		Not Reported	
	Cipralext /01588501/			S	Unknown	10 Mg, Qd		Not Reported	
	Cipralext /01588501/			S	Unknown	5 Mg, Qd		Not Reported	
	Abilify			C	Unknown	2 Mg, Qd		Not Reported	
	Abilify			C	Unknown	1 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14854785	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1824648US		65 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Dizziness; Dyspnoea; Haematochezia; Pain	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd (1-0-0-0)		Allergan
	Acetylsalicylsaeure			S	Unknown	100 Mg, Qd (1-0-0-0)		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd (0-0-1-0)		Not Reported
	Ramipril			C	Unknown	2.5 Mg, Qd (0-1-0-0)		Not Reported
	Spiriva			C	Unknown	18 Mg, Qd (1-0-0-0)		Not Reported
	Pantoprazol			C	Unknown	40 Mg, Qd (0-0-1-0)		Not Reported
	Euthyrox			C	Unknown	50 Mg, Qd (1-0-0-0)		Not Reported
	Allopurinol			C	Unknown	50 Mg, Qd (0-0-0.5-0)		Not Reported
	Metamizole			C	Unknown	15 Gtt, Tid (1-1-1-0)		Not Reported
	Metoprolol			C	Unknown	47.5 Mg, Bid (1-0-1-0)		Not Reported
	Alna			C	Unknown	4 Mg, Qd (0-0-1-0)		Not Reported
	Torasemid			C	Unknown	10 Mg, Qd (0-1-0-0)		Not Reported
	Tramal Long			C	Unknown	Unk, Mg, Prn		Not Reported
	Symbicort			C	Unknown	Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14854786	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1824640US		77 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Eferox			C	Unknown	50 Mg, Qam		Not Reported
	Hct			C	Unknown	12.5 Mg, Qam		Not Reported
	Metoprolol			C	Unknown	4.75 Mg, Qam		Not Reported
	Ventolair			C	Unknown	250 Mg, Qid		Not Reported
	Metamizole			C	Unknown	500 Mg, Tid		Not Reported
	Valsartan			C	Unknown	120 Mg, Unk		Not Reported
	Ass 100			C	Unknown	100 Mg, Unk		Not Reported

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	Simvastatin		C	Unknown	40 Mg, Qhs			Not Reported	
	Pantoprazol		C	Unknown	20 Mg, Qam			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14899361	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-893244		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper; Diarrhoea	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14899388	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-02400		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Guilty; Self Esteem Decreased; Suicidal Ideation; Therapy Partial Responder	Olanzapine			S	Unknown	15 Mg, Qd		Alkem	
	Risperidone			S	Unknown	Unk		Not Reported	
	Quetiapine Fumarate			S	Unknown	Unk		Alkem	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	Unk		Not Reported	
	Bupropion			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14900053	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018013305			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Unknown		Macleods	
	Aspirin			C	Unknown	Unknown		Not Reported	

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16-May-2018	14901831	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1825871US			Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Feeling Abnormal; Head Titubation; Laziness; Miosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Dextromethorphan			S	Unknown	60 Mg, Unk		Not Reported	
	Thiocolodin (Buflomedil Hydrochloride)			S	Unknown	16 Df, Unk		Not Reported	
	Aviomarin			S	Unknown	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14901835	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1825864US		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Drug Abuse	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Atarax			S	Oral	Unk		Not Reported	
	Zopiclone			S	Oral	Unk		Not Reported	
	Previscan (Pentoxifylline)			S	Oral	Unk		Not Reported	
	Venlafaxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14903710	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1031954		33 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Venlafaxine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Tranxene			S	Oral	40 Mg, Qd		Mylan	
	Bromazepam			C	Oral	12 Mg, Qd		Mylan	
	Debridat /00465201/			C	Oral	2 Df, Qd		Mylan	
	Loxapac /00401801/			C	Oral	20 Mg, Qd		Mylan	

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16-May-2018	14979938	DIRECT		DE			24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Emotional Disorder; Impaired Self-Care; Speech Disorder; Therapy Change; Weight Decreased	Escitalopram			S	Oral	Quantity:1 Df Dosage Form;		Not Reported	
	Escitalopram			S	Oral	Quantity:0.5 Df Dosage Form;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14874033	EXPEDITED (15-DAY)		OT	AU-APOTEX-2018AP012727			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysstasia; Insomnia; Loss Of Personal Independence In Daily Activities; Restlessness	Apo-Escitalopram			S	Oral	0.5 Df, Daily		Apotex	
	Apo-Escitalopram			S	Oral	1 Df, Daily		Apotex	
	Sotalol			C	Unknown	Unk		Not Reported	
	Sotalol			C				Not Reported	
	Amlol /00972402/			C	Unknown	Unk		Not Reported	
	Amlol /00972402/			C				Not Reported	
	Irbesartan			C	Unknown	Unk		Not Reported	
	Irbesartan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14907199	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-173019		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	36 Mg, In Total		Ranbaxy	
	Escitalopram			S	Oral	9 Mg, In Total		Not Reported	
	Theralene			C	Oral	Posologie Non Precisee ()		Not Reported	

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17-May-2018	14910464	EXPEDITED (15-DAY)		DS	GB-ALLERGAN-1826167US		33 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Lansoprazole			C	Unknown	30 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14910785	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1825626US		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	(20mg-0mg-0mg-0mg) In The Morning		Allergan	
	Milnacipran Unk			S	Oral	200 Mg, Qd		Allergan	
	Milnacipran Unk			S	Oral	50 Mg, Bid		Allergan	
	Lamotrigine			S	Unknown	100 Mg, Tid (1-1-1-0)		Not Reported	
	Mirtazapine			S	Unknown	45 Mg, Qhs (At Night)		Not Reported	
	Mirtazapine			S	Unknown	15 Mg, Qhs (At Night) (0-0-1)		Not Reported	
	Levothyroxine			C	Unknown	100 Mg (1-0-0-0) In The Morning		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14169981	EXPEDITED (15-DAY)		OT	FR-TEVA-822279ROM		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax	
	Bisoprolol			S	Unknown			Teva	

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18-May-2018	14202702	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-061174		88 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Heteroplasia; Syncope; Vomiting	Escitalopram			S	Oral			Accord	
	Ceftriaxone			C				Not Reported	
	Furosemide			C				Not Reported	
	Pentoxifylline			C				Not Reported	
	Insulin Human/Insulin Human			C				Not Reported	
	Biosynthetic/Insulin Human								
	Injection/Isoph/Insulin Human								
	Zinc Suspension								
	Ramipril			C				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Dutasteride			C				Not Reported	

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18-May-2018	14455260	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1804425US		41 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Maternal Exposure During Pregnancy; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Seretide			S	Unknown	Unk		Not Reported	
	Vilanterol Trifenatate			S	Unknown	Unk, Qd		Not Reported	
	Flixotide			S	Unknown	250 Mg, Bid		Not Reported	
	Ventolin			S	Unknown	100 Mg, Unk		Not Reported	
	Xanthium (Theophylline)			S	Unknown	20 Mg, Qd		Not Reported	
	Pantomed (Dexpanthenol)			S	Unknown	20 Mg, Qd		Not Reported	
	Xyzall			S	Unknown	5 Mg, Qd		Not Reported	
	Fluticasone Furoate			S	Unknown	Unk Unk, Qd		Not Reported	
	Avamys			S	Unknown	Unk, Bid		Not Reported	
	D-Cure			S	Unknown	25 Iu, Unk		Not Reported	
	Mepolizumab			S	Subcutaneous	100 Mg, Unk		Not Reported	

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18-May-2018	14911125	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-173058		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Venlafaxine			S	Oral	300 Mg, Daily		Sun	
	Alprazolam			S	Oral	1.5 Mg, Daily		Sun	
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported	
	Quetiapine			S	Oral	200 Mg, Daily		Not Reported	
	Clonazepam			S	Oral	0.5 Mg, Daily		Not Reported	
	Valproic Acid			S	Oral	300 Mg, Daily		Not Reported	
	Trazodone			S	Oral	75 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14912263	EXPEDITED (15-DAY)		DE, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM- 2010-00003		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Chloride Increased; Blood Creatinine Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Increased; C-Reactive Protein Increased; Cardio- Respiratory Arrest; Concomitant Disease Aggravated; Condition Aggravated; Hyperhidrosis; Monocyte	Quetiapine Fumarate			S	Oral	200 Mg, Od		Alkem	
	Lorazepam			S	Oral	6 Mg, Od		Not Reported	
	Abilify 3mg			S	Oral	20 Mg, Unk		Not Reported	
	Abilify 3mg			S	Oral	15 Mg, Unknown		Not Reported	
	Cipraxel			S	Oral	10 Mg, Unk		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Seroquel			S	Oral	200 Mg, Unk		Not Reported	
	Tavor (Lorazepam)			S	Oral	6 Mg, Unk		Not Reported	
	Tavor (Lorazepam)			S	Oral	2 Mg, Unk		Not Reported	
	Simeticone			C	Unknown	Unk		Not Reported	

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Percentage Increased; Neutrophil Percentage Increased; Restlessness; Schizoaffective Disorder	Movicol	C	Unknown	Unk		Not Reported
	Eferox	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14912582	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2018-025892		55 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Unk		Aurobindo	
	Acetylsalicylsaeure			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14913226	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2018-03687		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Gait Disturbance; Hallucination; Somnolence	Valproinsaeure			S	Oral	500 Mg, Qd		Not Reported	
	Quetiapine			S	Oral	100 Mg, Qd		Lupin	
	Quetiapine			S	Unknown	300 Mg, Unk		Lupin	
	Cipralext /01588501/			S	Oral	10 Mg, Qd		Not Reported	
	Levothyroxin			C	Oral	75 Mcg, Qd		Not Reported	
	Torasemid			C	Oral	10 Mg, Qd		Not Reported	
	Felodipine			C	Oral	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14914536	NON-EXPEDITED		OT	US-JAZZ-2018-US- 003980			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Fatigue; Somnolence	Xyrem			S	Oral	3 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Abilify			S				Not Reported	

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	Abilify	S				Not Reported
	Lexapro	S				Not Reported
	Lexapro	S				Not Reported
	Ciprofloxacin	S				Not Reported
	Morniflumate	S				Not Reported
	Hydrocodone Bitartrate And Acetaminophen	C		Unk		Not Reported
	Nuvigil	C		Unk		Not Reported
	Citalopram Hbr	C		Unk		Not Reported
	Citalopram	C				Not Reported
	Ibuprofen	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14914597	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2018SE62193		79 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1		Not Reported
	Quetiapine			S	Oral	Patient Took 300mg Instead Of 100mg.		Not Reported
	Cipralext			S	Oral	10 Mg, 1-0-0-0		Not Reported
	Valproic Acid			S	Oral	500 Mg, 0-0-0-1		Not Reported
	Levothyroxine			C	Oral	1-0-0-0		Not Reported
	Torsemide			C	Oral	1-0-0-0		Not Reported
	Felodipine			C	Oral	10 Mg, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14915069	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1825712US		84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chorea; Dementia; Serotonin Syndrome	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan
	Jakafi			S	Unknown	20 Mg, Bid		Not Reported
	Atorvastatin			C	Unknown	Unk Unk, Unknown		Not Reported
	Prolia			C	Unknown	Unk Unk, Unknown		Not Reported

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Levothyroxine	C	Unknown	Unk Unk, Unknown	Not Reported
Ranitidine	C	Unknown	Unk Unk, Unknown	Not Reported
Xarelto	C	Unknown	Unk Unk, Unknown	Not Reported
Tolterodine	C	Unknown	Unk Unk, Unknown	Not Reported
Clonazepam	C	Unknown	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14984970	DIRECT		OT			70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Change; Vision Blurred; Visual Impairment	Escitalopram 10mg			S	Oral	At Bedtime		Lupin	
	L-Thyroxine			C				Not Reported	
	Olmesartan			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14987798	DIRECT					37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Memory Impairment; Paraesthesia; Sleep Deficit; Somnolence; Visual Impairment	Escitalopram (Generic)			S	Oral	Quantity:1 Tablet(S);	3 YR	Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2018	14321027	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2017DE00434			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea;	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported	
Depression;	Valdoxan			S	Unknown	25 Mg, Qd		Not Reported	
Dysmenorrhoea;	Zoely			S	Oral	One Tablet A Day (One Df		Not Reported	
Hypomenorrhoea;						Contains 2.5mg			
Menorrhagia									

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Nomegestrel And 1.5mg
Estradiol)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2018	14916438	NON-EXPEDITED			US-JNJFOC-20180434118		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Tachypnea	Ibuprofen		Y	S	Oral			Not Reported	
	Ibuprofen			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2018	14916510	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-026262		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine Film-Coated Tablet			S	Oral	100 Milligram, 0-0-0-1		Aurobindo	
	Valproic Acid			S	Oral	500 Milligram, Once A Day		Not Reported	
	Ciprallex /01588501/			S	Oral	10 Milligram, Once A Day		Not Reported	
	Levothyroxine			C	Oral	75 Microgram, Once A Day		Not Reported	
	Torasemid			C	Oral	10 Milligram, Once A Day		Not Reported	
	Felodipine			C	Oral	10 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2018	14989304	DIRECT		OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Headache; Hypersensitivity; Neck Pain; Pharyngeal Swelling; Product Quality Issue;	Escitalopram			S	Oral	Quantity:5 MI;		Amneal	
	Vitamin D Nos			C				Not Reported	
	Vitamin B12			C				Not Reported	

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Product Substitution Issue; Iron C Not Reported
Product Taste Abnormal;
Pruritus; Throat Irritation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14707245	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-169091		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Prescribed Underdose	Esomeprazole			S	Oral	()		Sun
	Decapeptyl (Triptorelin)			S	Intramuscular	Cyclical		Not Reported
	Innohep			S	Subcutaneous	1 Df, Unk		Not Reported
	Amlor			S	Oral	()		Not Reported
	Novonorm			S	Oral	()		Not Reported
	Tramadol Base			S	Oral	()		Not Reported
	Xtandi			S	Oral	120 Mg, Unk		Not Reported
	Lipanthyl			S	Oral	145 Mg, Unk		Not Reported
	Seroplex			S	Oral	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14790115	EXPEDITED (15-DAY)		LT	JP-ALLERGAN- 1822180US		77 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased; Nausea; Neurogenic Bladder; Septic Shock; Urinary Retention; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Risperidone			S	Oral	0.5 Mg, Unk		Not Reported
	Risperidone			S	Oral	1 Mg, Unk		Not Reported
	Donepezil Hydrochloride			C	Oral	Unk		Not Reported
	Mosapride Citrate			C	Unknown	Unk		Not Reported
	Magnesium Oxide			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown			Not Reported

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Sodium Risedronate Hydrate	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Januvia	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Lansoprazole	C	Unknown	Unk	Not Reported
Epalrestat	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14917148	EXPEDITED (15-DAY)		HO, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-167153		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Depressed Level Of Consciousness;	Escitalopram			S	Oral	Unk		Not Reported	
Electrocardiogram Qt	Topiramate			S	Oral	Unk		Sun	
Prolonged; Irritability;	Citalopram			S	Oral	Unk		Sun	
Miosis; Overdose; Oxygen	Oxazepam			S	Oral	Unk		Sun	
Saturation Decreased;	Quetiapine			S	Oral	Unk		Sun	
Sinus Tachycardia;	Temazepam			S	Oral	Unk		Mutual	
Somnolence									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14918871	EXPEDITED (15-DAY)		OT	SE-ALLERGAN- 1826718US		27 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Erectile	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
Dysfunction	Lithonit			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14919266	EXPEDITED (15-DAY)		HO	DE-PFIZER INC- 2018205793		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Pain Upper; Dyspepsia	Ibuprofen	S		Unk	Pfizer
	Escitalopram Oxalate	S		20 Mg, 1x/Day (20 Mg, 1-0-0)	Not Reported
	Bornaprine	S		10 Mg, Daily (4 Mg, 1-0.5-1-0)	Not Reported
	Neupro	S	Transdermal	14 Mg, 1x/Day (14 Mg, 1-0-0-0)	Not Reported
	Madopar Depot	C		1 Df, 1x/Day (100 25 Mg, 0-0-0-1)	Not Reported
	Madopar	C		100 25 Mg, 1.5-1.5-1.5-1.5	Not Reported
	Amantadine Hcl	C		100 Mg, 2x/Day (100 Mg, 1-1-0-0)	Not Reported
	Amitriptylin	C		75 Mg, 1x/Day (75 Mg, 0-0-0-1)	Not Reported
	Madopar Lt	C		100 25 Mg, 1-0-0-0	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14920663	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018203360		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Drug Interaction; Dyspnoea; Pulmonary Embolism; Weight Fluctuation	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg, 2 In 1 D)		Pfizer
	Cymbalta			S		Unk (2 Weeks)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day (20 Mg, 1 In 1 D)		Not Reported
	Methotrexate			S	Oral	9 Df, Weekly (1 In1 Wk)(On Saturday)		Not Reported
	Methotrexate			S	Oral	Unk, Weekly (1 In 1 Wk)		Not Reported
	Progesterone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remeron			S	Oral	15 Mg, 1x/Day (Before		Not Reported

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Atorvastatin	C	Oral	Bed (15 Mg, 1 In 1 D)) 20 Mg, 1x/Day (At Bed Time And Taking For Atleast 6 Months (20 Mg, 1 In 1 D))	Not Reported
Cardiazem	C	Oral	240 Mg, 1x/Day (Taking For At Least 6 Months (240 Mg,1 In 1 D))	Not Reported
Cardiazem	C			Not Reported
Carvedilol	C	Oral	6.25 Mg, 2x/Day (6.25 Mg, 2 In 1 D)	Not Reported
Cozaar	C	Oral	25 Mg, 1x/Day (25 Mg,1 In 1 D)	Not Reported
Potassium	C	Oral	Unk Unk, 2x/Day (2 In 1 D)	Not Reported
Potassium	C	Oral	10 Meq, 1x/Day (10 Milliequivalents,1 In 1 D)	Not Reported
Pantoprazole	C	Oral	40 Mg, 1x/Day (40 Mg,1 In 1 D)	Not Reported
Folic Acid	C	Oral	1 Mg, Unk (1 Mg, 6 In 1 Wk)	Not Reported
Aldactone	C	Oral	2 Df, 1x/Day (2 Dosage Forms, 1 In 1 D)	Not Reported
Hydrocodone Bitartrate And Acetaminophen	C	Oral	1 Df, Unk (Hydrocodone Bitartrate:10 Mg/Acetaminophen:325 Mg One Tablet By Mouth Two To Three Times)	Not Reported
Tramadol	C		Unk, As Needed (As Required)	Not Reported
Bumex	C	Oral	2 Mg, 1x/Day (2 Mg,1 In 1 D)	Not Reported
Gabapentin	C		400 Mg, 3x/Day (400 Mg,3 In 1 D)	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14426581	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1004745		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Escitalopram			S	Oral	Unk		Not Reported	
	Pantoprazole			S	Oral	Unk		Not Reported	
	Lipanthyl			S	Oral	Unk		Mylan	
	Fondaparinux Sodium			S	Subcutaneous	Unk		Mylan	
	Xeloda			S	Oral	Unk		Mylan	
	Primperan			S	Oral	Unk		Mylan	
	Abasaglar			S	Subcutaneous	Unk		Mylan	
	Movicol			S	Oral	Unk		Mylan	
	Novorapid			S	Subcutaneous	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14432694	EXPEDITED (15-DAY)		HO, OT	FR-ABBVIE-18S-056-2233700-00		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Lipanthyl			S	Oral	Unknown		Not Reported	
	Fondaparinux Sodium			S	Subcutaneous	Unknown		Not Reported	
	Xeloda			S	Oral	Unknown		Not Reported	
	Primperan			S	Oral	Unknown		Not Reported	
	Abasaglar			S	Subcutaneous	Unknown		Not Reported	
	Movicol			S	Oral	Unknown		Not Reported	
	Novorapid			S	Subcutaneous	Unknown		Not Reported	
	Escitalopram			S	Oral	Unknown		Not Reported	
	Pantoprazole			S	Oral	Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14921476	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-01201		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Clopidogrel			S	Unknown	Unk		Not Reported	
	Gabapentin			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Not Reported	
	Escitalopram Beta			S	Oral	10 Mg, Qd		Not Reported	
	Olmesartan			S	Unknown	Unk		Lupin	
	Metformin			S	Unknown	Unk		Not Reported	
	Insulin			S	Unknown	Unk		Not Reported	
	Ass			S	Unknown	Unk		Not Reported	
	Molsidomin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14921515	EXPEDITED (15-DAY)		LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018013501			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Milligram		Macleods	
	Teralithe Lp 400 Mg			S	Oral	2 Dosage Form, Breakable Sustained Release Tablet		Not Reported	
	Seroplex 5 Mg			S	Oral	1 Dosage Form Of Coated Tablet.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14921742	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018013496			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram	S	Transplacental	10 Milligram, Qd, 1 {Trimester}, 7.5. - 11.6. Gestational Week	Macleods
	Quetiapine	C	Transplacental	25 Milligram, Qd, 2 {Trimester}, 14. - 38.1. Gestational Week	Macleods
	Sertraline	C	Transplacental	150 Milligram, Qd, 2 {Trimester}, 14. - 38.1. Gestational Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14921743	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018013497			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram, Qd, (0. - 28.6. Gestational Week) 1 Trimester		Macleods
	Femibion Pregnancy 1 (Nem)			C	Transplacental	0.8 Milligram, Qd, (0. - 40.5. Gestational Week), 1 Trimester		Not Reported
	Influenza Vaccine			C	Transplacental	Unk		Not Reported
	L-Thyroxin			C	Transplacental	Unk, 100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2 (0. - 40.5. Gestational		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14922753	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP014055		89 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage; Platelet Aggregation Inhibition	Escitalopram			S	Unknown	Unk		Apotex	
	Rivaroxaban			S	Unknown	15 Mg, Daily		Not Reported	

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Rivaroxaban	S				Not Reported
Heparin	S	Subcutaneous	5000 U, Every 12 Hours		Not Reported
Lidocaine	C	Unknown	3 MI, Unk		Not Reported
Epinephrine	C	Unknown	5 Microgram/ MI Unk, Unk		Not Reported
Bupivacaine	C	Unknown	1 Mg/MI, Unk		Not Reported
Hydromorphone	C	Unknown	10 Microgram/ MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14923427	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1826903US		45 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Desloratadine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14923747	NON-EXPEDITED			US-TEVA-2018-US-895053			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	10076441	EXPEDITED (15-DAY)		HO, OT	CA-FRI-1000059589		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Asenapine Maleate - Bp			S	Oral	1.25 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unknown		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14908509	NON-EXPEDITED			US-PFIZER INC-2018198368		38 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Lyrica			S		25 Mg, 3x/Day		Pfizer
Cyclic Vomiting	Lyrica			S		50 Mg, 3x/Day		Pfizer
Syndrome; Diarrhoea;	Lyrica			S		50 Mg, Unk		Pfizer
Fatigue; Hypersomnia;	Lyrica			S		25 Mg, 3x/Day		Pfizer
Hypotension; Intentional	Lyrica			S		75 Mg, Daily (25mg Twice		Pfizer
Product Use Issue;	Lyrica			S		A Day And 50mg At Night)		Pfizer
Nausea; Pain; Product	Lyrica			S		50 Mg, 3x/Day		Pfizer
Dispensing Error; Product	Lyrica			S		50 Mg, 2x/Day		Pfizer
Dose Omission; Retching	Bisoprolol			C	Oral	10 Mg, 1x/Day, (Started		Not Reported
	Pantoprazole			C	Oral	40 Mg, 1x/Day, (Started		Not Reported
	Vitamin D2			C	Oral	2000 Iu, 1x/Day, (Started		Not Reported
	Metoclopramide			C	Oral	10 Mg, 2x/Day, (Started		Not Reported
	Otezla			C	Oral	30 Mg, 2x/Day, (Started		Not Reported
	Otezla			C				Not Reported
	Naltrexone			C	Oral	4.5 Mg, 1x/Day, (Started		Not Reported
	Naltrexone			C				Not Reported
	Escitalopram			C	Oral	5 Mg, 1x/Day		Not Reported
	Mirtazapine			C	Oral	15 Mg, 1x/Day		Not Reported
	Mirtazapine			C				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14910375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2018200670		89 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Hypotension; Hypovolaemia; Paralysis; Spinal Cord Compression; Spinal Cord Oedema	Heparin Sodium			S	Subcutaneous	5000 Iu, 2x/Day		Unknown	
	Escitalopram			S		Unk		Not Reported	
	Lidocaine			C		3 MI, Unk (A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI)		Not Reported	
	Hydromorphone			C		10 Ug/MI, Unk (10 ?G/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion)		Not Reported	
	Epinephrine			C		5 Ug/MI, Unk (Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI)		Not Reported	
	Bupivacaine			C		1 Mg/MI, Unk (Infusion)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14922125	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-03069		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Toxicity To Various Agents	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Lamotrigine			S	Unknown	100 Mg, Unk		Alkem	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14926717	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR- 895188		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Tramadol (Chlorhydrate De)			S	Oral			Teva	
	Seroplex			S	Oral			Not Reported	
	Bilaska			S	Oral			Not Reported	

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Seresta	S	Oral	Not Reported
Nocertone	S	Oral	Not Reported
Simponi 50 Mg, Solution Injectable En Seringue Préremplie	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927080	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004412		53 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Espran			S	Oral	Unknown		Torrent

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927096	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018013572			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Milligram, Qd		Macleods
	Indapamide			S	Oral	2.5 Milligram, Qd		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927768	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2017-36384			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Product Substitution Issue	Escitalopram			S	Unknown			Aurobindo

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14927801	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827166US		44 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Off Label Use; Somnolence	Escitalopram Oxalate - Bp			S	Oral	70 Mg, Unk		Allergan	
	Noctamide			S	Oral	14 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928313	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-027064		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 [Mg/D] 1 {Trimester} 0. - 28.6. Gestational Week		Aurobindo	
	Femibion /07499601/			C	Transplacental	0.8 [Mg/D], 1 {Trimester} 0. - 40.5. Gestational Week		Not Reported	
	Influenza Vaccine			C	Transplacental	Unk		Not Reported	
	L-Thyroxin /00068001/			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928343	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2018-027227		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Milligram, Daily		Aurobindo	
	Quetiapine			C	Transplacental	25 Milligram, Daily		Not Reported	
	Sertraline			C	Transplacental	150 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928785	EXPEDITED (15-DAY)		HO, LT, OT	US-		25 YR	Female	USA

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GLAXOSMITHKLINE-
US2018089769

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Lamotrigine			S				Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14929579	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2018M1033126		93 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intracranial Haematoma	Escitalopram			S		10 Mg, Qd		Not Reported
	Kardegic			S	Oral	75 Mg, Qd		Mylan
	Levocetirizine Dihydrochloride			C		5 Mg, Qd		Mylan
	Amlodipine			C		5 Mg, Qd		Mylan
	Levothyroxine Sodique			C		50 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14929654	EXPEDITED (15-DAY)		DE	IT-PFIZER INC- 2018210181			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicide Attempt	Xanax			S		Unk		Pfizer
	Sonirem			S		Unk		Not Reported
	Zarelis			S		Unk		Not Reported
	Cipralext /01588501/			S		Unk		Not Reported

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Rivotril			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	13881576	EXPEDITED (15-DAY)		HO, LT	PL-ALLERGAN-1735394US		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Off Label Use; Overdose; Suicide Attempt; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan	
	Concor			S	Unknown	Unk Unk, Unknown		Not Reported	
	Polisen			S	Unknown	10 Mg, Qd		Not Reported	
	Clarithromycin			S	Oral	Unk, Qhs		Not Reported	
	Perindopril			S	Oral			Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Atoris			S	Unknown	Unk Unk, Unknown		Not Reported	
	Sertraline			S	Oral	50 Mg, Qam		Not Reported	
	Trosicam			S	Unknown	Unk Unk, Unknown		Not Reported	
	Doxepin			S	Oral	25 Mg, Qhs		Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Meloxicam			S	Oral	Unk Unk, Qhs		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qhs		Not Reported	
	Bisoprolol			S	Oral	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14259519	EXPEDITED (15-DAY)		HO	CA-APOTEX-2017AP021993		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Apo-Buspirone			S	Oral	5 Mg, Qd		Apotex	
	Amitriptyline			S	Oral	20 Mg, Qd		Apotex	
	Escitalopram			S	Oral	30 Mg, Unk		Apotex	
	Zyprexa			S	Oral	2.5 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14860950	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018187748		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypomagnesaemia; Mental Disorder	Pantoprazole			S	Unknown	Unk		Pfizer	
	Escitalopram Oxalate			S	Unknown	15 Mg, Daily		Not Reported	
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933181	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2018SP003699			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Sexual Dysfunction	Fluoxetine			S	Unknown	Up To 40mg Daily		Not Reported	
	Citalopram			S	Unknown	Up To 40mg Daily		Not Reported	
	Buspirone Hydrochloride			S	Unknown	Up To 45 Mg Daily		Strides	
	Escitalopram			S	Unknown	Up To 20mg Daily		Not Reported	
	Venlafaxine			S	Unknown	Extended Release, Up To 225mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933625	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2018-027143		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tremor	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934014	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-027309		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram	S	Oral	10 Milligram, Once A Day	Aurobindo
	Indapamide	S	Oral	2.5 Milligram, Once A Day	Not Reported
	Lactulose	C	Unknown	Unk	Not Reported
	Perindopril	C	Unknown	Unk	Not Reported
	Enoxaparin Sodium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14935180	EXPEDITED (15-DAY)		HO	BE-ALLERGAN-1827413US		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Lactation Disorder; Live Birth; Off Label Use; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Abilify			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	15001656	DIRECT		DS			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Impaired Quality Of Life; Intrusive Thoughts; Unevaluable Event; Withdrawal Syndrome	Lexapro			S			6 MTH	Not Reported
	Minocycline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	13849471	NON-EXPEDITED			US-PFIZER INC-2017339156		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erectile Dysfunction	Metoprolol Tartrate			S	Oral	100 Mg, 1x/Day		Not Reported
	Zyprexa			S	Oral	20 Mg, 1x/Day		Not Reported
	Lexapro			S	Oral	10 Mg, 1x/Day		Not Reported
	Lexapro			S				Not Reported

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Seroquel	S	Oral	150 Mg, 1x/Day(Every Evening)	Not Reported
Klonopin	S	Oral	1 Mg, 1x/Day(At Bedtime)	Not Reported

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25-May-2018	14700247	EXPEDITED (15-DAY)		HO, OT	RU-ALLERGAN-1816286US		61 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalopathy; Off Label Use; Seizure	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan	
	Atarax			S	Oral	Unk, Qd		Not Reported	
	Betaserc			S	Oral	Unk, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14726869	EXPEDITED (15-DAY)		OT	US-TORRENT-00005996			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depersonalisation/Derealisation Disorder; Lethargy; Suicidal Ideation; Therapeutic Response Decreased; Weight Increased	Aripiprazole			S		Unknown		Unknown	
	Bupropion			S		Unknown		Unknown	
	Buspirone			S		Unknown		Unknown	
	Escitalopram			S		Unknown		Unknown	
	Gabapentin			S		Unknown		Unknown	
	Lorazepam			S		Unknown		Unknown	
	Lurasidone			S		Unknown		Unknown	
	Risperidone			S		Unknown		Unknown	
	Sertraline			S		Unknown		Unknown	
	Trazodone			S		Unknown		Unknown	
	N-Acetylcysteine			C		Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14738390	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1819479US		95 YR	Male	CHN

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Dizziness; Haemorrhage; Skin Haemorrhage; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Cefuroxime			S	Intravenous (not otherwise specified)	0.75 G, Q8hr		Not Reported	
	Cefuroxime Sodium			S	Oral	1.5 G, Q8hr		Not Reported	
	Nifedipine			C	Oral	1 Df, Qd		Not Reported	
	Nicergoline			C	Oral	1 Df, Qd		Not Reported	
	Finasteride			C	Oral	2 Df, Qd		Not Reported	
	Trimetazidine Dihydrochloride			C	Oral	1 Df, Bid		Not Reported	
	Calcium Carbonate			C	Oral			Not Reported	
	Alfacalcidol			C	Oral	2 Df, Qd		Not Reported	
	Ambroxol Hydrochloride			C	Oral	1 Df, Qd		Not Reported	
Olanzapine			C	Oral	1 Df, Bid		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14936803	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR- 896724		21 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Escitalopram			S	Oral	15 - 20 Tablets Of Unknown Strength		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937761	EXPEDITED (15-DAY)		OT	US-TORRENT- 00006182			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Product Quality Issue; Product Substitution Issue	Escitalopram			S		Once At Night		Torrent	
	Aspirin			C				Unknown	
	Verapamil			C		One Capsule At Bed Time		Unknown	
	Lexapro			C				Forest	

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25-May-2018	14937893	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827597US		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Noctamide			S	Oral	2 Df, Qd		Not Reported	
	Xanax			S	Oral	3 Df, Qd		Not Reported	
	Zyprexa			S	Oral	1 Df, Qd		Not Reported	
	Tercian			S	Oral	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14940433	EXPEDITED (15-DAY)		DS	FI-GLAXOSMITHKLINE-FI2018088918		37 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Voxra			S	Oral	450,Mg,Daily		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Triptyl			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14940747	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1827832US		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Extrapyramidal Disorder;	Escitalopram Oxalate - Bp			S	Oral	9 Mg, In Total		Allergan	

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Mydriasis; Off Label Use; Off Label Use; Sinus Tachycardia	Risperidone Theralene	S C	Oral Oral	36 Mg, In Total Dosage Not Reported	Not Reported Not Reported

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25-May-2018	14941051	EXPEDITED (15-DAY)		HO	JP- OSMOTICA_PHARMAC EUTICAL_US_LLC- POI0573201800151		48 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Divigel			S	Transdermal			Osmotica
	Lexapro			S				Not Reported
	Brotizolam			S				Not Reported
	Solanax			S				Not Reported
	Calcitriol			S				Not Reported
	Ternelin			S				Not Reported
	Loxoprofen Na			S				Not Reported
	Hochuekkito Extract Granules For Ethical Use			S				Not Reported
	Tokishigyakukagoshuyushokyo o Extract Granules For Ethical Use			S				Not Reported
	Keiskikaryukotsuboreito Extract Granules For Ethical Use			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14690842	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN- 1816147US		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Off Label Use; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Suicide Attempt	Fluoxetine Hcl Unk			S	Oral	Unk		Allergan
	Hydrochlorothiazide Unk			S	Oral	Unk		Allergan
	Escitalopram Oxalate Unk			S	Oral	Unk		Allergan
	Venlafaxine			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported

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Amlodipine			S		Oral		Unk		Not Reported	
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28-May-2018	14869817	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1824734US		34 YR	Male	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Activation Syndrome;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan		
Activation Syndrome	Tecipul			S	Oral	2 Mg, Bid		Not Reported		
	Depas (Etizolam)			S	Oral	1 Mg, Tid		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-May-2018	14942965	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE- HET2018CA00476		89 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Extradural Haematoma;	Escitalopram			S	Unknown	Unk		Hetero		
Haemorrhage;	Heparin			S	Subcutaneous	5000 U		Not Reported		
Hypotension;	Lidocaine 2 %			C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI		Not Reported		
Hypovolaemia; Oedema;	Hydromorphone			C	Unknown	10 ?G/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion		Not Reported		
Paralysis; Platelet Aggregation Inhibition;	Epinephrine			C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI		Not Reported		
Platelet Count Decreased; Spinal Cord Compression	Bupivacaine			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-May-2018	14942981	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00006189		25 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

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Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Rhabdomyolysis; Sinus Tachycardia; Somnolence; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram	S	Unknown	Unknown
	Lamotrigine	S	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14943335	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1827579US		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Grippe Impfstoff			C	Transplacental			Not Reported	
	L-Thyroxin			C	Transplacental	100 Mg, Qd		Not Reported	
	L-Thyroxin			C	Transplacental	75 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14943336	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1827584US		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Quetiapine			S	Transplacental	25 Mg, Qd		Not Reported	
	Sertraline			S	Transplacental	150 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14278478	EXPEDITED (15-DAY)		OT	ES-OTSUKA-2016_007918		23 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Product Use In Unapproved Indication; Suicide Attempt	Abilify	S	Unknown	10 Mg, Qd	Otsuka
	Abilify	S			Otsuka
	Abilify	S			Otsuka
	Escitalopram	S	Oral	15 Mg, Unk	Not Reported
	Escitalopram	S			Not Reported
	Escitalopram	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14702937	EXPEDITED (15-DAY)		HO, OT	US-ALVOGEN-2018-ALVOGEN-095657		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Muscle Necrosis; Rhabdomyolysis; Seizure; Suicide Attempt	Fluoxetine			S	Oral			Not Reported
	Amphetamine/Dextroamphetamine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944943	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2018-FR-898874		93 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Intracranial Haematoma	Escitalopram			S		10 Milligram Daily;		Ivax
	Kardegic			S	Oral	75 Milligram Daily;		Not Reported
	Dichlorhydrate De Levocetirizine			C		5 Milligram Daily;		Not Reported
	Amlodipine			C		3 Milligram Daily;		Not Reported
	Levothyrox 50 Microgrammes, Comprimé Sécable			S		50 Microgram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945010	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18690			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Diltiazem			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Metformin			S	Oral	Unk		Not Reported	
	Glyburide			S	Oral	Unk		Not Reported	
	Losartan			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945011	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18681			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Not Reported	
	Lithium			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945070	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 898589		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Disturbance In Attention; Poisoning Deliberate	Paracetamol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Ivax	
	Alprazolam			S	Oral			Actavis	

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Codeine			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945101	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18734			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945164	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18689			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Flecainide			S	Oral	Unk		Not Reported	
	Verapamil			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945167	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18683			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Diphenhydramine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945168	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18680			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	

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		Gabapentin	S	Oral	Unk		Invagen		
		Amitriptylline	S	Oral	Unk		Not Reported		
		Ibuprofen	S	Oral	Unk		Not Reported		
		Ethanol	S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945813	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2018US18454			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Invagen	
	Ethanol			S	Unknown	Unk		Not Reported	
	Benzodiazepine Derivatives			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14948227	NON-EXPEDITED			US-PFIZER INC- 2018218063		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Codeine			S		Unk		Not Reported	
	Cefuroxime			S		Unk		Unknown	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14948421	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 898843		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Libido Disorder; Priapism	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14949714	EXPEDITED (15-DAY)		OT	CA- ELI_LILLY_AND_COMP ANY-CA201805011449		90 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Duloxetine Hydrochloride			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co	
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported	
	Venlafaxine			S	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	15010683	DIRECT		DE			19 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Depersonalisation/Dereali sation Disorder; Dissociation	Cipralex			S	Oral			Lundbeck	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	15011046	DIRECT		DS			23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Panic Attack; Suicidal Ideation	Escitalopram			S	Oral	Quantity:.5 Tablet(S);	2 DAY	Accord	
	Progesterone			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Fe Gluconate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14344134	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2017-035611		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Metformin Hydrochloride			S	Oral			Santarus	
	Terbutaline Sulfate			S	Respiratory (inhalation)			Not Reported	
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Microg, Unknown(8 T)		Not Reported	

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Dafalgan	S	Oral		Not Reported
Irbesartan	S	Oral		Not Reported
Alprazolam	S	Oral		Not Reported
Tavanic	S	Oral	Divisible Coated Tablet	Not Reported
Xarelto	S	Oral		Not Reported
Colchicine Opocalcium	S	Oral		Not Reported
Bisoprolol Fumarate	S	Oral		Not Reported
Seroplex	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Diffu-K	S	Oral		Not Reported
Diffu-K	S	Oral		Not Reported
Pantoprazole	S	Oral		Not Reported
Furosemide	S	Oral		Not Reported
Furosemide	S	Unknown		Not Reported
Amlodipine	S	Oral		Not Reported
Mirtazapine	S	Oral		Not Reported
Valium Roche	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14378479	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-159721		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor; Suicide Attempt	Escitalopram			S	Oral	12 MI, In Total		Not Reported	
	Alprazolam			S	Oral	16 Mg, In Total		Sun	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14402289	EXPEDITED (15-DAY)		HO, LT	GR-MYLANLABS-2018M1003908		67 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Psychomotor Hyperactivity; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Not Reported	
	Methylene Blue			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Mylan	
	Methylene Blue			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14618374	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK039583		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Anaemia; Arthralgia; Chills; Cold Sweat; Confusional State; Crohn'S Disease; Dizziness; Dyspnoea; Fatigue; Feeling Abnormal; Haemorrhage; Headache; Night Sweats; Pain; Pyrexia	Bupropion Hydrochloride			S		Unk		Glaxosmithkline	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14695532	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018126444		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Seizure	Amlodipine Besilate	S	Oral	Unk	Pfizer
	Atorvastatin Calcium	S	Oral	Unk	Pfizer
	Venlafaxine Hcl	S	Oral	Unk	Pfizer
	Escitalopram	S	Oral	Unk	Not Reported
	Hydrochlorothiazide	S	Oral	Unk	Not Reported
	Amphetamine / Dextroamphetamine	S	Oral	Unk	Not Reported
	Fluoxetine	S	Oral	Unk	Not Reported
	Buspirone	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14731126	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2018-008618		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose	Venlafaxine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Amphetamine, Dextroamphetamine			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14837700	EXPEDITED (15-DAY)		HO	BE-OTSUKA-2018_010222		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth;	Abilify			S	Unknown	Unk		Otsuka
	Abilify			S	Oral	20 Mg, Unk		Otsuka
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Maternal Exposure During
Pregnancy; Therapeutic
Product Effective For
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14915243	EXPEDITED (15-DAY)		HO, OT	US-IMPAX LABORATORIES, INC- 2018-IPXL-01652		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Unresponsive To Stimuli	Lamotrigine Odt			S	Unknown	100 Mg, Tablets Unk		Impax	
	Escitalopram			S	Unknown	20 Mg, Tablets Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14949892	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2018US18679			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Folic Acid			S	Oral	Unk		Invagen	
	Ethylene Glycol			S	Oral	Unk		Not Reported	
	Loratadine			S	Oral	Unk		Not Reported	
	Furosemide			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
	Vitamin B-1			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14949923	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18688			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Valproic Acid /00228502/			S	Oral	Unk		Not Reported	
	Carvedilol			S	Oral	Unk		Not Reported	
	Sitagliptin			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
	Phenytoin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14949928	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18691			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Naproxen			S	Oral	Unk		Invagen	
	Alprazolam			S	Oral	Unk		Not Reported	
	Glucophage			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14949990	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18682			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Lamotrigine			S	Oral	Unk		Cipla	
	Citalopram			S	Oral	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14950450	EXPEDITED (15-DAY)		DS	FI-MACLEODS PHARMACEUTICALS US LTD- MAC2018013738			Unknown	FIN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Voxra			S	Oral	450 Milligram, Qd		Not Reported	
	Triptyl			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14950504	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18753			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Invagen	
	Amlodipine			S	Oral	Unk		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
	Salicylate Sodium			S	Oral	Unk		Not Reported	
	Losartan			S	Oral	Unk		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14950870	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18780			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Bupropion			S	Unknown	Unk		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	

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		Cocaine		S	Unknown	Unk			Not Reported
		Alprazolam		S	Unknown	Unk			Not Reported
		Ethanol		S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951276	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.- 2018US18684			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Risperidone			S	Oral	Unk		Not Reported	
	Fluoxetine			S	Oral	Unk		Not Reported	
	Diphenhydramine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951277	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18686			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen	
	Propranolol			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Acetaminophen			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
	Cocaine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951278	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2018US18687			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Escitalopram			S	Oral	Unk		Invagen	

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Toxicity To Various Agents	Lamotrigine	S	Oral	Unk	Cipla
	Propranolol	S	Oral	Unk	Not Reported
	Ibuprofen	S	Oral	Unk	Not Reported
	Ondansetron	S	Oral	Unk	Not Reported
	Acyclovir /00587301/	S	Oral	Unk	Not Reported
	Alprazolam	S	Oral	Unk	Not Reported
	Acetaminophen	S	Oral	Unk	Not Reported
	Oxycodone	S	Oral	Unk	Not Reported
	Singulair	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951296	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18685			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Unknown	Unk		Invagen
	Cyclobenzaprine			S	Unknown	Unk		Invagen
	Lamotrigine			S	Unknown	Unk		Cipla
	Propranolol			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Activated Charcoal			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951567	NON-EXPEDITED			US-TEVA-2018-US- 896778		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Insomnia; Tinnitus	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax
	Escitalopram			S				Ivax

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14952982	EXPEDITED (15-DAY)		HO	FR-ANIPHARMA-2018-FR-000060		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Atacand			S	Oral	16 Mg Daily		Ani	
	Escitalopram			S	Oral	15 Mg Daily		Not Reported	
	Plegridy			S	Subcutaneous	125 Mcg Every 14 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14954111	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2018-IPXL-01821		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Cardiac Failure Congestive; Respiratory Failure; Serotonin Syndrome	Mirtazapine Odt			S	Unknown	Unk		Impax	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk, Decreased		Not Reported	
	Trazodone			S	Unknown	Unk		Not Reported	
	Trazodone			S	Unknown	Unk, Decreased		Not Reported	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk,Decreased		Not Reported	
	Lorazepam			S	Unknown	Unk, Low Dose		Not Reported	
	Gabapentin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14660045	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00125		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Rectal Ulcer	Escitalopram			S	Unknown	Unk		Taro	
	Lansoprazole			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14744626	EXPEDITED (15-DAY)		DE, HO, OT	DE-TEVA-2018-DE-880628		1 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Pneumonia; Respiratory Failure	Spironolactone			S	Unknown			Actavis	
	Sildenafil Citrate			S	Unknown			Actavis	
	Topiramate			S	Unknown			Teva	
	Phenobarbital			S	Unknown			Not Reported	
	Varivax			S	Intramuscular			Not Reported	
	Synagis			S	Intramuscular			Not Reported	
	Exodus (Escitalopram Oxalate)			S	Unknown			Not Reported	
	Nutrition With Nutriini Mixed With Water			C	Other			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14916463	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-067073		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Overdose; Serotonin Syndrome	Escitalopram			S		20 Mg Tablets		Not Reported	
	Lamotrigine			S		100 Mg Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14925309	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1826693US		87 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14949995	EXPEDITED (15-DAY)		HO, LT, OT	US-GLENMARK PHARMACEUTICALS-2018GMK035357		25 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Lamotrigine Tablets			S	Unknown	Unk		Glenmark	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14955374	EXPEDITED (15-DAY)		DE, HO	US-CIPLA (EU) LIMITED-2018US18760			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unk, (Extended Release)		Invagen	
	Escitalopram			S	Oral	Unk		Invagen	
	Venlafaxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14955569	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2018013910			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Escitalopram Tablet			S	Oral	15 Milligram, Qd		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14955572	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018013913			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Escitalopram Oxalate			S	Oral	15 Milligram, Qd		Macleods	
	Plegridy 125 Micrograms			S	Subcutaneous	125 Microgram (Solution		Not Reported	

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Atacand 16 Mg		S		Oral		For Injection In Pre-Filled Pen) 14 Day		1 Dosage Form, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
31-May-2018	14955929	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-027781		47 YR	Male	FRA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Milligram		Aurobindo			
	Plegridy			S	Subcutaneous	125 Microgram		Not Reported			
	Atacand			S	Oral	1 Dosage Form		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
31-May-2018	14956021	EXPEDITED (15-DAY)		OT	US-TORRENT-00006194		69 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Akathisia; Serotonin Syndrome	Escitalopram			S		Unknown		Unknown			
	Lorazepam			C		Unknown		Unknown			
	Trazodone			S		Unknown		Unknown			
	Mirtazapine			S		Unknown		Unknown			
	Gabapentin			C		Unknown		Unknown			
	Olanzapine			S		Unknown		Unknown			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
31-May-2018	14957264	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018216485		65 YR	Male	FRA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine Hcl			S	Oral	Unk		Pfizer			
	Atarax /00058401/			S	Oral	Unk		Not Reported			
	Zopiclone			S	Oral	Unk		Not Reported			

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Previscan /00789001/	S	Oral	Unk	Not Reported
Seroplex	S	Oral	Unk	Not Reported

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31-May-2018	14957302	EXPEDITED (15-DAY)		HO	FR-009507513-1805FRA013262		40 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Circulatory Collapse	Norset			S	Oral			Merck
	Valium			S	Oral	Prise Unique		Not Reported
	Seroplex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14958461	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2018-027253		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure	Escitalopram Arrow Film-Coated Tablet 10mg			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Escitalopram Arrow Film-Coated Tablet 10mg			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Preterax /01421201/			C	Oral	Unk		Not Reported	
	L Thyroxine Serb			C	Oral	40 Microgram, Once A Day		Not Reported	
	Efferalgan /00020001/			C	Oral	3 Gram, Once A Day		Not Reported	
	Bisoprolol Accord			C	Oral	Unk		Not Reported	
	Lactulose Sandoz			C	Oral	40 Milligram, Once A Day		Not Reported	
	Primperan			C	Oral	30 Milligram, Once A Day, (Si Nausées Et/Ou Vomissements)		Not Reported	
	Lansoprazole Mylan			C	Oral	15 Milligram, Once A Day		Not Reported	
	Ogast			C	Unknown	Unk		Not Reported	
	Kardegic			C	Oral	75 Milligram, Once A Day		Not Reported	
	Crestor			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14958910	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1828425US		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14288593	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017006770			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Irbesartan			S	Oral	300 Mg, Qd		Macleods	
	Metformin Hydrochloride 1000mg Tablet			S	Oral	500 Mg, Bid (Film-Coated Tablet)		Macleods	
	Pantoprazole			S	Oral	20 Mg, Qd		Macleods	
	Amlodipine Besylate			S	Oral	10 Mg, Qd, (Hard Capsule)		Macleods	
	Alprazolam			S	Oral	0.75 Mg, Qd, (0.25 Mg, 3x/Day (Tid))		Not Reported	
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg, Qd		Not Reported	
	Colchicine Opocalcium			S	Oral	1 Mg, Qd		Not Reported	
	Dafalgan			S	Oral	1000 Mg, Tid (3x/Day (Tid)) Capsule		Not Reported	
	Diffu K			S	Oral	6 Df, Qd (6df Daily (2-1-0) 2x/Day (Bid) (2 In 1 D))		Not Reported	
	Diffu K			S	Oral	3 Df, Unk		Not Reported	
	Diazepam			S	Oral	10 Mg, Tid (30 Mg/Day), 3 Df Si Besoin		Not Reported	
	Furosemide			S	Oral	2 Df, Qd		Not Reported	
	Furosemide			S	Oral	Unk, Bid		Not Reported	
	Furosemide			S	Oral	30 Mg, Qd, (30 Mg Daily		Not Reported	

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Mirtazapine	S	Oral	(2-1-0), 2x/Day (Bid)) 15 Mg, Qd	Not Reported
Nefopam Hydrochloride	S	Oral	3 Df, Qd, 1 Df, 3x/Day (Tid) Si Besoin	Not Reported
Seroplex	S	Oral	1 Df, Qd	Not Reported
Tavanic	S	Oral	250 Mg, Bid, 250 Mg, (2x/Day (Bid)), 2 Df, Film Coated Tablet	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Xarelto	S	Oral	20 Mg, Qd (Film-Coated Tablet)	Not Reported

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01-Jun-2018	14723847	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ALLERGAN- 1819304US			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea;	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
Electrocardiogram Qt Prolonged;	Clonazepam			S	Oral	Unk		Not Reported
Electrocardiogram Qt Shortened; Epilepsy;	Metoclopramid			S	Oral	Unk		Not Reported
Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Melperon			S	Oral			Not Reported
	Olanzapin			S	Oral	Unk		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Levomepromazine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14765837	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1820695US		41 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Intentional Product	Escitalopram Oxalate - Bp			S	Oral	In Total Overdose: 60 Mg		Allergan

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Misuse; Intentional Self-Injury; Sluggishness; Sopor	Minias	S	Unknown	; In Total	Not Reported
	Kivexa	S	Unknown	; In Total, Strength=600 Mg+300 Mg	Not Reported
	Ethanol	S	Unknown	Dosage Form: Unspecified	Not Reported
	Lyrica	S	Oral	Strength=150 Mg	Not Reported
	Rezolsta	S	Oral	Strength=800 Mg/150 Mg	Not Reported
	Tavor (Lorazepam)	S	Unknown	; In Total; Strength=2.5 Mg	Not Reported

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01-Jun-2018	14802711	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018164795		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis	Amlor			S	Oral	Unk		Pfizer	
	Esomeprazole Magnesium			S	Oral	Unk		Unknown	
	Decapeptyl /00486501/			S	Intramuscular	1 Df, Cyclic		Not Reported	
	Innohep			S	Subcutaneous	1 Df, 1x/Day		Not Reported	
	Novonorm			S	Oral	Unk		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Xtandi			S	Oral	120 Mg, 1x/Day		Not Reported	
	Lipanthyl			S	Oral	145 Mg, 1x/Day		Not Reported	
	Seroplex			S	Oral	10 Mg, 1x/Day		Not Reported	

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01-Jun-2018	14859943	EXPEDITED (15-DAY)		DS	PHHY2018DE002216			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Muscle Twitching	Escitalopram			S	Unknown	10 Mg, (In The Morning)		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Qd (In The Morning)		Not Reported	
	Oxazepam Hexal			S	Unknown	10 Mg, (Night)		Novartis	

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01-Jun-2018	14948766	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1827996US		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Lamotrigine			S	Unknown	Unk		Not Reported	
	Lamotrigine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14962459	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-900784		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14962701	EXPEDITED (15-DAY)		HO, LT, OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018013983			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate 20mg Tablet			S	Unknown	20 Milligram		Macleods	
	Escitalopram Oxalate 20mg Tablet			S				Macleods	
	Lamotrigine			S	Unknown	100 Milligram		Not Reported	
	Lamotrigine			S				Not Reported	

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01-Jun-2018	14962887	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04094		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia	Lorazepam			S	Unknown	Unk (Low Dose)		Lupin	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S		Unk (Decreased Dose)		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Gabapentin			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk (Decreased Dose)		Not Reported	
	Trazodone			S	Unknown	Unk		Not Reported	
	Trazodone			S	Unknown	Unk (Decreased Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14963077	EXPEDITED (15-DAY)		OT	US-009507513- 1805USA013965		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Remeron			S	Oral			Merck	
	Escitalopram			S				Not Reported	
	Olanzapine			S				Not Reported	
	Trazodone Hydrochloride			S		Unk		Not Reported	
	Gabapentin			S				Not Reported	
	Lorazepam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14963153	EXPEDITED (15-DAY)		OT	ES-MYLANLABS- 2018M1035039		40 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thyroid Mass	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	

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04-Jun-2018	13231794	EXPEDITED (15-DAY)		OT	US-JNJFOC-20151102623		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia; Hyperprolactinaemia; Obesity	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported	
	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported	
	Risperdal			S	Oral	0.2 Mg - 1 Mg		Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported	
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported	
	Risperdal			S	Oral	0.2 To 1 Mg (1 Mg Twice Daily)		Not Reported	
	Invega			S	Oral			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Depakote			S	Oral			Not Reported	
	Abilify			S	Unknown	In Varying Doses Of 2.5 Mg, 5 Mg And 10 Mg.		Not Reported	
	Olanzapine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14274736	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2017TEU005216		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported	
	Pantoprazole			S	Oral	20 Mg, Unk		Not Reported	

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Metformine	S	Oral	500 Mg, Bid	Not Reported
Amlodipine	S	Oral	10 Mg, Qd	Not Reported
Colchicine	S	Oral	1 Mg, Qd	Not Reported
Dafalgan	S	Oral	1000 Mg, Tid	Not Reported
Dafalgan	S	Oral	3000 Mg, Unk	Not Reported
Valium	S	Oral	10 Mg, Tid	Not Reported
Furosemide	S	Oral	30 Mg, Bid	Not Reported
Alprazolam	S	Oral	0.75 Mg, Tid	Not Reported
Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
Nefopam Hydrochloride	S	Oral	Unk Unk, Tid	Not Reported
Nefopam Hydrochloride	S	Oral	3 Ug, Qd	Not Reported
Diffu K	S	Oral	Unk Unk, Qd	Not Reported
Xarelto	S	Oral	20 Mg, Qd	Not Reported
Seroplex	S	Oral	Unk Unk, Qd	Not Reported
Tavanic	S	Oral	500 Mg, Qd	Not Reported
Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	Unk Unk, Qd	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	1 Ug, Unk	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Not Reported
Irbesartan	S	Oral	300 Mg, Unk	Not Reported
Terbutaline	S	Respiratory (inhalation)	Unk	Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Unk	Not Reported
Nefopam	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14596614	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-30929		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam 1mg	S	Oral	1 Mg, Total	Aurobindo
	Lorazepam 1mg	S	Oral	1 Mg, Total	Aurobindo
	Clozapine	S	Oral	100 Mg, Total ; In Total	Not Reported
	Entact	S	Oral	20 Mg, Total	Not Reported
	Entact	S	Oral	20 Mg, Once/Single ; In Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14853356	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018181688		46 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Efexor Er			S	Oral	7 Df, Single		Pfizer	
	Escitalopram Oxalate			S	Oral	300 Mg, Single		Not Reported	
	Lexotan			S	Oral	20 Ml, Single		Not Reported	
	Lamictal			S	Oral	1400 Mg, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14922937	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-894270		16 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Pressure Increased; Diarrhoea; Diarrhoea Haemorrhagic; Haematochezia; Heart Rate Increased; Hypertension; Tachycardia	Quetiapine Tablet Fo 25mg Filmomhulde Tablet, 25 Mg (Milligram)			S	Unknown	12.5 Milligram Daily; For The Night Half A Tablet		Teva	
	Quetiapine Tablet Fo 25mg Filmomhulde Tablet, 25 Mg (Milligram)			S				Teva	
	Escitalopram Tablet 10mg Tablet, 10 Mg (Milligram)			S	Unknown	40 Milligram Daily;		Not Reported	
	Cholecalciferol 800ie			C	Unknown	800 Iu (International Unit) Daily;		Not Reported	
	Melatonine			C	Unknown	1 Milligram Daily;		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14966678	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805- 001786		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Progesterone			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Gabapentin			C				Not Reported
	Atorvastatin			C	Oral			Not Reported
	Cardiaze			C	Oral	Taking For At Least 6 Months		Not Reported
	Cardiaze			C				Not Reported
	Carvedilol			C	Oral			Not Reported
	Cozaar			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Folic Acid			C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two (1 Mg, 6 In 1 Wk)		Not Reported
	Aldactone			C	Oral			Not Reported
	Aldactone			C	Oral			Not Reported

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Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily	Not Reported
Tramadol	C		As Required	Not Reported
Bumex	C	Oral		Not Reported

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04-Jun-2018	14967655	EXPEDITED (15-DAY)		OT	US-ZYDUS-020292		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Serotonin Syndrome	Gabapentin			S	Unknown			Zydus Pharm	
	Escitalopram			S	Unknown			Zydus Pharm	
	Mirtazapine			S	Unknown			Zydus Pharm	
	Trazodone			S	Unknown			Zydus Pharm	
	Olanzapine			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14968325	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-028934			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anxiety; Dysphoria; Headache; Hyperhidrosis; Insomnia; Sexual Dysfunction; Somnolence; Tachycardia; Vision Blurred; Withdrawal Syndrome	Atomoxetine			S	Unknown	18 Milligram		Aurobindo	
	Buspirone Hydrochloride			S	Unknown			Aurobindo	
	Citalopram			S	Unknown	40 Milligram, Daily		Aurobindo	
	Clonidine			S	Unknown	0.05-0.1 Mg		Aurobindo	
	Dexamfetamine			S	Unknown	10 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo	
	Fluoxetine			S	Unknown	40 Milligram, Daily		Aurobindo	
	Trazodone			S	Unknown	12.5 Milligram		Aurobindo	
	Venlafaxine			S	Unknown	225 Milligram, Daily		Aurobindo	

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	Amphetamine	S	Unknown	5 Milligram, Daily	Not Reported
	Bupropion	S	Unknown	18.75 Milligram, Four Times/Day	Not Reported
	Bupropion	S	Unknown	37.5mg,	Not Reported
	Bupropion	S		150 Unk	Not Reported
	Dexmethylphenidate	S	Unknown	0.625-1.25mg Daily	Not Reported
	Methylphenidate	S	Unknown		Not Reported
	Clonazepam	S	Unknown	0.25 Milligram	Not Reported
	Guanfacine /00547902/	S	Unknown	1 Milligram	Not Reported
	Guanfacine /00547902/	S	Unknown	0.51 Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14968373	EXPEDITED (15-DAY)		OT	US-DRREDDYS- USA/USA/18/0099582		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dysphoria; Dyspnoea; Headache; Hyperhidrosis; Product Substitution Issue; Rash Pruritic; Sexual Dysfunction; Social Anxiety Disorder; Somnolence; Vision Blurred; Withdrawal Syndrome	Citalopram 40 Mg			S	Unknown	Up To 40 Mg Daily		Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Fluoxetine Capsules 40 Mg			S	Unknown			Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Fluoxetine Capsules 40 Mg			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S	Unknown	Extended Release		Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Venlafaxine Hydrochloride Er Capsules			S				Not Reported
	Guanfacine Hydrochloride			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Buspirone			S	Unknown			Not Reported
	Propranolol			C	Unknown			Not Reported

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Bupropion	C	Unknown	Not Reported
Clonazepam	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Amphetamine	C	Unknown	Not Reported
Amphetamine	C	Unknown	Not Reported
Dextroamphetamine	C	Unknown	Not Reported
Methylphenidate	C	Unknown	Not Reported
Dexmethylphenidate	C	Unknown	Not Reported
Atomoxetine	C	Unknown	Not Reported
Clonidine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14968529	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1828573US		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematuria	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14968597	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04113		17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Citalopram			S	Unknown	40 Mg, Qd		Not Reported
Anxiety; Drug Ineffective;	Citalopram			S				Not Reported
Drug Intolerance;	Citalopram			S				Not Reported
Dysphoria; Headache;	Citalopram			S				Not Reported
Insomnia; Sexual	Escitalopram			S	Unknown	Up To 20 Mg, Qd		Not Reported
Dysfunction; Somnolence;	Fluoxetine			S	Unknown	Up To 40 Mg, Qd		Not Reported
Withdrawal Syndrome	Fluoxetine			S				Not Reported

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Venlafaxine	S	Unknown	Up To 225 Mg, Qd	Not Reported
Venlafaxine	S			Not Reported
Venlafaxine	S			Not Reported
Venlafaxine	S			Not Reported
Bupropion	S	Unknown	150 Mg, Qd (Extended Release)	Not Reported
Bupropion	S			Not Reported
Methylphenidate Hydrochloride	S	Unknown	Unk	Novel Labs
Dexmethylphenidate	S	Unknown	Unk	Not Reported
Clonidine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14968681	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-015619		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Serotonin Syndrome	Lorazepam			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Mirtazapine			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Gabapentin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14969593	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP015075		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dysphoria; Headache; Insomnia; Sexual Dysfunction; Somnolence	Citalopram			S	Unknown	Up To 40 Mg, Daily		Apotex	
	Escitalopram			S	Unknown	Up To 20 Mg, Daily		Apotex	
	Fluoxetine			S	Unknown	Up To 40 Mg, Daily		Apotex	
	Buspirone			S	Unknown	Up To 45 Mg, Daily		Apotex	
	Bupropion			S	Unknown	150 Mg, Daily		Apotex	

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Clonazepam	S	Unknown	0.25 Mg, Unk	Apotex
Trazodone	S	Unknown	12.5 Mg, Unk	Apotex
Atomoxetine	S	Unknown	Unk	Apotex
Clonidine	S	Unknown	0.05–0.1 Mg	Apotex
Venlafaxine	S	Unknown	Up To 225 Mg, Daily	Not Reported
Propranolol	S	Unknown	10 Mg, Unk	Not Reported
Guanfacine	S	Unknown	0.5-1 Mg	Not Reported
Guanfacine	S	Unknown	1 Mg, Unk	Not Reported
Amphetamine	C	Unknown	5 Mg, Daily	Not Reported
Amphetamine	C	Unknown	30 Mg, Daily	Not Reported
Dextroamphetamine /00016601/	C	Unknown	10 Mg, Daily	Not Reported
Methylphenidate	C	Unknown	Unk	Not Reported
Dexmethylphenidate	C	Unknown	0.625-1.25 Mg Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14969817	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1036398		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14845363	NON-EXPEDITED		HO	US-CELGENEUS-USA-20180500178		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Revlimid			S	Oral	5 Milligram		Celgene

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Dysarthria; Gait Disturbance; Pneumonia	Revlimid	S	Oral	10 Milligram	Celgene
	Lexapro	S	Unknown	10 Milligram	Not Reported
	Lexapro	S	Unknown	20 Milligram	Not Reported
	Lexapro	S	Unknown	10 Milligram	Not Reported
	Colace	C	Unknown	100 Milligram	Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported
	Breo Ellipta	C	Unknown	100-25 Mcg	Not Reported
	Doxycycline Monohydrate	C	Unknown		Not Reported
	Cephalexin	C	Unknown	750 Milligram	Not Reported
	Gabapentin	C	Unknown	100 Milligram	Not Reported
	Ondansetron Hcl	C	Unknown	4 Milligram	Not Reported
	Tylenol Extra Strength	C	Unknown		Not Reported
	Hydrocodone- Acetaminophen	C	Unknown		Not Reported
	Remodulin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14929550	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1033063		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S		5 Mg, Unk		Not Reported	
	Bisoprolol			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14938651	EXPEDITED (15-DAY)		HO, OT	US-ENDO PHARMACEUTICALS INC-2018-039187		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Serotonin Syndrome; Toxicity To	Lamotrigine			S	Oral	Unkmg, Unknown		Par	
	Escitalopram			S	Oral	Unk Mg, Unknown		Not Reported	

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Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972053	NON-EXPEDITED		OT	US-APOTEX-2018AP015358		94 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Therapeutic Product Effect Incomplete; Urinary Retention	Oxybutynin			S	Unknown	Unk		Apotex	
	Mirtazapine			S	Unknown	Maximum Dose Of 30 Mg, Q.H.S		Apotex	
	Mirtazapine			S				Apotex	
	Quetiapine			S	Unknown	Unk		Apotex	
	Quetiapine			S	Unknown	50 Mg, Per Day		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex	
	Trazodone			S	Unknown	Unk		Apotex	
	Trazodone			S	Unknown	50 Mg, Unk		Apotex	
	Melatonin			S	Unknown	3 Mg, Q.H.S.		Not Reported	
	Melatonin			S				Not Reported	
	Aspirin /00002701/			C	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Finasteride			C	Unknown	5 Mg, Daily		Not Reported	
	Tamsulosin			C	Unknown	0.8 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972535	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ACCORD-067611		28 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Odour; Facial Asymmetry; Gait Disturbance; Head Discomfort; Muscle Spasms; Musculoskeletal Stiffness; Parkinson'S	Escitalopram			S				Not Reported	
	Olanzapine			S				Not Reported	
	Xeplion			S				Not Reported	
	Risperidone			S				Not Reported	
	Risperdal			S		Unk		Not Reported	

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Disease; Personality Change; Shoulder Deformity; Weight Increased	Paliperidone Zyprexa Abilify Ciprallex	S S S S			Unk Unk		Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972608	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-174607		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Serotonin Syndrome	Mirtazapine			S	Unknown	Unk		Sun	
	Olanzapine			S	Unknown	Unk		Sun	
	Trazodone			S	Unknown	Unk		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972979	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2018- 015843		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Venlafaxine			S	Oral			Not Reported	
	Olanzapine			S	Oral			Not Reported	
	Ciprallex			S	Oral			Not Reported	
	Delorazepam			S	Oral			Not Reported	
	Donepezil			C				Not Reported	
	Bisoprolol Fumarate			C				Not Reported	
	Madopar			C				Not Reported	
	Terazosin Hydrochloride			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14973306	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-		69 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Trazodone			S	Unknown			Apotex
	Escitalopram			S	Unknown			Apotex
	Mirtazapine			S	Unknown			Apotex
	Olanzapine			S	Unknown			Apotex
	Gabapentin			S	Unknown			Apotex
	Lorazepam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974332	NON-EXPEDITED			US-APOTEX- 2018AP009228			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Ageusia; Diarrhoea; Drug Hypersensitivity; Myalgia; Nausea; Oedema; Swelling; Weight Decreased	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Amlodipine			S	Unknown	10 Mg, Qd		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Fenofibrate			S	Unknown	Unk		Apotex
	Lisinopril			S	Unknown	Unk		Apotex
	Mirtazapine			S	Unknown	Unk		Apotex
	Pravastatin			S	Unknown	Unk		Apotex
	Tramadol			S	Oral	50 Mg, Tid, When Needed		Apotex
	Triamterene And Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown			Apotex
	Ciprofloxacin			C	Oral	1 Df, Q.12h		Not Reported
	Atenolol			C	Oral	1 Df, Qd		Not Reported
	Acetaminophen			C	Oral	2 Df, Q.6h, As Needed		Not Reported

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Prednisone	C	Oral	1 Df, 2 Daily For 4 Days And 1 Daily For 6 Daysunk	Not Reported
Comfort Gel /00723801/	C	Unknown	Unk	Not Reported
Losartan	C	Oral	1 Df, Qd	Not Reported
Lyrica	C	Oral	1 Df, Bid	Not Reported
Furosemide	C	Oral	1 Df, Qd, As Needed	Not Reported
Allegra	C	Oral	1 Df, Qd	Not Reported
Ranitidine	C	Oral	1 Df, Bid	Not Reported
Calcium + Vit D	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974386	EXPEDITED (15-DAY)		OT	KR-TAKEDA- 2018TUS018732		27 YR	Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Cold Sweat; Drug Ineffective; Fatigue; Hallucination; Rash; Suicide Attempt; Tremor; Tremor; Weight Increased	Brintellix			S	Unknown	10 Mg, Qd		Takeda
	Brintellix			S	Oral	Unk, Bid		Takeda
	Brintellix			S	Oral	10 Mg, Qd		Takeda
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Lexapro			S	Oral	10 Mg, Bid		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Diazepam			C	Unknown	1 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	25 Mg, Unk		Not Reported
	Alprazolam			C	Oral	0.25 Mg, Bid		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.75 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.125 Mg, Qd		Not Reported
	Quetiapine			C	Oral	125 Mg, Qd		Not Reported
	Trazodone			C	Oral	50 Mg, Qd		Not Reported

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	Trazodone	C	Oral	25 Mg, Qd	Not Reported
	Efexor	C	Unknown	75 Mg, Unk	Not Reported
	Clonazepam	C	Unknown	0.25 Mg, Unk	Not Reported
	Abilify	C	Unknown	1 Mg, Unk	Not Reported
	Wellbutrin	C	Unknown	150 Mg, Unk	Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd	Not Reported
	Wellbutrin	C	Unknown	150 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974590	EXPEDITED (15-DAY)		HO, LT	PH-OTSUKA-2018_013493		26 YR	Male	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Multiple Drug Therapy; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	Unk Unk, Qd		Otsuka	
	Aripiprazole			S				Otsuka	
	Aripiprazole			S				Otsuka	
	Risperidone			S	Unknown	Unk		Not Reported	
	Risperidone			S				Not Reported	
	Risperidone			S				Not Reported	
	Multiple Vitamins			S	Unknown	Unk		Not Reported	
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Clonazepam			C	Unknown	10 Mg, Unk (As Needed)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974850	EXPEDITED (15-DAY)		DE	FI-MYLANLABS-2017M1080022			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ventricular Fibrillation	Ciprofloxacin			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14975064	EXPEDITED (15-DAY)		HO	PHHY2018FR014695		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Valaciclovir			S	Oral	500 Mg, Qd		Novartis	
	Metoclopramide			S	Oral			Not Reported	
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported	
	Ramipril			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14976451	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1829292US		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14576146	EXPEDITED (15-DAY)		OT	ES-ROCHE-2032435			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Musculoskeletal Pain; Somnolence; Treatment Noncompliance	Diazepam			S	Unknown	0.5 Dosage Forms ; 5 Mg		Not Reported	
	Naproxen			S	Unknown	2 Dosage Forms Daily; Last Administration On 18/Nov/2016		Not Reported	
	Amitriptyline			S	Unknown	12.5 Milligram Daily;		Not Reported	
	Amitriptyline			S	Unknown	25 Milligram Daily;		Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Glibenclamide			S	Unknown	2 Dosage Forms Daily;		Not Reported	
	Paracetamol/Tramadol			S	Unknown	1 Df = 37.5/325mg		Not Reported	

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Topiramate	S	Unknown	Last Dose On 09/May/2017 1 Df 50 Mg	Not Reported
Topiramate	S	Unknown		Not Reported
Omeprazole	S	Unknown	20 Mg Date Of Last Dose On 25/Nov/2016	Not Reported
Amlodipine	S	Unknown	1 Dosage Forms Daily; 5 Mg	Not Reported
Simvastatin	S	Unknown	1 Df = 40mg Last Dose On 20/Apr/2017	Not Reported
Simvastatin	S	Unknown		Not Reported
Topiramato	S	Unknown	Last Dose On 20/Apr/2017	Not Reported
Topiramato	S	Unknown	1 Dosage Forms Daily; 50 Mg	Not Reported
Paracetamol	S	Unknown	3 Dosage Forms Daily; 1 G	Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrochlorothiazide	S	Unknown	Qd	Not Reported
Lormetazepam	S	Unknown	1 Dosage Forms Daily; 1 Mg	Not Reported
Enalapril	S	Unknown	1 Df = 20/12.5 Mg	Not Reported
Temazepam	S	Unknown	Qd	Not Reported
Escitalopram	S	Unknown	1 Dosage Forms = 10 Mg	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14701876	EXPEDITED (15-DAY)		HO, LT, OT	CZ-AUROBINDO-AUR- APL-2018-017876			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea;	Olanzapine			S	Oral	Unk		Aurobindo	
Electrocardiogram Qt	Clonazepam			S	Oral	Unk		Not Reported	
Prolonged;	Clonazepam			S	Oral	()		Not Reported	
Electrocardiogram Qt									
Shortened; Epilepsy;									

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Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning; Toxicity To Various Agents	Levopromazin	S	Oral	Unk	Not Reported
	Metoclopramide	S	Oral	Unk	Not Reported
	Metoclopramide	S	Oral	()	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	()	Not Reported
	Venlafaxine	S	Oral	Unk	Not Reported
	Venlafaxine	S	Oral	()	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	()	Not Reported
	Melperone	S	Oral	Unk	Not Reported
	Melperone	S	Oral	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14941434	EXPEDITED (15-DAY)		OT	CA-ACCORD-067392		89 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Subcutaneous	5000 U		Not Reported
	Heparin			S				Not Reported
	Lidocaine			C				Not Reported
	Hydromorphone/Hydromorphone Hydrochloride			C		10 Ug/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion		Not Reported
	Epinephrine			C		A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 Ug/MI		Not Reported
	Bupivacaine			C		1 Mg/MI, Infusion		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14977618	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-CIPLA LTD.- 2018GB18910			Unknown	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Escitalopram			S	Oral	15 Mg, Unk		Invagen
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Nefopam			C	Unknown	Unk		Not Reported
	Tiotropium			C	Unknown	Unk		Not Reported
	Sodium Picosulfate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Cassia Senna			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Meptazinol			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Temazepam			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Pyridoxine			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14977805	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-900690		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Lorazepam			S	Unknown			Actavis

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Serotonin Syndrome	Trazodone	S	Unknown	Actavis
	Escitalopram	S	Unknown	Ivax
	Mirtazapine	S	Unknown	Teva
	Gabapentin	S	Unknown	Ivax
	Olanzapine	S	Unknown	Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14978546	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-AUROBINDO-AUR- APL-2018-028698		37 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	15 Milligram		Aurobindo
	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Nefopam			C	Unknown	Unk		Not Reported
	Tiotropium			C	Unknown	Unk		Not Reported
	Sodium Picosulfate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Cassia Senna			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Meptazinol			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Temazepam			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported

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	Pyridoxine	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Adcal D3	C	Unknown	Unk		Not Reported

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06-Jun-2018	14979760	NON-EXPEDITED			US-PFIZER INC-2018230046		12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Obsessive-Compulsive Disorder; Serum Serotonin Decreased	Methylphenidate Hydrochloride			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14980120	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1829301US		66 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Olanzapine			C	Oral	5 Mg, Unk		Not Reported	
	Olanzapine			C	Oral	2.5 Mg, Unk		Not Reported	
	Triazolam			C	Oral	0.25 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14980121	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1829058US		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan	
	Valium			S	Oral	Once		Not Reported	
	Norset			S	Oral	Unk, Unknown		Not Reported	

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06-Jun-2018	14980408	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1829045US		27 YR	Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Cold Sweat; Drug Ineffective; Fatigue; Hallucination; Rash; Suicide Attempt; Tremor; Tremor; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Brintellix			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S	Oral	20 Mg, Qd		Not Reported
	Diazepam			C	Unknown	1 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	25 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Amitriptyline			C	Unknown	10 Mg, Unk		Not Reported
	Alprazolam			C	Unknown	0.125 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	0.75 Mg, Qd		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Qd		Not Reported
	Alprazolam			C	Oral	0.25 Mg, Bid		Not Reported
	Quetiapine			C	Oral	125 Mg, Qd		Not Reported
	Trazodone			C	Oral	25 Mg, Qd		Not Reported
	Trazodone			C	Oral	50 Mg, Qd		Not Reported
	Efexor			C	Unknown	75 Mg, Unk		Not Reported
	Clonazepam			C	Unknown	0.25 Mg, Unk		Not Reported
	Abilify			C	Unknown	1 Mg, Unk		Not Reported
	Wellbutrin			C	Unknown	150 Mg, Qd		Not Reported
Wellbutrin			C	Unknown	300 Mg, Qd		Not Reported	
Wellbutrin			C	Unknown	150 Mg, Unk		Not Reported	

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06-Jun-2018	14980880	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1829291US		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Peginterferon			S	Subcutaneous	125 Mg, Q2weeks		Not Reported	
	Atacand			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14560005	EXPEDITED (15-DAY)		OT	PHHY2017ES192959			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence	Paracetamol			S	Unknown	1 Df, Tid		Not Reported	
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Df, Qd		Not Reported	
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported	
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported	
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported	
	Simvastatin			S	Unknown	40 Mg, Qd		Not Reported	
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported	
	Topiramato			S	Unknown	0.5 Df, Qd		Not Reported	
	Topiramato			S	Unknown	1 Df (50 Mg), Qd		Not Reported	
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported	
	Paracetamol + Tramadol			S	Unknown	1 Df, Tid		Not Reported	
	Naproxen			S	Unknown	1 Df, Bid		Not Reported	
	Amitriptyline			S	Unknown	5 Mg, Qd		Not Reported	
	Amitriptyline			S	Unknown	25 Mg, Unk		Not Reported	
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported	
	Diazepam			S	Unknown	0.5 Df (5 Mg), Qd		Not Reported	
	Glibenclamida			S	Unknown	1 Df, Bid		Not Reported	

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		Tepazepam		S	Unknown	Unk Unk, Qd		Not Reported	
		Metoclopramide		C	Unknown	Unk (1 Week Treatment)		Not Reported	
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07-Jun-2018	14672224	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE36458		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Prescribed Underdose	Esomeprazole Magnesium			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral			Not Reported	
	Amlor			S	Oral	Unk		Not Reported	
	Novonorm			S	Oral	Unk		Not Reported	
	Lipanthyl			S	Oral			Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Decapeptyl [Triptorelin Acetate]			S	Intramuscular	1 Df, Cyclic		Not Reported	
	Innohep			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14981935	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US18931			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Omeprazole			C	Unknown	40 Mg, Qd		Not Reported	
	Lorazepam			C	Unknown	0.5 Mg, Upto 8 Hours As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14982133	EXPEDITED (15-DAY)		OT	IT-APOTEX-2018AP015418		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Olanzapine			S	Oral	Unk		Apotex	

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Venlafaxine	S	Oral	1 Df, Daily	Apotex
Ciprallex /01588501/	S	Oral	Unk	Not Reported
Delorazepam	S	Oral	Unk	Not Reported
Donepezil	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Madopar	C	Unknown	Unk	Not Reported
Terazosin Hydrochloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14983566	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18- 04		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Serotonin Syndrome	Lorazepam			S	Unknown			Westward
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14983680	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1829305US		51 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Tranxene			S	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985048	EXPEDITED (15-DAY)		DS, HO	CA-MYLANLABS- 2018M1038221		89 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Motor Dysfunction; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Not Reported	
	Heparin			S	Subcutaneous	5000 U Every 12 Hours		Not Reported	
	Rivaroxaban			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985127	EXPEDITED (15-DAY)		HO, OT	BE-MACLEODS PHARMACEUTICALS US LTD- MAC2018014148			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Aripiprazole Tablet			S	Oral	Unk, Tablet		Macleods	
	Aripiprazole Tablet			S	Oral	20 Milligram		Macleods	
	Escitalopram Oxalate			S	Oral	20 Milligram		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985149	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018014156			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole Tablet			S	Oral	210 Milligram, Total		Macleods	
	Escitalopram Tablet			S	Oral	140 Milligram, Total, Abuse / Misuse		Macleods	
	Alprazolam			S	Oral	15 Milliliter, Total		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Milligram, Total, 25 Mg Covered Tablets, Abuse / Misuse		Not Reported	
	Zitromax			S	Oral	1500 Milligram, Total, 500 Mg Coated Tablets With Film		Not Reported	

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07-Jun-2018	15076132	DIRECT	N	OT			29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Panic Attack	Escitalopram Oxalate			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	13323555	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1709333US		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	20 Mg, In Total		Allergan	
	Clozapine			S	Oral	100 Mg, In Total		Not Reported	
	Lorazepam			S	Oral	1 Mg, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	13335968	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-135809		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg Total		Sun	
	Clozapine			S	Oral	100 Mg Total		Sun	
	Entact			S	Oral	20 Mg Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	13679510	NON-EXPEDITED			US-ALLERGAN-1716426US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	

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Bentyl Capsules

S

Unknown

Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14336241	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-158208		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Irbesartan			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Sun
	Pantoprazole			S	Oral	20 Mg, Once Daily (Qd)		Sun
	Metformine			S	Oral	500 Mg, 2x/Day (Bid)		Sun
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid) ()		Not Reported
	Amlodipine			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Sun
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Once Daily (Qd)		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day (Tid)		Not Reported
	Alprazolam			S	Oral	0.25 Mg, 3x/Day (Tid)		Not Reported
	Tavanic			S	Oral	250 Mg, 2x/Day (Bid)		Not Reported
	Xarelto			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Diazepam			S	Oral	10 Mg, 3x/Day (Tid)		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, Once Daily (Qd)		Not Reported
	Seroplex			S	Oral	1 Df, Once Daily (Qd)		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day (Tid)		Not Reported
	Diffu-K			S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid) ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14987961	EXPEDITED (15-DAY)		HO, LT, OT	TR-OTSUKA- DJ201404925		31 YR	Female	TUR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Incontinence; Drug Interaction; Overdose; Suicide Attempt; Urinary Incontinence	Aripiprazole			S	Oral	14 Tabs		Otsuka	
	Escitalopram			S	Oral	20 Tabs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14988729	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMP ANY-US201805014720		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Serotonin Syndrome	Olanzapine			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co	
	Escitalopram			S	Unknown	Unk Unk, Unknown		Not Reported	
	Mirtazapine			S	Unknown	Unk Unk, Unknown		Not Reported	
	Trazodone			S	Unknown	Unk Unk, Unknown		Not Reported	
	Lorazepam			S	Unknown	Unk Unk, Unknown		Not Reported	
	Gabapentin			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14991226	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2017-032995			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Diazepam			S	Unknown	5 Mg		Not Reported	
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Df = 20/12.5 Mg		Not Reported	
	Paracetamol			S	Unknown	3 Dosage Forms Daily 1g		Not Reported	
	Simvastatin			S	Unknown	1 Dosage Form Daily 40 Mg		Not Reported	
	Simvastatin			S	Unknown	Reduced Dose		Not Reported	
	Topiramate			S	Unknown	0.5 Dosage Forms Daily		Not Reported	
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Not Reported	
	Tramadol/Paracetamol			S	Unknown			Not Reported	

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Naproxen	S	Unknown	2 Dosage Forms Daily	Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported
Amitriptyline Hydrochloride	S	Unknown	Once A Day	Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported
Topiramato	S	Unknown		Not Reported
Amlodipine	S	Unknown	1 Dosage Forms Daily	Not Reported
Glibenclamide	S	Unknown		Not Reported
Escitalopram	S	Unknown	1 Dosage Forms Daily	Not Reported
Omeprazole	S	Unknown	1 Dosage Forms Daily; 20 Mg	Not Reported
Lormetazepam	S	Unknown	1 Mg	Not Reported
Tepazepam	S	Unknown		Not Reported
Metoclopramide	C		1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2018	14992335	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-029859		77 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Encephalopathy	Amiodarone			S	Oral	200 Milligram, Once A Day		Aurobindo
	Allopurinol			S	Oral	100 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Topalgic Lp			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Oxynormoro			S	Oral	5 Milligram		Not Reported
	Xanax			S	Oral	0.38 Milligram, Once A Day		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Once A Day		Not Reported

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Tazocilline	S	Intravenous (not otherwise specified)	3 Dosage Form, Once A Day	Not Reported
Mycophenolate Sodium	C	Oral	360 Milligram, Once A Day	Not Reported
Ciclosporine	C	Oral	100 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2018	14992410	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-903347		20 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error; Product Prescribing Error; Product Prescribing Error	Escitalopram			S		Nk		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2018	14992415	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014219			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Olanzapine			S	Oral	Unk		Macleods	
	Venlafaxine			S	Oral	1 Dosage Form, Qd		Macleods	
	Cipralext			S	Oral	Unk		Not Reported	
	Delorazepam			S	Oral			Not Reported	
	Donepezil			C	Unknown	Unk		Macleods	
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported	
	Madopar			C	Unknown	Unk		Not Reported	
	Terazosin Hydrochloride			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2018	14992562	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS			Unknown	USA

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US LTD-
MAC2018014213

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Serotonin Syndrome	Olanzapine			S	Unknown	Unk		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Lorazepam			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2018	14676925	EXPEDITED (15-DAY)		OT	US-TORRENT-00005954		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S		Unknown		Unknown
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Unknown
	Venlafaxine			S				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2018	15097716	DIRECT		OT			18 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Product Substitution Issue	Generic Escitalopram Oxalate	Y		S	Oral	Quantity:1 Tablet(S);		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14678924	EXPEDITED (15-DAY)		OT	DE-ACCORD-064558			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Amenorrhoea; Dysmenorrhoea; Menorrhagia	Escitalopram	S	Daily	Not Reported
	Valdoxan	S	Also Received Unknown Dose From Unknown Date	Not Reported
	Zoely	S	Oral One Tablet A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14931571	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018013579			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Self-Injury; Overdose; Sopor	Escitalopram			S	Oral	600 Milligram, Oral Drops, Total		Macleods
	Minias 2.5 Mg / MI			S	Oral	100 Milligram, Oral Drops, Total		Not Reported
	Paroxetine 20 Mg			S	Oral	200 Milligram, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14954354	EXPEDITED (15-DAY)		OT	PHHY2018FR011469			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Novartis
	Seroplex			S	Oral	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14971924	EXPEDITED (15-DAY)		HO	BE-AUROBINDO-AUR- APL-2018-028824		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration;	Aripiprazole Tablets			S	Oral	20 Mg, Unk		Aurobindo
Hospitalisation; Lactation Disorder; Live Birth;	Aripiprazole Tablets			S	Unknown	Unk ()		Aurobindo
Maternal Exposure During Pregnancy; Pregnancy;	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

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Product Use In
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14993570	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-030305		85 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Aurobindo
	Venlafaxine			S	Oral	1 Dosage Form, Daily		Aurobindo
	Cipralex /01588502/			S	Oral	Unk		Not Reported
	Donepezil			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Madopar			C	Unknown	Unk		Not Reported
	Terazosin Hydrochloride			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14993731	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE- 904129		44 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	1-0-0		Ivax
	Ibuprofen			S	Unknown	Nk		Actavis
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported
	Bornaprin			S	Unknown	1-0.5-1-0		Not Reported
	Madopar Depot			C	Unknown	100 25 Mg, 0-0-0-1		Not Reported
	Madopar Depot			C	Unknown	100 25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Depot			C	Unknown	100 25 Mg, 1-0-0-0		Not Reported
	Amantadin			C	Unknown	1-1-0-0		Not Reported
	Amitriptylin			C	Unknown	0-0-0-1		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994053	EXPEDITED (15-DAY)		OT	FR-MERCK KGAA-2049233		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Novothyrox			S	Oral			Merck Kgaa	
	Escitalopram			S	Oral			Not Reported	
	Naproxene			S	Oral			Not Reported	
	Bromazepam			S	Oral			Not Reported	
	Irbesartan			S	Oral			Not Reported	
	Fenofibrate			S	Oral			Not Reported	
	Pregabaline			S	Oral			Not Reported	
	Pregabaline			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994869	NON-EXPEDITED			US-PFIZER INC-2018237389		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor			S		Unk		Pfizer	
	Cymbalta			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14995692	EXPEDITED (15-DAY)		OT	AU-TEVA-2018-AU-905663			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Withdrawal Syndrome	Tevaripirazole			S	Unknown			Teva	
	Escitalopram			S	Unknown			Not Reported	
	Aripirazole			S	Unknown			Not Reported	
	Elevit			C				Not Reported	
	Folate			C				Not Reported	

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Aspirin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14996233	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004450		90 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Donepezil Hydrochloride			S	Oral			Unknown	
Blood Pressure Increased;	Escitalopram Oxalate			S	Oral			Unknown	
Dementia Alzheimer'S	Alprazolam			C	Oral			Unknown	
Type; Dizziness; Seizure;	Amitriptyline Hydrochloride			C	Oral	Unknown		Unknown	
Syncope; Vomiting									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14996267	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018230022		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Xanax			S	Oral	3 Df, 1x/Day		Pfizer	
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported	
	Noctamide			S	Oral	2 Df, 1x/Day		Not Reported	
	Zyprexa			S	Oral	1 Df, 1x/Day		Not Reported	
	Tercian /00759301/			S	Oral	100 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14996959	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-905746		37 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia;	Escitalopram			S	Oral	15 Milligram Daily;		Not Reported	
Thrombocytopenia	Naftidrofuryl			C	Oral	200 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14309429	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-TEVA-2017-BE-832465			Male	BEL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Milligram Daily;		Teva
	Pantomed (Dexpanthenol)			S	Transplacental			Not Reported
	Nucala Powder For Solution For Injection			S	Transplacental			Not Reported
	D-Cure			S	Transplacental	25 Kiu		Not Reported
	Flixotide			S	Transplacental	500 Microgram Daily;		Not Reported
	Avamys Nasal Spray			S	Transplacental			Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Milligram Daily;		Not Reported
	Ventolin			S	Transplacental			Not Reported
	Relvar Ellipta Inhalation Powder			S	Transplacental	1 Dosage Forms Daily;		Not Reported
	Sipralaxa Tablet			S	Transplacental			Not Reported
	Seretide			S	Transplacental			Not Reported
	Fluticasone Furoate Inhalation Powder			S	Transplacental			Not Reported
	Vilanterol Trifenatate Inhalation Powder			S	Transplacental			Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Transplacental			Not Reported
	Xyzall			S	Transplacental	5 Milligram Daily;		Not Reported
	Theophylline			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14335627	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MACLEODS PHARMACEUTICALS US LTD- MAC2017007583			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product	Escitalopram Oxalate			S	Oral	10 Milligram, Qd, 10 Mg, Before Sleeping, Doctor Switched The Patient Fromsertraline Toescitalopram		Macleods
	Escitalopram Oxalate			S	Unknown	Unk		Macleods

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Misuse; Loss Of	Escitalopram Oxalate	S				Macleods
Consciousness; Loss Of	Escitalopram Oxalate	S				Macleods
Personal Independence In	Clarithromycin	S	Oral	Unk, Qd, Two 10 Day Courses, Bed Time		Not Reported
Daily Activities; Overdose;						
Product Use In	Clarithromycin	S	Unknown	Unk		Not Reported
Unapproved Indication;	Tramadol Hydrochloride	S	Oral	Unk, Qd, Bed Time, Tramadol In Combination With Meloxicam For About Two Years Ago		Macleods
Suicide Attempt; Tinnitus						
	Tramadol Hydrochloride	S	Unknown	Unk		Macleods
	Tramadol Hydrochloride	S	Unknown	Unk		Macleods
	Tramadol Hydrochloride	S				Macleods
	Atorvastatin	S	Oral	Unk Unk, Qd , Bedtime		Not Reported
	Atorvastatin	S	Unknown	Unk		Not Reported
	Atoris	S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate	S	Intracardiac	Unk		Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate	S	Oral	Unk		Not Reported
	Doxepin	S	Oral	25 Mg, Qd, At Bedtime,At Night		Not Reported
	Doxepin	S				Not Reported
	Doxepin	S				Not Reported
	Doxepin	S				Not Reported
	Perindopril	S	Unknown	Unk		Not Reported
	Perindopril	S	Unknown	Unk		Not Reported
	Perindopril	S	Oral	Unk		Not Reported
	Zolpidem Tartrate	S	Oral	10 Mg, Qd, At Bedtime		Not Reported
	Zolpidem Tartrate	S				Not Reported
	Sertraline	S	Oral	50 Mg, Qd Am, In The Morning		Not Reported
	Sertraline	S				Not Reported
	Movalis	S	Oral	Unk, Qd, Bed Time, Tramadol In Combination With Meloxicam, For		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				About Two Years Ago	
Movalis	S				Not Reported
Movalis	S				Not Reported
Polisen	S	Oral	10 Mg, Qd, At Bed Time		Not Reported
Polisen	S				Not Reported
Concor	S	Unknown	Unk		Not Reported
Trosicam	S	Unknown	Unk, Taken Since About 2 Years		Not Reported
Trosicam	S	Unknown	Unk		Not Reported
Trosicam	S		Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14893122	EXPEDITED (15-DAY)		HO	AU-ALLERGAN-1825583US		50 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delusion;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
Eczema; Emotional	Clozaril			S	Oral	700 Mg, Qd		Not Reported
Distress; Eosinophil Count	Olanzapine			S	Unknown	5 Mg, Unk		Not Reported
Decreased; Feeling Cold;	Paliperidone Depot			S	Unknown	100 Mg, Qd		Not Reported
Frustration Tolerance	Caltrate			C	Unknown	Unk		Not Reported
Decreased; Haemoglobin	Lorazepam			C	Unknown	Unk		Not Reported
Decreased; Hallucination,	Lurasidone			C	Unknown	Unk		Not Reported
Auditory; Hyperhidrosis;	Metformin			C	Unknown	Unk		Not Reported
Intentional Self-Injury;	Mirtazepine Teva			C	Unknown	Unk		Not Reported
Lymphocyte Count	Crestor			C	Unknown	Unk		Not Reported
Decreased; Mean Cell	Zuclopenthixol-Form-Unknown			C	Unknown	Unk		Not Reported
Haemoglobin Decreased;	Calcium Carbonate			C	Unknown	Unk		Not Reported
Mental Impairment;	Rosuvastatin			C	Unknown	Unk		Not Reported
Metamyelocyte Count								
Increased; Mitral Valve								
Incompetence; Monocyte								
Count Decreased;								
Myelocyte Count								
Increased; Neutropenia;								
Platelet Count Increased;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmonary Valve Incompetence; Thermal Burn; Tinea Infection; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Coloxyl	C	Unknown	Unk	Not Reported
	Senna	C	Unknown	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Vitamin B12	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14998706	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-905171		77 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk		Ivax
	Eferox			C		50 Mg, 1-0-0-0		Not Reported
	Hct			C		12.5 Mg, 1-0-0-0		Not Reported
	Metoprolol			C		47.5 Mg, 1-0-0-0		Not Reported
	Ventolair			C		250 Mg, 2-0-0-2		Not Reported
	Metamizole			C		500 Mg, 1-1-1-0		Not Reported
	Valsartan			C		80 Mg, 0.5-0-0-1		Not Reported
	Ass 100			C		100 Mg, 0-1-0-0		Not Reported
	Simvastatin			C		40 Mg, 0-0-0-1		Not Reported
	Pantoprazol			C		20 Mg, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14998989	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US19044			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Non-Responder	Levetiracetam			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Clonazepam			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Clobazam			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14999667	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1830029US		74 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Cognitive Disorder; Delusion; Depression; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Lexotanil			S	Oral	3.5 Mg, Qd		Not Reported	
	Olanzapine			C	Unknown			Not Reported	
	Enoxaparin			C	Unknown	Unk, Unknown		Not Reported	
	Acetylsalicylic Acid			C	Unknown	Unk, Unknown		Not Reported	
	Ascorbic Acid			C	Unknown	Unk, Unknown		Not Reported	
	Gabapentin			C	Unknown	Unk, Unknown		Not Reported	
	Ibuprofen			C	Unknown	Unk, Unknown		Not Reported	
	Ondansetron			C	Unknown	Unk, Unknown		Not Reported	
	Paracetamol			C	Unknown	Unk, Unknown		Not Reported	
	Picosulfate			C	Unknown	Unk, Unknown		Not Reported	
	Esomeprazole			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15000980	EXPEDITED (15-DAY)		OT	PHHY2018FR018228		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Malaise	Gilenya			S	Oral	1 Df, Qd		Novartis	
	Seroplex			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15001796	EXPEDITED (15-DAY)		DS	GB-TEVA-2018-GB-906362		33 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram			S	Oral			Ivax	

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Lansoprazole

C

30 Milligram Daily;

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15002172	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ALLERGAN-1830406US		37 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan
	Metformin Hydrochloride			C	Unknown	Unk, Unknown		Not Reported
	Generics Uk Nifedipine			C	Unknown	Unk Unk, Unknown		Not Reported
	Pregabalin			C	Unknown	Unk, Unknown		Not Reported
	Nefopam			C	Unknown	Unk, Unknown		Not Reported
	Tiotropium			C	Unknown	Unk, Unknown		Not Reported
	Sodium Picosulfate			C	Unknown	Unk, Unknown		Not Reported
	Cetirizine			C	Unknown	Unk, Unknown		Not Reported
	Naproxen			C	Unknown	Unk, Unknown		Not Reported
	Diazepam			C	Unknown	Unk, Unknown		Not Reported
	Cassia (Senna Alexandrina)			C	Unknown	Unk, Unknown		Not Reported
	Methotrexate Sodium			C	Unknown	Unk, Unknown		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk, Unknown		Not Reported
	Lansoprazole			C	Unknown	Unk, Unknown		Not Reported
	Meptazinol			C	Unknown	Unk, Unknown		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk, Unknown		Not Reported
	Temazepam			C	Unknown	Unk, Unknown		Not Reported
	Montelukast			C	Unknown	Unk, Unknown		Not Reported
	Pyridoxine			C	Unknown	Unk, Unknown		Not Reported
	Folic Acid			C	Unknown	Unk, Unknown		Not Reported
	Adcal-D3			C	Unknown	Unk, Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14253811	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2017SF20968		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Candesartan			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Aripiprazole			S	Oral			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	Risperdal			C	Unknown			Not Reported
	L-Thyroxin			C	Oral	100ug/Inhal Daily		Not Reported
	Amisulpride			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14301361	EXPEDITED (15-DAY)		OT	ES-ASTRAZENECA-2017SF23248			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Omeprazole			S	Oral			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Simvastatin			S	Unknown	20 Mg		Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Paracetamol, Tramadol			S	Unknown	37.5/325 Mg, 3 Df Daily		Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Tepazepam			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Glibenclamide			S	Unknown			Not Reported
	Lormetazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Metoclopramide			C	Unknown	1 Week Treatment		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14311091	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2017007014			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Besylate Tablet			S	Oral	1 Df, Qd		Macleods
	Amitriptylline			S	Unknown	12.5 Mg, Qd		Not Reported
	Amitriptylline			S	Unknown	25 Mg, Unk		Not Reported
	Amitriptylline			S	Unknown	5 Mg, Qd		Not Reported
	Amitriptylline			S	Unknown	10 Mg, Qd		Not Reported
	Amitriptylline			S		Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 10 Mg		Macleods
	Paracetamol			S	Unknown	3 Df, Qd;		Not Reported
	Paracetamol			S	Unknown	1 Df, Qd, 3 Dosage Form Daily;1 Df= 37.5/325 Mg		Not Reported
	Tramadol / Acetaminophen			S	Unknown	1 Df, Tid; 1 Df=37.5/325 Mg		Macleods
	Omeprazole			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 20 Mg		Not Reported
	Diazepam, Sulpiride			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	0.5 Df, Qd, 5 Dosage Forms Daily; 5 Mg		Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown	1 Df, Qd; 1 Df= 20/12.5 Mg		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Glibenclamide			S	Unknown	2 Df, Qd		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Simvastatin			S	Unknown	1 Df, Qd, 1 Dosage Forms Daily; 40 Mg		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported
	Topiramate			S	Unknown	1 Df, Qd, 50 Mg		Not Reported
	Metoclopramide			C	Unknown	Unk, 1 Week Treatment		Not Reported

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13-Jun-2018	14339621	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-AUROBINDO-AUR-APL-2017-48301		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Tramadol			S	Oral	B/D ()		Aurobindo	
	Tramadol			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo	
	Tramadol			S		()		Aurobindo	
	Tramadol			S	Unknown	()		Aurobindo	
	Tramadol			S	Unknown	()		Aurobindo	
	Tramadol			S	Unknown	()		Aurobindo	
	Tramadol			S	Unknown	()		Aurobindo	
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo	
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo	
	Tramadol			S	Unknown	()		Aurobindo	
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo	
	Tramadol			S	Unknown	Tramadol In Combination With Meloxicam For About Two Years Ago ()		Aurobindo	
	Perindopril			S	Unknown	Unk		Aurobindo	
	Perindopril			S	Oral	Unk ()		Aurobindo	
	Perindopril			S	Unknown	()		Aurobindo	
	Perindopril			S	Unknown	()		Aurobindo	
	Perindopril			S	Unknown	()		Aurobindo	

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Perindopril	S	Unknown	()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Oral	Unk ()	Aurobindo
Perindopril	S	Unknown	Unk ()	Aurobindo
Sertraline	S	Unknown	50 Mg In The Morning	Aurobindo
Sertraline	S	Oral	50 Mg, Od, (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Sertraline	S	Unknown	50 Mg, Qd	Aurobindo
Sertraline	S	Oral	50 Mg, Am (In The Morning)	Aurobindo
Escitalopram	S	Unknown	Unk	Aurobindo
Escitalopram	S	Oral	10 Mg, Before Sleeping	Aurobindo
Escitalopram	S	Unknown	Unk ()	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Unknown	()	Aurobindo
Escitalopram	S	Oral	Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Oral	Doctor Switched The Patient From Sertraline To	Aurobindo

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Escitalopram	S	Oral	Escitalopram Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Escitalopram	S	Unknown	Doctor Switched The Patient From Sertraline To Escitalopram	Aurobindo
Escitalopram	S	Oral	10 Mg, Hs	Aurobindo
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Unknown	()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Atorvastatin	S	Oral	Unk (Bedtime) ()	Not Reported
Bisoprolol	S	Unknown	Unk	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Bisoprolol	S	Unknown	Unk ()	Aurobindo
Trosicam	S	Unknown	Unk	Not Reported
Trosicam	S	Unknown	()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Trosicam	S	Unknown	Unk ()	Not Reported
Concor	S	Unknown	Unk	Not Reported
Concor	S	Unknown	Unk ()	Not Reported

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Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Concor	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	Two 10 Day Courses	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Oral	B/D ()	Not Reported
Clarithromycin	S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses ()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	()	Not Reported
Clarithromycin	S	Unknown	Two 10 Day Courses ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Clarithromycin	S	Oral	Total Drug Duration: 2 X 10 Days ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Clarithromycin	S	Oral	Two 10 Day Cycles. ()	Not Reported
Atoris	S	Unknown	Unk	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Atoris	S	Unknown	()	Not Reported
Polisen	S	Unknown	10 Mg At Bedtime	Not Reported
Polisen	S	Unknown	10 Mg At Bedtime	Not Reported
Polisen	S	Oral	10 Mg At Bedtime	Not Reported
Polisen	S	Oral	10 Mg At Bedtime	Not Reported
Polisen	S	Oral	10 Mg At Bedtime	Not Reported
Doxepin	S	Unknown	25 Mg At Bedtime	Not Reported

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Doxepin	S		()	Not Reported
Doxepin	S		()	Not Reported
Doxepin	S		25 Mg, Od, At Bed Time	Not Reported
Doxepin	S		()	Not Reported
Doxepin	S	Unknown		Not Reported
Doxepin	S	Unknown	25 Mg At Bedtime	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Doxepin	S	Oral	25 Mg, Hs	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Zolpidem	S	Oral	10 Milligram Daily; At Bedtime	Not Reported
Movalis	S	Unknown	Tramadol In Combination With Meloxicam, For About Two Years Ago ()	Not Reported
Perindopril	C		()	Not Reported
Perindopril	C		()	Not Reported
Perindopril	C		()	Not Reported
Atorvastatin	C		()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14649919	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1813926US		45 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyperventilation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qpm		Allergan

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		Bisoprolol	C	Oral	2.5 Mg, Q12h			Not Reported	
		Amiodarone Hydrochloride	C	Oral	50 Mg, Q12h			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14676018	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0097005		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Venlafaxine Hydrochloride			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14745797	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE-IT2018058180		46 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral	In Total		Glaxosmithkline	
	Efexor			S	Oral	In Total		Glaxosmithkline	
	Lamictal			S	Oral	In Total		Glaxosmithkline	
	Lexotan			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14903682	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1031929		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Bisoprolol			S				Not Reported	
	Escitalopram			S		5 Mg, Unk		Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15003350	EXPEDITED (15-DAY)		OT	AU-TEVA-2018-AU-905662			Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gestational Diabetes; Hypotension	Aripiprazole			S	Unknown			Teva	
	Escitalopram			S	Unknown			Not Reported	
	Elevit			C				Not Reported	
	Folate			C				Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15003949	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-906716		45 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	
	Desloratadine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15004066	EXPEDITED (15-DAY)		OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-2018-03963		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Seizure; Torsade De Pointes; Ventricular Fibrillation	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Alkem	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15004134	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-175651		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole			S	Oral	In Total		Not Reported	
	Zitromax 500 Mg Compresse			S	Oral	In Total		Not Reported	
	Rivestite Con Film								
	Prozin 25 Mg Compresse			S	Oral	In Total		Not Reported	

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Rivestite									
Escitalopram		S	Oral	In Total					Not Reported
Alprazolam		S	Oral	In Total					Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15006597	NON-EXPEDITED			US-US WORLDMEDS, LLC-USW201709- 001361			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Delusion	Apokyn			S	Subcutaneous			Us Worldmeds
	Mirapex			S				Not Reported
	Sinemet			S				Not Reported
	Nuplazid			S				Not Reported
	Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	11148954	EXPEDITED (15-DAY)		HO, OT	PHHY2015US010045			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthralgia;	Lioresal Intratecal			S	Intrathecal	968.7 Ug, Qd		Not Reported
Asterixis; Asthenia; Device	Lioresal Intratecal			S	Intrathecal	50 Ug/Bolus		Not Reported
Damage; Dizziness; Drug	Lioresal Intratecal			S	Intrathecal	30 Ug/Bolus		Not Reported
Withdrawal Syndrome;	Lioresal Intratecal			S	Intrathecal	968.7 Ug, Qd		Not Reported
Headache; Lethargy; Loss	Lioresal Intratecal			S	Intrathecal	931.8 Ug, Qd		Not Reported
Of Consciousness;	Lioresal Intratecal			S	Intrathecal	1017.7 Ug, Qd		Not Reported
Memory Impairment;	Lioresal Intratecal			S	Intrathecal	806.3 Ug, Qd		Not Reported
Micturition Urgency; Mood	Lioresal Intratecal			S	Intrathecal	806.3 Ug, Qd		Not Reported
Altered; Pollakiuria;	Lioresal Intratecal			S	Intrathecal	806.3 Ug, Qd		Not Reported
Seizure; Sleep Disorder;	Carbamazepine			S	Unknown	Unk		Novartis
Somnolence; Tremor;	Lexapro			S	Oral	Unk		Not Reported
Urinary Retention; Vision	Vimpat			S	Unknown	Unk		Not Reported
Blurred	Efexor Xr			C	Unknown	75 Mg, Qd		Not Reported
	Efexor Xr			C	Unknown	Unk (Increased Dose)		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	13926309	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1748408US		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Dextromethorphan/Promethazine			S	Unknown			Not Reported	
	Dextromethorphan/Promethazine			S				Not Reported	
	Amlodipine			C	Unknown	5 Mg, Q12h		Not Reported	
	Labetalol			C	Unknown	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	13950218	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-TEVA-803404ISR		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Condition Aggravated; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Movalis			S	Oral	Tramadol In Combination With Meloxicam, At Bedtime.		Teva	
	Movalis			S	Unknown			Teva	
	Perindopril			S	Oral			Not Reported	
	Perindopril			S	Unknown			Not Reported	
	Atorvastatin			S	Oral	At Bedtime.		Teva	
	Atorvastatin			S	Unknown			Teva	
	Sertraline			S	Oral	50 Milligram Daily; At The Morning		Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Zolpidem			S	Oral	10 Milligram Daily; Before Bedtime		Teva	
	Zolpidem			S				Teva	
	Zolpidem			S				Teva	
	Escitalopram			S	Oral	Doctor Switched The		Ivax	

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Escitalopram	S	Unknown	Patient From Sertraline To Escitalopram, Before Sleeping 10mg.	Ivax
Escitalopram	S		Doctor Switched Patient From Sertraline To Escitalopram Oxalate	Ivax
Doxepin	S	Oral	25 Milligram Daily; At Night	Not Reported
Doxepin	S	Unknown		Not Reported
Doxepin	S			Not Reported
Bisoprolol	S	Oral		Duramed
Tramadol	S	Oral	Tramadol In Combination With Meloxicam; At Bedtime.	Not Reported
Tramadol	S			Not Reported
Tramadol	S			Not Reported
Clarithromycin	S	Oral	Total Drug Duration: 2 X 10 Days	Not Reported
Atoris	S	Unknown		Not Reported
Polisen	S	Oral	10 Milligram Daily; At Bed Time	Not Reported
Polisen	S			Not Reported
Concor	S	Unknown		Not Reported
Trosicam	S	Oral		Not Reported
Trosicam	S			Not Reported
Atorvastatin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	14760380	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018012584			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Escitalopram	S	Oral	300 Mg, Unk, Toatal	Macleods
	Efexor	S	Oral	7 Df, Unk, 37,5 Mg Prolonged-Release Hard Capsules, Toatal	Not Reported
	Lexotan	S	Oral	20 ML, Unk, 2,5 Mg/ML Oral Drops Solution, Toatal	Not Reported
	Lamictal	S	Oral	1400 Mg, Unk, 100 Mg Chewable / Dispersible Tablets, Toatal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	14992582	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-030838		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Serotonin Syndrome	Escitalopram			S	Unknown	()		Aurobindo
	Mirtazapine			S	Unknown	()		Aurobindo
	Olanzapine			S	Unknown	()		Aurobindo
	Trazodone			S	Unknown	()		Aurobindo
	Lorazepam			S	Unknown	()		Aurobindo
	Gabapentin			C		()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15009367	EXPEDITED (15-DAY)		DE	IE-TEVA-2018-IE- 907928		40 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Oral	Duration: 10mg For 1 Month Moved To 15mg For 1 Month.		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15009797	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS			Unknown	FRA

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US LTD-
MAC2018014264

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Aldactazine Divisible Coated Tablet			S	Oral	1 Dosage Form, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15009884	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-031125		46 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor	Escitalopram			S	Oral	In Total		Aurobindo
	Lexotan			S	Oral	In Total		Not Reported
	Efexor			S	Oral	In Total		Not Reported
	Lamictal			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15011260	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2018-CA- 905536		89 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extradural Haematoma; Motor Dysfunction; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Ivax
	Rivaroxaban			S	Oral			Not Reported
	Unfractionated Heparin			S	Subcutaneous	5000 U Every 12 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15011831	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE- 907562		55 YR	Female	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Nk		Ivax	
	Acetylsalicylsaeure			C	Unknown	Nk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15013091	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1039907		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Bisoprolol			S	Oral	10 Mg, Unk		Not Reported	
	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported	
	Modopar			S	Oral	3 Df, Unk		Mylan	
	Risperdal			S	Oral	Unk		Mylan	
	Seroplex			S	Oral	1 Df, Unk		Mylan	
	Kardegic			C	Oral	1 Df, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15013599	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1830857US		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Stresam			S	Oral	2 Df, Unk		Not Reported	
	Tanganil			C	Oral	4 Df, Unk		Not Reported	
	Mopral			C	Oral	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15125285	DIRECT		DS, HO			24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Impaired Quality Of Life	Zoloft			S				Not Reported	
	Wellbutrin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro	S	Not Reported
Seroquel	S	Not Reported
Adderall	C	Not Reported
Bystolic	C	Not Reported
Vitamins	C	Not Reported
Vitamin D Nos	C	Not Reported
Vitamin C	C	Not Reported
Magnesium	C	Not Reported
Fish Oil	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	14894940	EXPEDITED (15-DAY)		DE, HO, OT	DE-TORRENT-00008396		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Product Use Issue; Respiratory Failure	Exodus (Escitalopram Oxalate)			S		Unknown		Unknown
	Phenobarbital			S		Unknown		Unknown
	Sildenafil Citrate			S		Unknown		Unknown
	Spironolactone			S		Unknown		Unknown
	Synagis			S	Intramuscular			Unknown
	Topiramate			S	Unknown	Unknown		Unknown
	Varivax			S	Intramuscular	1 Df		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	14907415	EXPEDITED (15-DAY)		DE, HO, OT	DE-DRREDDYS-GER/GER/18/0098908		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil			S	Unknown			Not Reported
	Spironolactone			S				Not Reported
	Phenobarbital			S				Not Reported
	Varivax			S	Intramuscular	1 Df		Not Reported
	Topiramate			S				Not Reported
	Synagis			S	Intramuscular			Not Reported
	Exodus (Escitalopram Oxalate)			S				Not Reported
	Nutrition With Nutrini Mixed With			C	Other			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Water

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014558	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-907350		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia;	Risperidone			S	Oral			Pliva	
Extrapyramidal Disorder;	Escitalopram			S	Oral			Not Reported	
Mydriasis; Sinus	Theralene			C	Oral	Dosage Not Specified		Not Reported	
Tachycardia									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014644	EXPEDITED (15-DAY)		OT	CH-TEVA-2018-CH-909203		58 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome	Escitalopram Mepha 5 Mg			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014907	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014268			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Escitalopram Oxalate			S	Oral	20 Milligram		Macleods	
	Irbesartan			S	Oral			Macleods	
	Bromazepam			S	Oral	18 Milligram		Not Reported	
	Fenofibrate			S	Oral			Not Reported	
	Levothyroxine Sodium			S	Oral			Not Reported	
	Naproxene			S	Oral			Not Reported	
	Pregabalin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014917	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018014267			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Omeprazole Mylan 20 Mg			S	Oral	20 Milligram, Qd		Not Reported
	Ramipril Mylan 5 Mg			S	Oral	5 Milligram, Qd, Tablet Breakable		Not Reported
	Alendronic Acid			C	Oral	70 Milligram, 1 Second		Not Reported
	Calperos D3			C	Oral	500 Milligram, Qd, Sucking Tablet		Not Reported
	Ceris 20 Mg			C	Oral	40 Milligram, Qd		Not Reported
	Icaz Lp 2.5 Mg			C	Oral	2.5 Milligram, Qd		Not Reported
	Lactulose Mylan 10 G/15 MI			C	Oral	10 Gram, Qd, Oral Solution In Sachet		Not Reported
	Sodium Alginate Sodium Bicarbonate Mylan			C	Oral	4 Dosage Form, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014939	EXPEDITED (15-DAY)		DS	DE-AUROBINDO-AUR- APL-2018-027044			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Gait Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram 10 Mg			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram 10 Mg			S	Oral	20 Milligram, Once A Day		Aurobindo
	Oxazepam			S	Oral	10 Milligram, Once A Day, (At Night)		Not Reported
	Monostep			C	Oral	()		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15015866	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-031060		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo	
	Aldactazine			S	Oral	1 Dosage Form, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016120	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1830894US		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Amiodarone			S	Oral	200 Mg, Qd		Not Reported	
	Topalgic Lp			S	Oral	3 Df, Qd		Not Reported	
	Oxynormoro			S	Oral	5 Mg, Qd		Not Reported	
	Xanax			S	Oral	0.38 Mg, Qd		Not Reported	
	Kardegic			S	Oral	1 Df, Qd		Not Reported	
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, Qd		Not Reported	
	Allopurinol			S	Oral	100 Mg, Qd		Not Reported	
	Mycophenolate Sodium			C	Oral	360 Mg, Qd		Not Reported	
	Ciclosporine			C	Oral	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016366	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1830912US		65 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiogenic Shock; Drug Abuse; Hypotension; Intentional Overdose; Somnolence; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	12 Dosage Forms In Total (Overdose)		Allergan	
	Anafranil			S	Oral	30 Df In Total		Not Reported	
	Cardensiel			S	Oral	20 Df, In Total		Not Reported	
	Nordazepam			S	Oral	4 Df, In Total		Not Reported	
	Lysanxia			S	Oral	12 Df, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016414	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1830909US		86 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Prescription Drug Used Without A Prescription; Spinal Fracture	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016425	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1830904US		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Malaise; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016884	EXPEDITED (15-DAY)		HO, OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN00286		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Overdose; Rhabdomyolysis; Serotonin Syndrome;	Escitalopram			S	Oral			Prinston Pharmaceutical	
	Lamotrigine			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Sinus Tachycardia;
Toxicity To Various
Agents; Unresponsive To
Stimuli

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15017948	EXPEDITED (15-DAY)		HO, OT	US-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00220		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left; Overdose; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Unresponsive To Stimuli	Escitalopram			S	Oral			Jubilant
	Lamotrigine			S	Oral			Jubilant

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15018271	EXPEDITED (15-DAY)		OT	TR-MYLANLABS- 2018M1041109		34 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Sinus Bradycardia	Cetirizine			S	Oral	Started On Hospitalisation Day 26 And Discontinued On Hospitalisation Day 28		Not Reported
	Escitalopram			S	Unknown			Not Reported
	Ampicillin			C	Intravenous (not otherwise specified)			Mylan
	Pantoprazole			C	Unknown			Mylan
	Enoxaparin			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15018400	EXPEDITED (15-DAY)		OT	ES-CANTON LABORATORIES, LLC- 2049500			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Depression; Dizziness;	Naprosyn	S	Unknown	Canton Laboratories
Drug Ineffective; Fall;	Amitriptyline Hydrochloride	S	Unknown	Not Reported
Headache; Insomnia; Pain	Amitriptyline Hydrochloride	S	Unknown	Not Reported
In Extremity; Somnolence;	Amitriptyline Hydrochloride	S	Unknown	Not Reported
Treatment Noncompliance	Amlodipine	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Diazepam	S	Unknown	Not Reported
	Enalapril Maleate And Hydrochlorothiazide	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported
	Glibenclamide	S	Unknown	Not Reported
	Lormetazepam	S	Unknown	Not Reported
	Omeprazole	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Paracetamol And Tramadol	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Simvastatin	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Metoclopramide	C	Unknown	Not Reported
	Diazepam Sulpride	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2018	15018978	EXPEDITED (15-DAY)		HO	ZA-DRREDDYS-SAF/SAF/18/0100478			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation	Dopaquel			S	Oral			Not Reported	
	Cardicor			S	Oral			Not Reported	
	Lexamil			S	Oral			Not Reported	
	Lanoxin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mylan Furosemide	S	Oral	Not Reported
Aldactone	S	Oral	Not Reported
Zopivane	S	Oral	Not Reported
Brazepam	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	13908939	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-057716		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Withdrawal Syndrome; Atrioventricular Block First Degree; Decreased Appetite; Dehydration; Drug Interaction; Hallucination, Auditory; Hallucination, Visual; Serotonin Syndrome; Sleep Talking; Tongue Biting; Viral Upper Respiratory Tract Infection	Escitalopram			S				Accord
	Dextromethorphan/Promethazine			S				Not Reported
	Amlodipine			C				Not Reported
	Labetalol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	14266983	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2017006492			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole			S	Oral	5 Mg, Qd		Macleods
	Aripiprazole			S	Oral	10 Mg, Qd		Macleods
	Candesartan			S	Oral	16 Mg, Qd		Macleods
	Escitalopram			S	Oral	10 Mg, Qd		Macleods
	Escitalopram			S	Oral	15 Mg, Qd		Macleods
	Escitalopram			S	Oral	20 Mg, Qd		Macleods
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported

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Aspirin	C	Oral	100 Mg, Qd	Not Reported
L-Thyroxine Sodium	C	Oral	100 Mg, Qd	Not Reported
Metformin Hydrochloride	C	Oral	1500 Mg, Qd	Macleods
Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Qd	Not Reported
Risperdal	C	Unknown	1.5 Mg, Qd	Not Reported
Risperdal	C	Unknown	2 Mg, Unk (For Nights),Hs	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15019629	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-031290		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Escitalopram			S	Oral	20 Milligram		Aurobindo	
	Bromazepam			S	Oral	18 Milligram		Not Reported	
	Pregabalin			S	Oral	150 Milligram		Not Reported	
	Fenofibrate			S	Oral	67 Milligram		Aurobindo	
	Irbesartan			S	Oral	75 Milligram		Aurobindo	
	Naproxen			S	Oral	1100 Milligram		Aurobindo	
	Levothyroxine Sodium			S	Oral	75 Microgram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15019630	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-031288		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Mirtazapine			S	Oral			Aurobindo	
	Mirtazapine			S	Oral			Aurobindo	
	Bisoprolol			S	Oral			Aurobindo	
	Modopar			S	Oral			Not Reported	
	Risperdal			S	Oral	Inconnue ()		Not Reported	

FDA Adverse Event Reporting System

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Seroplex	S	Oral	Not Reported
Kardegic	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15019937	EXPEDITED (15-DAY)		OT	US-ACI HEALTHCARE LIMITED-2049536		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Serotonin Syndrome	Gabapentin			S	Unknown			Aci Healthcare
	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15020348	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2018-032161		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown			Aurobindo
	Hydrochlorothiazide			S	Unknown			Not Reported
	Gliclazide			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported
	Metformin			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15020510	EXPEDITED (15-DAY)		OT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00351			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Akathisia; Serotonin Syndrome	Gabapentin Tablets,Usip	S		Unk		Sciegen
	Lorazepam	S	Unknown	Unk		Not Reported
	Trazodone	S	Unknown	Unk		Not Reported
	Escitalopram	S	Unknown	Unk		Not Reported
	Mirtazapine	S	Unknown	Unk		Not Reported
	Olanzapine	S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15021112	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016641			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Substitution Issue	Escitalopram			S		Unknown		Torrent	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15021377	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-031260		16 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hypotension; Loss Of Consciousness	Escitalopram Arrow Film-Coated Tablet 20mg			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Tercian /00759301/			S	Oral	25 Gtt, Once A Day		Not Reported	
	Alprazolam Mylan			S	Oral	1.5 Milligram, Once A Day		Mylan	
	Diane			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15021842	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831224US		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Aldactazine			S	Oral	1 Df, Qd		Not Reported	

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Inappropriate Antidiuretic
Hormone Secretion;
Incorrect Dose
Administered; Vertigo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15021863	EXPEDITED (15-DAY)		HO, OT	TR-ALLERGAN-1831007US		71 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15023799	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040541		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Libido Disorder; Priapism	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15023822	EXPEDITED (15-DAY)		OT	PHHY2018ES023314		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction	Escitalopram			S	Oral	1 Df, Qd		Not Reported	
	Enalapril			S	Oral	2 Df, Qd		Novartis	
	Carvedilol			S	Oral	1 Df, Qd		Not Reported	
	Insulin Glargine			S	Unknown	1 Df, Qd		Not Reported	
	Orvatez			S	Oral	1 Df, Qd		Not Reported	
	Lantus			S	Subcutaneous	30 lu, Qd		Not Reported	
	Seguril			S	Oral	1 Df, Qd		Not Reported	
	Lyxumia			C	Subcutaneous	1 Df, Qd (20 Unit(S))		Not Reported	
	Toujeo			C	Subcutaneous	32 lu, Qd		Not Reported	
	Novorapid			C	Subcutaneous			Not Reported	

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Insulin Glargine			C	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15024059	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1040742		44 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported	
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15026768	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-175737			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Allopurinol			S	Oral	100 Mg, Daily		Sun	
	Amiodarone			S	Oral	200 Mg, Daily		Taro	
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Df, Daily		Not Reported	
	Oxynormoro 5 Mg, Comprime Orodispersible			S	Oral	Unk; 5 Mg		Not Reported	
	Seroplex 5 Mg, Comprime Pellicule			S	Oral	1 Df, Daily		Not Reported	
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion			S	Intravenous (not otherwise specified)	3 Df, Daily		Not Reported	
	Topalgic Lp 50 Mg, Comprime A Liberation Prolongee			S	Oral	3 Df, Daily		Not Reported	
	Xanax 0,25 Mg, Comprime Secable			S	Oral	0.38 Mg, Daily		Not Reported	
	Ciclosporine			C	Oral	100 Mg, Daily		Not Reported	
	Mycophenolate Sodique			C	Oral	360 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15141328	DIRECT		OT			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety	Escitalopram			S				Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14270696	EXPEDITED (15-DAY)		HO	DE-OTSUKA-2017_025746		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Prescribed Underdose; Stupor; Vertigo	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka
	Aripiprazole			S	Oral	5 Mg, Qd		Otsuka
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Candesartan			S	Oral	16 Mg, Qd		Not Reported
	L-Thyroxine			C	Oral	100 Mg, Qd		Not Reported
	Metformin			C	Oral	1500 Mg, Qd		Not Reported
	Ass			C	Oral	100 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Mg, Hs		Not Reported
	Risperdal			C	Unknown	2 Mg, Qd		Not Reported
	Risperdal			C	Unknown	1.5 Mg, Qd		Not Reported
	Amisulpride			C	Unknown	200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14280001	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2017-07072		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Aripiprazole	S	Oral	10 Mg, Qd	Not Reported
	Aripiprazole	S	Oral	5 Mg, Qd	Not Reported
	Escitalopram	S	Oral	15 Mg, Qd	Lupin
	Escitalopram	S	Oral	20 Mg, Qd	Lupin
	Escitalopram	S	Oral	10 Mg, Qd	Lupin
	Candesartan	S	Oral	16 Mg, Qd	Not Reported
	Risperdal	C	Unknown	1.5 Mg, Qd	Not Reported
	Risperdal	C	Unknown	2 Mg, Unk (For Nights)	Not Reported
	Risperdal	C	Unknown	2 Mg, Qd	Not Reported
	L-Thyroxin	C	Oral	100 Mcg, Qd	Not Reported
	Amisulpride	C	Unknown	200 Mg, Qd	Not Reported
	Metformin	C	Oral	1500 Mg, Qd	Not Reported
	Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Oral	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14341547	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-158623		50 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Suicide Attempt; Tinnitus; Tinnitus	Atorvastatin			S	Unknown	Unk		Sun
	Clarithromycin			S	Unknown	Unk		Sun
	Clarithromycin			S	Unknown	Two 10 Day Courses		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Atoris			S	Unknown	Unk		Not Reported
	Concor			S	Unknown	Unk		Not Reported
	Doxepin			S	Unknown	25 Mg At Bedtime		Not Reported

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	Polisen	S	Unknown	10 Mg At Bedtime	Not Reported
	Sertraline	S	Unknown	50 Mg, Daily; 50 Mg In The Morning	Not Reported
	Sertraline	S	Unknown	50 Mg, Qd	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Trosicam	S	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14381601	EXPEDITED (15-DAY)		HO, OT	SI-ALLERGAN-1801175US		48 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Sclerosis; Off Label Use; Palpitations	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan	
	Tolterodine			S	Unknown	4 Mg, Qam		Not Reported	
	Fty 720			S	Unknown	0.5 Mg, Qd		Not Reported	
	Fampridine			S	Unknown	10 Mg, Bid		Not Reported	
	Pregabalin			S	Unknown	150 Mg, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14684112	EXPEDITED (15-DAY)		OT	PHHY2017FR115515		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Aliskiren			S	Unknown			Not Reported	
	Digoxin			S	Unknown	Unk		Novartis	
	Amiodarone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
	Bisoprolol			S	Unknown	Unk		Not Reported	

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19-Jun-2018	14961360	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-174430		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Sopor	Escitalopram			S	Oral	In Total		Not Reported	
	Paroxetine			S	Oral	In Total		Sun	
	Minias 2,5 Mg/Ml Gocce Orali, Soluzione			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14981366	EXPEDITED (15-DAY)		HO	IT-OTSUKA- 2018_013993		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Intentional Self- Injury; Partner Stress; Prescribed Overdose; Product Administration Error; Product Use In Unapproved Indication; Sopor	Aripiprazole			S	Oral	210 Mg, Unk		Otsuka	
	Zitromax			S	Oral	1500 Mg, Unk		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Unk		Not Reported	
	Escitalopram Oxalate			S	Oral	140 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	15 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15005737	EXPEDITED (15-DAY)		DE, HO	GB-BAYER-2018- 111680		88 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid(<=100 Mg)			S	Oral	75 Mg, Qd		Bayer	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Dihydrocodeine			C	Oral	120 Mg, Qd		Not Reported	

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19-Jun-2018	15027884	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-176001		34 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported	
	Cetirizine			S	Oral	10 Mg, Daily		Ranbaxy	
	Ampicillin			C	Intravenous (not otherwise specified)	2 G, Q4h		Not Reported	
	Enoxaparin			C	Unknown	60 Mg, Daily		Not Reported	
	Pantoprazole			C	Unknown	40 Mg, Daily		Not Reported	
	Aspirin			C	Unknown	100 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028966	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2018M1040055		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Escitalopram			S	Unknown	Unknown		Not Reported	
	Venlafaxine Hydrochloride			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15029723	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE- 909134		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax	
	Sertraline			C	Transplacental	150 Milligram Daily;		Not Reported	
	Quetiapine			C	Transplacental	25 Milligram Daily;		Not Reported	

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19-Jun-2018	15030158	EXPEDITED (15-DAY)		DS, OT	US-OTSUKA-2018_014850		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disability; Feeling Abnormal; Seizure; Therapeutic Response Unexpected	Rexulti			S	Unknown	Unk		Otsuka	
	Aripiprazole			S	Unknown	Unk		Otsuka	
	Wellbutrin			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Cymbalta			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030556	EXPEDITED (15-DAY)		OT	FR-CANTON LABORATORIES, LLC-2049639		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Naprosyn			S	Oral			Canton Laboratories	
	Bromazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Fenofibrate			S	Oral			Not Reported	
	Irbesartan			S	Oral			Not Reported	
	Levothyroxine Sodium			S	Oral			Not Reported	
	Pregabalin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15031946	EXPEDITED (15-DAY)		OT	PHHY2018DE021143			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Juvenile Myoclonic Epilepsy; Myoclonus	Clozapine			S	Unknown	75 Mg, Unk		Not Reported	
	Oxcarbazepine			S	Unknown	2400 Mg, Unk		Novartis	
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	

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Brivaracetam			S	Unknown	200-250 Mg, Unk			Not Reported	
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19-Jun-2018	15031959	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-910458		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Learning Disorder; Mental Impairment	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15031989	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1040378		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness;	Paracetamol			S	Oral	40 G, Unk		Not Reported	
Disturbance In Attention;	Escitalopram			S	Oral	27 Df, Unk		Not Reported	
Intentional Overdose;	Alprazolam			S	Oral	15 Df, Unk		Not Reported	
Poisoning Deliberate	Codeine			S	Oral	6 Df, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	13953115	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2017-39918		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Cognitive Disorder; Decreased Appetite; Drug Interaction; Electrocardiogram Qt Prolonged; Hallucinations, Mixed; Poor Quality Sleep; Serotonin Syndrome; Sleep Talking	Escitalopram			S	Unknown			Aurobindo	
	Escitalopram			S				Aurobindo	
	Dextromethorphan W/Promethazine			S	Unknown			Not Reported	
	Labetalol			C				Not Reported	
	Amlodipine			C				Not Reported	

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20-Jun-2018	14310552	EXPEDITED (15-DAY)		DE	FI-ALLERGAN-1772900US			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ventricular Fibrillation	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Ciprofloxacin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	14623001	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1813185US		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan	
	Bilaska			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Nocertone			S	Oral			Not Reported	
	Simponi			S	Subcutaneous	50 Mg, Q Month		Not Reported	
	Tramadol			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	14770767	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1820706US		46 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Gases Abnormal; Drug Abuse; Intentional Overdose; Muscle Rigidity; Sopor	Escitalopram Oxalate Unk			S	Oral	300 Mg, Unk (In Total)		Allergan	
	Lexotan			S	Oral	20 MI, Unk (In Total)		Not Reported	
	Efexor			S	Oral	7 Df, Unk (In Total)		Not Reported	
	Lamictal			S	Oral	1400 Mg, Unk (In Total)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	14795109	EXPEDITED (15-DAY)		HO, LT	CZ-PFIZER INC-2018162505			Male	CZE

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Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Epilepsy; Loss Of Consciousness; Overdose; Poisoning	Venlafaxine Hcl			S	Oral	Unk		Pfizer	
	Ibuprofen			S	Unknown	Unk		Pfizer	
	Clonazepam			S	Oral	Unk		Not Reported	
	Levopromazin			S	Oral	Unk		Not Reported	
	Olanzapine			S	Oral	Unk		Not Reported	
	Metoclopramide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Melperone			S	Oral	Unk		Not Reported	
	Amphetamine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15034235	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00546		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram			S	Oral	15 Milligram		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15034415	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-909197		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1,		Teva	
	Quetiapine			S	Oral	100 Mg, 0-0-0-1,		Teva	
	CipraleX 10mg - Filmtabletten			S	Oral	10 Mg, 1-0-0-0,		Not Reported	
	Levothyroxin			C	Oral	75 Mg, 1-0-0-0,		Not Reported	
	Torasemid			C	Oral	10 Mg, 1-0-0-0,		Not Reported	
	Felodipine			C	Oral	10 Mg, 1-0-0-0,		Not Reported	

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20-Jun-2018	15035797	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018248029		83 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Aspavor			S		20 Mg, Unk		Pfizer	
	Zanidip			S		10 Mg, Unk		Not Reported	
	Lasix			S		20 Mg, Unk		Not Reported	
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported	
	Ganfort			S		5 Mg, Unk		Not Reported	
	Ecotrin			S		81 Mg, Unk		Not Reported	
	Glucophage Xr			S		500 Mg, Unk		Not Reported	
	Stilpane (Acetaminophen/Caffeine/Codeine/Phosphate/Meprobamate)			S		Unk		Not Reported	
	Lexamil			S		5 Mg, Unk		Not Reported	
	Bilocor			S		5 Mg, Unk		Not Reported	
	Epleptin			S		100 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15037372	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-908967		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram Daily; 10 [Mg/D]		Ivax	
	Femibion Pregnancy 1 (Nem)			C	Transplacental	.8 Milligram Daily; 0.8 [Mg/D]		Not Reported	
	Vaccine Flu (Seasonal)			C	Transplacental			Not Reported	
	L-Thyroxin			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported	

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20-Jun-2018	15037402	EXPEDITED (15-DAY)		OT	FR-ROCHE-2142065		26 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Valium			S	Oral			Not Reported	
	Theralene			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Lepticur			S	Oral			Not Reported	
	Macrogol			S	Oral			Not Reported	
	Tercian			S	Oral			Not Reported	
	Leponex			S	Oral			Not Reported	
	Xeplion			S	Intramuscular			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15037767	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-911578		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Escitalopram 15 Mg 28 Comprimidos			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15038966	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1831358US		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Completed Suicide	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	13932018	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2017-05022		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Atrioventricular Block First Degree; Drug Interaction; Electrocardiogram Qt Prolonged; Serotonin Syndrome	Escitalopram	S	Unknown	10 Mg, Qd	Lupin
	Dextromethorphan/Promethazine	S	Unknown	Unk	Not Reported
	Dextromethorphan/Promethazine	S			Not Reported
	Naltrexone	C	Intramuscular	Unk	Not Reported
	Amlodipine	C	Unknown	5 Mg, Bid	Not Reported
	Labetalol	C	Unknown	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	13939669	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2017005815			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Lethargy; Mental Status Changes; Myoclonus; Serotonin Syndrome; Tongue Biting; Tongue Haemorrhage; Viral Upper Respiratory Tract Infection	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Macleods
	Dextromethorphan/Promethazine			S	Oral	Unk		Not Reported
	Dextromethorphan/Promethazine			S				Not Reported
	Dextromethorphan/Promethazine			S				Not Reported
	Amlodipine Besylate			C	Unknown	5 Milligram, Bid, 12 Hour		Macleods
	Levetiracetam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Labetalol			C	Unknown	100 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	14615566	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018010921			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Tramadol Hydrochloride			S	Oral	Unk, Unknown Dosage		Macleods
	Seroplex			S	Oral	20 Mg, Unk		Not Reported

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Bilaska	S	Oral	Unk	Not Reported
Seresta	S	Oral	Unk	Not Reported
Nocertone	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	50 Mg, Unk, 50 Mg Solution For Injection In Pre-Filled Pen	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	14961354	EXPEDITED (15-DAY)		HO, LT, OT	US-DRREDDYS- USA/USA/18/0099557		25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Rhabdomyolysis; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Lamotrigine Tablets			S	Unknown			Not Reported
	Lamotrigine Tablets			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15041208	EXPEDITED (15-DAY)		HO	FR-009507513- 1806FRA006201		61 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Corneal Oedema	Sinemet L.P.			S	Oral	2 Df, Q4d		Merck
	Mantadix			S	Oral	300 Mg, Qd		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042496	EXPEDITED (15-DAY)		OT	ZA-CIPLA (EU) LIMITED-2018ZA19024			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Condition	Escitalopram			S	Oral	10 Mg, Qd		Invagen

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Aggravated; Confusional State; Drug Ineffective; Fatigue; Feeling Cold; Feeling Jittery; Insomnia; Myalgia; Nervousness; Thinking Abnormal; Tinnitus; Treatment Noncompliance; Tremor; Unevaluable Investigation	Escitalopram Serdep /00724402/ Metformin	S C C	Unknown Unknown Unknown	5 Mg, Per Day Unk Unk	Invagen Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042714	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040908		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported	
	Valaciclovir			S	Oral	500 Mg, Qd		Not Reported	
	Ramipril			S	Oral	Unk		Not Reported	
	Metoclopramide			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042756	EXPEDITED (15-DAY)		DS	GB-TORRENT-00016683		33 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram			S	Oral			Unknown	
	Lansoprazole			C				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042869	EXPEDITED (15-DAY)		HO	FR-009507513-1806FRA008796		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Mirtazapine			S	Oral			Merck	
	Bisoprolol Fumarate			S	Oral			Not Reported	

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Modopar	S	Oral		Not Reported
Risperdal	S	Oral	Inconnue	Not Reported
Seroplex	S	Oral		Not Reported
Kardegic	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043579	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018248040		67 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Head Injury; Loss Of Consciousness	Xanor			S		0.5 Mg, Unk		Pfizer
	Zartan (Losartan Potassium)			S		50 Mg, Unk		Not Reported
	Fedaloc			S		30 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Foxair			S		50/250mcg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043676	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1041372		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Chills; Headache; Loss Of Consciousness; Nausea; Tremor	Escitalopram			S	Oral	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043809	EXPEDITED (15-DAY)		HO, LT	PH-ABBVIE-18S-128-2393888-00		26 YR	Male	PHL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Drug Ineffective; Emotional Disorder; Flashback; Multiple Drug	Valproic Acid			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported

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Therapy; Off Label Use	Abilify	S	Unknown	Not Reported
	Abilify	S		Not Reported
	Risperidone	S		Not Reported
	Risperidone	S	Unknown	Not Reported
	Risperidone	S		Not Reported
	Escitalopram	S		Not Reported
	Clonazepam	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043876	NON-EXPEDITED			US-009507513-1805USA013240			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diarrhoea; Dizziness; Feeling Abnormal; Gait Disturbance; Headache; Malaise; Muscular Weakness	Janumet Xr			S	Oral	1 Df (Strenght: 100/1000 Mg), Once Daily		Merck
	Escitalopram			S				Not Reported
	Pravastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043892	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831230US		61 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Corneal Oedema	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Mantadix			S	Oral	300 Mg, Qd		Not Reported
	Sinemet			S	Oral	2 Df, Every 4 Days		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043939	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1831839US		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperkalaemia; Hypoglycaemia; Hyponatraemia;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported

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Inappropriate Schedule Of Product Administration	Ramipril Mylan	S	Oral	5 Mg, Qd	Not Reported
	Acide Alendronique	C	Oral	70 Mg, Time Interval: 1	Not Reported
	Icaz Lp	C	Oral	2.5 Mg, Qd	Not Reported
	Sodium Alginate Sodium Bicarbonate Mylan	C	Oral		Not Reported
	Ceris	C	Oral	40 Mg, Qd	Not Reported
	Calperos D3	C	Oral	500 Mg, Qd	Not Reported
	Lactulose Mylan	C	Oral	10g/15ml	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15044775	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1045351		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event; Therapy Non-Responder	Valproic Acid			S				Not Reported	
	Levetiracetam			S				Not Reported	
	Clonazepam			S				Not Reported	
	Escitalopram			S				Not Reported	
	Clobazam			S				Not Reported	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15044904	EXPEDITED (15-DAY)		DS	FI-TEVA-2018-FI-911813		37 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram			S				Ivax	
	Voxra			S	Oral	450,Mg,Daily		Not Reported	
	Triptyl			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	13873251	EXPEDITED (15-DAY)		OT	FR-NODEN PHARMA DAC-NOD-2017-000089		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Aliskiren			S	Unknown	Unk		Noden Pharma	
	Digoxin			S	Unknown	Unk		Not Reported	
	Amiodarone			S	Unknown	Unk		Not Reported	
	Domperidone			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
	Bisoprolol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	14095395	EXPEDITED (15-DAY)		HO, LT, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-152373		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depression; Insomnia; Loss Of Consciousness; Suicide Attempt; Tinnitus	Tramadol			S	Unknown	Unk		Sun	
	Meloxicam			S	Unknown	Unk		Ranbaxy	
	Perindopril			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Sun	
	Clarithromycin			S	Unknown	Two Cycles Of Treatment Of 10 Days		Sun	
	Sertraline			S	Unknown	50 Mg In The Morning		Sun	
	Zolpidem			S	Unknown	10 Mg Before Bedtime		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Doxepin			S	Unknown	25 Mg, Daily, In The Evening		Sun	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	14415324	EXPEDITED (15-DAY)		OT	ES-009507513-1712ESP000156			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Simvastatin			S	Oral	1 Dosage Forms Daily; 40 Mg		Merck
	Simvastatin			S	Oral	20 Mg, Unk		Merck
	Enalapril Maleate (+) Hydrochlorothiazide			S	Unknown	1 Dosage Form Daily; 1 Df = 20/12.5 Mg		Merck
	Omeprazole			S	Unknown	Dosage Forms Daily; 20 Mg		Not Reported
	Amitriptyline Hydrochloride			S		12.5 Milligram Daily		Not Reported
	Amitriptyline Hydrochloride			S	Oral	25 Milligram Daily		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	5 Mg, Qd		Not Reported
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Not Reported
	Topiramate			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	0.5 Df, Qd		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Acetaminophen			S	Unknown	1 Df, Tid		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Acetaminophen (+) Tramadol Hydrochloride			S	Unknown	1 Df, Tid		Not Reported
	Acetaminophen (+) Tramadol Hydrochloride			S	Unknown	3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Not Reported
	Glibenclamid			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Tepazepam			S	Unknown	Unk, Qd		Not Reported
Lormetazepam			S	Unknown	1 Df, Qd		Not Reported	
Metoclopramide			C	Unknown	1 Week Treatment		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	14702793	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-160286			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Not Reported
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Astrazeneca
	Paracetamol		Y	S	Unknown	1 Df, Tid		Ohm Lab
	Simvastatin			S	Unknown	20 Mg, Unk		Sun
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Sun
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Sun
	Amitriptyline			S	Unknown	25 Milligram Daily;		Not Reported
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported
	Amitriptyline			S	Unknown	Qd		Not Reported
	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Diazepam			S	Unknown	.5 Dosage Forms Daily; 5 Mg		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported
	Glibenclamida			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Topiramato			S	Unknown	0.5 Df, Qd		Not Reported
	Tramadol/ Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Tramadol W/Paracetamol			S	Unknown	3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Not Reported
	Tepazepam			S	Unknown	Qd ()		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metoclopramide			C	Unknown	1 Week Treatment ()			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	14936035	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1826976US		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Arrhythmia; Confabulation; Disorientation; Electrocardiogram Qt Prolonged	Escitalopram Oxalate Unk			S	Unknown	13 Ml, Single		Allergan	
	Acetylsalicylic Acid			C	Oral	100 Mg, Unk		Not Reported	
	Triatec (Ramipril)			C	Oral	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15048364	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00561		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Escitalopram			S	Unknown	Unk		Hetero	
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15048414	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-911192		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Plegridy 125 Microgrammes, Solution Injectable En Stylo Prérempli			S	Subcutaneous			Not Reported	
	Atacand 16 Mg, Comprimé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15049421	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-910628		90 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Fall; Feeling Abnormal; Hallucination; Head Injury; Hip Arthroplasty; Humerus Fracture; Upper Limb Fracture	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Hydrocodone Bitartrate And Acetaminophen			S		7.5 Mg/325 Mg		Not Reported
	Tramadol			S				Not Reported
	Carvedilol			C				Not Reported
	Benicar			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15051645	EXPEDITED (15-DAY)		OT	US-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00246		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Olanzapine			S	Unknown			Jubilant
	Escitalopram			S	Unknown			Jubilant
	Lorazepam			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15053829	EXPEDITED (15-DAY)		HO	DE-MYLANLABS- 2018M1043520		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Escitalopram			S	Unknown	In A Morning Target Dose Of 20 Mg		Not Reported
	Escitalopram			S	Unknown	Reduced To 15 Mg/Day		Not Reported
	Escitalopram			S	Unknown	Increased To A Dose Of 20 Mg Daily		Not Reported
	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported

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	Aripiprazole	S	Unknown	5 Mg/Day	Not Reported
	Atorvastatin	C	Unknown		Mylan
	Promethazine	C	Unknown		Mylan
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Mylan
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Mylan
	Pregabalin	C	Unknown	Evening Dose Of 100 Mg	Mylan
	Pregabalin	C			Mylan
	Pregabalin	C			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15055172	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1831831US		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp En			S	Oral	14 Df, (In Total)		Allergan	
				S	Oral	20 ML, Unk (In Total)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15055187	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1831859US		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disability; Feeling Abnormal; Seizure	Lexapro			S	Unknown			Allergan	
	Brexiprazole			S	Unknown	0.5 Mg, Unk		Not Reported	
	Aripiprazole			S	Unknown	2.5 Mg, Unk		Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Cymbalta			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	14738818	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CZ055149			Male	CZE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Dyskinesia; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal Hypermotility; Loss Of Consciousness; Muscle Spasms; Poisoning; Toxicity To Various Agents	Clonazepam			S	Oral			Novartis
	Escitalopram			S	Oral			Not Reported
	Metoclopramide			S	Oral			Not Reported
	Olanzapin			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Melperon			S	Oral			Not Reported
	Levomepromazine			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15057412	EXPEDITED (15-DAY)		HO, OT	DK-ACCORD-068490		32 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram			S				Not Reported
	Spironolactone			S				Accord
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported
	Octreotide/Octreotide Acetate			S				Not Reported
	Victoza			S				Not Reported
	Mercaptopurine/Mercaptopurine Anhydrous			C				Not Reported
	Imodium			C				Not Reported
	Cholestagel			C				Not Reported
	Levetiracetam			C				Not Reported
	Lamotrigine			C				Not Reported
	Infliximab			C				Not Reported
	Adalimumab			C				Not Reported
	Natalizumab			C				Not Reported
	Vedolizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Loperamide			C		2-8 Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15057461	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-176432			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Mirtazapine			S	Oral			Sun	
	Bisoprolol			S	Oral			Sun	
	Modopar 125 (100 Mg/25 Mg), Gelule			S	Oral			Not Reported	
	Risperdal 1 Mg, Comprime Pellicule Secable			S	Oral	Inconnue ()		Not Reported	
	Seroplex 10 Mg, Comprime Pellicule Secable			S	Oral			Not Reported	
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet- Dose			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15057462	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-176461			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Escitalopram			S	Oral			Not Reported	
	Irbesartan			S	Oral			Not Reported	
	Fenofibrate			S	Oral			Sun	
	Naproxene			S	Oral			Not Reported	
	Bromazepam			S	Oral			Not Reported	
	Levothyroxine Sodique			S	Oral			Not Reported	
	Pregabalin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15058615	EXPEDITED (15-DAY)		HO, OT	LU-MACLEODS PHARMACEUTICALS			Unknown	LUX

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US LTD-
MAC2018014354

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram Oxalate			S	Oral			Macleods
	Gilenya 0.5 Mg Capsule Novartis			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrice			C	Oral	100 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15058943	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018251665		21 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Sopor	Alprazolam			S	Oral	15 MI, Single (Total)		Pfizer
	Zitromax			S	Oral	1500 Mg, Total		Pfizer
	Aripiprazole			S	Oral	210 Mg, Single (Total)		Not Reported
	Prozin /00011902/			S	Oral	1200 Mg, Single (Total)		Not Reported
	Escitalopram Oxalate			S	Oral	140 Mg, Single (Total)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15059513	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180626500		80 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage; Fall	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Vitamin B Nos			C	Oral			Not Reported
	Benerva			C	Oral			Not Reported
	Calcimagon			C	Oral			Not Reported
	Concerta			C	Oral			Not Reported
	Concor			C	Oral			Not Reported

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Cordarone	C	Oral	Not Reported
Euthyrox	C	Oral	Not Reported
Magnesium	C	Oral	Not Reported
Pantoprazole Sodium	C	Oral	Not Reported
Candesartan Cilexetil	C	Oral	Not Reported
Quetiapine Fumarate	C	Oral	Not Reported
Seresta	C	Oral	Not Reported
Targin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15060403	EXPEDITED (15-DAY)		HO	PH-ALLERGAN-1831865US		26 YR	Male	PHL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Drug Therapy	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan
	Abilify			S	Unknown	Unk		Not Reported
	Abilify			S				Not Reported
	Abilify			S				Not Reported
	Risperidone			S	Unknown	Unk Unk, Unknown		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Clonazepam			C	Unknown	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15061555	EXPEDITED (15-DAY)		OT	TR-EYEVANCE PHARMACEUTICALS-2018EYE00002		34 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Sinus Bradycardia	Cetirizine Hydrochloride			S	Oral	10 Mg, 1x/Day		Eyevance Pharmaceuticals
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Ampicillin			C	Intravenous (not	2 G, 6x/Day		Not Reported

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		otherwise specified)	
Enoxaparin	C	60 Mg, 1x/Day	Not Reported
Pantoprazole	C	40 Mg, 1x/Day	Not Reported
Aspirin	C	100 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15062132	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1831835US		26 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Theralene			S	Oral	20 Mg, Qd		Not Reported
	Valium			S	Oral	40 Mg, Qd		Not Reported
	Lepticur			S	Oral	20 Mg, Qd		Not Reported
	Macrogol			S	Oral	1 Df, Qd		Not Reported
	Tercian			S	Oral	100 Mg, Qd		Not Reported
	Leponex			S	Oral	600 Mg, Qd		Not Reported
	Xeplion			S	Intramuscular	1 Df, Q Month		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	9759936	EXPEDITED (15-DAY)		DE, LT, OT	NO-FRI-1000052215		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Intentional Self-Injury; Medication Error	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Sarotex			S	Unknown	Unk		Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Levomepromazine Maleate			S	Unknown			Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Hydroxyzine Hydrochloride			S	Unknown			Not Reported
	Nobligan			S	Unknown	200 Mg, Unk		Not Reported

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Catapresan	S	Unknown	50 Mg, Unk	Not Reported
Lamictal	S	Unknown	100 Mg, Unk	Not Reported
Diazepam	S	Unknown		Not Reported
Remeron	S	Unknown	Unk	Not Reported
Pinex Forte	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Atarax	S	Unknown	Unk	Not Reported
Orfiril	S	Unknown	1200 Mg, Unk	Not Reported
Sobril	S	Unknown	Unk	Not Reported
Imovane	S	Oral	Unk	Not Reported
Nozinan	S	Unknown	Unk	Not Reported
Oxynorm	S	Unknown	10 Mg, Unk	Not Reported
Rivotril	S	Unknown	Unk	Not Reported
Vival	S	Unknown	Unk	Not Reported
Forte	C	Unknown	Unk	Not Reported
Diamorphine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14617787	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR- APL-2018-011934		45 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Sertraline			S	Unknown	Unk		Aurobindo	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Venlafaxin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14968505	EXPEDITED (15-DAY)		DS	DE-ALLERGAN- 1827590US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Gait	Escitalopram Oxalate - Bp			S	Oral	10 Mg, In The Morning For		Allergan	

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Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram Oxalate - Bp	S	Unknown	2 Days	Allergan
	Oxazepam Hexal	S	Oral	20 Mg, Once In The Morning	Not Reported
	Monostep	C	Oral	10 Mg, For Night For Three Days	Not Reported
				Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15002444	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1039008			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	20 Mg, Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065835	EXPEDITED (15-DAY)		HO, OT	PL-MACLEODS PHARMACEUTICALS US LTD-MAC2018014365			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine 150 Mg			S	Unknown	150 Milligram, Qd		Macleods
	Cyproheptadine			S	Oral	16 Milligram		Not Reported
	Ivabradine			S	Unknown	Unk		Not Reported
	Moklar			S	Unknown	150 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk (10 Mg Before A Sleep)		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065836	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018014367			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Macleods	
	Folic Acid, Potassium Iodide			C	Transplacental	0.4 [Mg/D]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065876	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00008678		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Venlafaxine Hydrochloride			S	Unknown	Unknown		Unknown	
	Escitalopram			S	Unknown	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15066005	EXPEDITED (15-DAY)		DE, HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018009160			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Tablet			S	Oral	Unk		Macleods	
	Paracetamol			S	Oral	245, Tablet		Not Reported	
	Baclofen			S	Oral	Unk		Not Reported	
	Baclofen			S				Not Reported	
	Dextropropoxyphene			S	Oral	Unk		Not Reported	
	Valpromide			S	Oral	Unk		Not Reported	

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26-Jun-2018	15067096	EXPEDITED (15-DAY)		DS, OT	US- GLAXOSMITHKLINE- US2018GSK110865		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Ill- Defined Disorder; Seizure; Therapeutic Product Effect Incomplete	Wellbutrin			S				Glaxosmithkline	
	Cymbalta			S				Glaxosmithkline	
	Rexulti			S		0.5 Mg, Unk		Not Reported	
	Rexulti			S		Unk		Not Reported	
	Aripiprazole			S		2.5 Mg, U		Not Reported	
	Aripiprazole			S		Unk, U		Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15067338	EXPEDITED (15-DAY)		OT	US-EPIC PHARMA LLC- 2018EPC00308		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Gabapentin			S	Unknown			Epic Pharm	
	Olanzapine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Mirtazapine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15067415	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-04637		67 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Zartan (Losartan Potassium)			S	Oral	50 Mg, Unk		Lupin	
	Fedaloc Sr			S	Oral	30 Mg, Unk		Not Reported	

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Xanor	S	Oral	0.5 Mg, Unk	Not Reported
Spiractin /00006201/	S	Oral	25 Mg, Unk	Not Reported
Lexamil	S	Oral	10 Mg, Unk	Not Reported
Foxair	S	Oral	50/250 Mcg, Unk (Inhalation)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15067703	EXPEDITED (15-DAY)		HO	CH-OTSUKA-2018_016636		45 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Anxiety;	Abilify			S	Oral	10 Mg, Qd		Otsuka	
Condition Aggravated;	Ciprallex			S	Unknown	Unk		Not Reported	
Extrapyramidal Disorder;	Olanzapine			C	Unknown	Unk		Not Reported	
Fear; Impaired Driving	Sequase			C	Unknown	Unk		Not Reported	
Ability; Therapy Cessation;	Sequase			C	Unknown	100 Mg, Unk		Not Reported	
Tinnitus									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	14678334	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU13032			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder;	Escitalopram			S	Unknown	Unk		Invagen	
Fatigue; Insomnia; Loss	Diazepam			S	Unknown	Unk		Not Reported	
Of Personal Independence	Lyrica			S	Unknown	Unk		Not Reported	
In Daily Activities; Memory	Gilenya			S	Oral	Unk		Not Reported	
Impairment; Muscle	Vitamin D /00107901/			S	Unknown	Unk		Not Reported	
Spasms; Pain	B Complex /00322001/			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15028156	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-032411			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole	S	Oral	40 Milligram, Once A Day	Aurobindo
	Esidrex	S	Oral	0.5 Df, Qd	Not Reported
	Seroplex	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Procoralan	C	Unknown	Unk	Not Reported
	Procoralan	C	Unknown	()	Not Reported
	Aspirine Protect	C	Unknown	Unknown	Not Reported
	Seresta	C	Unknown	Unknown	Not Reported
	Seresta	C	Unknown	Breackable ()	Not Reported
	Dafalgan	C	Unknown	Unknown	Not Reported
	Dafalgan	C	Unknown	()	Not Reported
	Pravastatine /00880401/	C	Unknown	Unknown	Not Reported
	Mediatensyl /00631801/	C	Unknown	Unknown	Not Reported
	Ramipril	C	Unknown	Unknown	Not Reported
	Ramipril	C	Unknown	()	Not Reported
	Acebutolol	C	Unknown	Unknown	Not Reported
	Acebutolol	C	Unknown	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073217	EXPEDITED (15-DAY)		HO, LT	GR-REGULIS-2050022		67 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental Status Changes; Muscle Rigidity; Mydriasis; Off Label Use; Psychomotor	Methylene Blue			S	Intravenous (not otherwise specified)			Regulis
	Escitalopram			S				Not Reported

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Detailed Report

Hyperactivity; Serotonin Syndrome

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27-Jun-2018	15073219	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2018-032632		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D ()		Aurobindo	
	Folio /06866801/			C	Transplacental	0.4 [Mg/D]		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073612	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-TEVA-2018-GB-912201		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral			Ivax	
	Escitalopram			S	Oral			Ivax	
	Metformin Hydrochloride			C	Unknown			Not Reported	
	Generics Uk Nifedipine			C	Unknown			Not Reported	
	Pregabalin			C	Unknown			Not Reported	
	Nefopam			C	Unknown			Not Reported	
	Tiotropium			C	Unknown			Not Reported	
	Sodium Picosulfate			C	Unknown			Not Reported	
	Cetirizine			C	Unknown			Not Reported	
	Naproxen			C	Unknown			Not Reported	
	Diazepam			C	Unknown			Not Reported	
	Cassia (Senna Alexandrina)			C	Unknown			Not Reported	
	Methotrexate Sodium			C	Unknown			Not Reported	
	Budesonide And Formoterol Fumarate			C	Unknown			Not Reported	

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Lansoprazole	C	Unknown	Not Reported
Meptazinol	C	Unknown	Not Reported
Quetiapine Fumarate	C	Unknown	Not Reported
Temazepam	C	Unknown	Not Reported
Montelukast	C	Unknown	Not Reported
Pyridoxine	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Adcal-D3	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073895	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/18/0100730		44 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Dyspepsia	Ibuprofen			S	Unknown	Nk		Not Reported
	Escitalopram			S		20 Mg, 1-0-0		Not Reported
	Neupro			S		14 Mg, 1-0-0-0		Not Reported
	Bornaprin			S		4 Mg, 1-0.5-1-0		Not Reported
	Madopar Depot			C		100 25 Mg, 0-0-0-1		Not Reported
	Amantadin			C		100 Mg, 1-1-0-0		Not Reported
	Amitriptylin			C		75 Mg, 0-0-0-1		Not Reported
	Madopar			C		100 25 Mg, 1.5-1.5-1.5-1.5		Not Reported
	Madopar Lt			C		100 25 Mg, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073924	EXPEDITED (15-DAY)		HO	DE-HETERO-HET2018DE00584		44 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Paraesthesia; Prescribed Underdose	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported

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Aripiprazole			S	Oral	10 Mg	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15074121	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018014373			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram, Qd		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15074125	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018014380			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram Oxalate			S	Oral	140 Milligram		Macleods	
	Paracetamol			S	Unknown	8.8 Gram		Not Reported	
	Atarax			S	Oral	750 Milligram		Not Reported	
	Coltramyl			S	Oral	48 Milligram		Not Reported	
	Ibuprofen			S	Oral	6 Gram		Not Reported	
	Alprazolam			C	Oral	5 Milligram		Not Reported	
	Brexin			C	Oral	20 Milligram		Not Reported	
	Cefuroxime			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15074234	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018255702		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Venlafaxine Hcl			S	Oral	1 Df, 1x/Day		Pfizer	
	Olanzapine			S	Oral	Unk		Not Reported	

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Delorazepam	S	Oral	Unk	Not Reported
Cipralex /01588501/	S	Oral	Unk	Not Reported
Donepezil	C			Not Reported
Bisoprolol Fumarate	C		Unk	Not Reported
Madopar	C		Unk	Not Reported
Terazosin Hydrochloride	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15074452	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-032565		46 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	140 Milligram		Aurobindo
	Ibuprofen			S	Oral	6 Gram		Aurobindo
	Paracetamol			S	Unknown	8.8 Gram		Aurobindo
	Atarax /00058401/			S	Oral	750 Milligram		Not Reported
	Coltramyl			S	Oral	48mg		Not Reported
	Alprazolam			C	Oral	5mg		Not Reported
	Brexin /00500404/			C	Oral	20mg		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15075528	NON-EXPEDITED		HO, OT	US-SAOL THERAPEUTICS- 2018SAO00690		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthralgia; Asterixis; Asthenia; Device Damage; Dizziness; Drug Withdrawal Syndrome; Headache; Lethargy; Loss Of Consciousness; Micturition Urgency; Mood Altered; Muscle Twitching;	Lioresal			S	Intrathecal	806.3 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	968.7 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	1017.7 Mg, \Day		Saol Therapeutics
	Lexapro			S	Oral			Not Reported
	Vimpat			S				Not Reported
	Carbamazepine			S				Not Reported

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Pollakiuria; Seizure; Sleep Disorder; Somnolence; Tremor; Urinary Retention; Vision Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076540	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018257495		47 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Henoch-Schonlein Purpura; Lymphoedema	Neurontin			S		600 Mg, Unk		Pfizer	
	Zytomil			S		20 Mg, Unk		Not Reported	
	Macrochantin			S		100 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076541	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018257325		66 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypokinesia; Intentional Overdose; Intentional Self-Injury	Halcion			S	Oral	20 Df, Single		Pfizer	
	Escitalopram			S	Oral	200 Mg, Single		Not Reported	
	Depakin			S	Oral	3.5 G, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076669	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018253888		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Xanax			S	Oral	0.38 Mg, 1x/Day		Pfizer	
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, 1x/Day		Pfizer	
	Amiodarone			S	Oral	200 Mg, 1x/Day		Not Reported	
	Topalgic Lp			S	Oral	3 Df, 1x/Day		Not Reported	
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported	

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Oxynormoro	S	Oral	5 Mg, Unk	Not Reported
Kardegic	S	Oral	1 Df, 1x/Day	Not Reported
Allopurinol	S	Oral	100 Mg, 1x/Day	Not Reported
Mycophenolate Sodium	C	Oral	360 Mg, 1x/Day	Not Reported
Ciclosporine	C	Oral	100 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076963	EXPEDITED (15-DAY)	HO		ZA-PFIZER INC-2018257574		60 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertension	Aspavor			S		20 Mg, Unk		Pfizer
	Methotrexate			S		2.5 Mg, Unk		Pfizer
	Salazopyrin			S		500 Mg, Unk		Pfizer
	Amloc /00550802/			S		10 Mg, Unk		Not Reported
	Co-Tareg			S		100/12.5 Mg, Unk		Not Reported
	Carloc			S		25 Mg, Unk		Not Reported
	Disprin			S		Unk		Not Reported
	Cardiocare			S		100 Mg, Unk		Not Reported
	Myoprin			S		100 Mg, Unk		Not Reported
	Ciplavasc			S		5 Mg, Unk		Not Reported
	Coxflam			S		7.5 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15201812	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro			S				Not Reported
	Cymbalta			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15027621	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1827407US		40 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Long Qt Syndrome; Malaise; Palpitations; Ventricular Extrasystoles	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15080690	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-913729		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Amiodarone			S	Oral	200 Milligram Daily;		Teva	
	Allopurinol			S	Oral	100 Milligram Daily;		Actavis	
	Seroplex 5 Mg, Coated Tablet			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Topalgic Lp 50 Mg, Extended Release Tablet			S	Oral	3 Dosage Forms Daily;		Not Reported	
	Oxynormoro 5 Mg, Orodispersible Tablet			S	Oral			Not Reported	
	Xanax 0.25 Mg, Scored Tablet			S	Oral	.38 Milligram Daily;		Not Reported	
	Kardegic 75 Mg, Powder For Oral Solution In Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Tazocilline 4 G/500 Mg, Powder For Solution For Infusion			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily;		Not Reported	
	Mycophenolate Sodique			C	Oral	360 Milligram Daily;		Not Reported	
	Ciclosporine			C	Oral	100 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15082074	NON-EXPEDITED			US-TEVA-2018-US-916310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Exposure Via Breast Milk		Escitalopram	S	Unknown		Ivax			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15082196	NON-EXPEDITED			US-TEVA-2018-US-912975			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vitreous Floaters	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15082277	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-032575		31 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15083137	EXPEDITED (15-DAY)		HO	TR-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00249		71 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15083994	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1045492			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	20 Mg, Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15084109	EXPEDITED (15-DAY)		HO	TR-PRINSTON PHARMACEUTICAL INC.-2018PRN00329		71 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15085104	EXPEDITED (15-DAY)		HO	PHHY2018DE019842			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Respiratory Tract Infection	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Risperidone			S	Unknown	0.5 Mg, Unk (For 10 Days)		Novartis	
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported	
	Pregabalin			S	Unknown	100 Mg, Unk (Evening Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	12456545	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2016CA078068		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Electrocardiogram T Wave Peaked; Fall; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Metformin			S	Unknown	1 G, Bid		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk		Novartis	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Gliclazide			C	Unknown	Unk		Not Reported	
	L-Thyroxine			C	Unknown	Unk		Not Reported	
	Telmisartan			C	Unknown	Unk		Not Reported	

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Insulin	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	14320362	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017511493			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Besilate			S		1 Dosage Form (Df, 5mg), Once Daily		Pfizer
	Paracetamol			S		1 Df, 1x/Day		Not Reported
	Simvastatin			S		1 Df (40 Mg), 1x/Day		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Topiramate			S		0.5 Df, 1x/Day		Not Reported
	Topiramate			S		50 Mg, 1x/Day (1 Df)		Not Reported
	Paracetamol W/Tramadol			S		1 Df, Thrice Daily (3 Dosage Forms Daily, 1 Df =37.5/325 Mg)		Not Reported
	Naproxen			S		1 Df, 1x/Day (1 Df, Bid)		Not Reported
	Amitriptyline			S		5 Mg, 1x/Day		Not Reported
	Amitriptyline			S		12.5 Mg, 1x/Day		Not Reported
	Amitriptyline			S		25 Mg, Daily		Not Reported
	Enalapril, Hydrochlorothiazide			S		1 Df, Once Daily (1df = 20/12.5 Mg)		Not Reported
	Topiramato			S		0.5 Df, Once Daily		Not Reported
	Topiramato			S		1 Df (50mg), 1x/Day		Not Reported
	Diazepam			S		5 Mg, Once Daily (0.5 Df)		Not Reported
	Diazepam			S		Unk		Not Reported
	Glibenclamida			S		2 Df, 1x/Day		Not Reported
	Escitalopram			S		1 Df (10mg), 1x/Day		Not Reported
	Omeprazole			S		1 Df (20 Mg), 1x/Day		Not Reported
	Lormetazepam			S		1 Df, Once Daily (1 Mg)		Not Reported

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	Tepazepam	S			1 Df, 1x/Day		Not Reported
	Glibenclamide	S			2 Df, 1x/Day		Not Reported
	Diazepam/Sulpiride	S			1 With Unknown Unit, Daily		Not Reported
	Amlodipine	S	Unknown		1 Df, 1x/Day		Not Reported
	Paracetamol + Tramadol	S			3 Df, 1x/Day (Df0 37.5/325 Mg)		Not Reported
	Paracetamol + Tramadol	S			Unk		Not Reported
	Metoclopramide	C			Unk (1 Week Treatment)		Not Reported
	Metoclopramide	C	Unknown		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15006971	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 904387		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Fibromyalgia; Peritonitis	Escitalopram			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15073044	NON-EXPEDITED			US-TEVA-2018-US- 914112			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palpitations; Therapy Change; Tremor	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15087599	EXPEDITED (15-DAY)		DE, HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018014481			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods
Haemorrhage Intracranial	Duoplatin			S	Oral	75 Milligram, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15090805	NON-EXPEDITED			US-TEVA-2018-US-912988			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Dose Omission	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15092959	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-915286		28 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dyskinesia; Juvenile Myoclonic Epilepsy; Myoclonus; Schizophreniform Disorder	Zopiclone			S	Unknown			Not Reported	
	Zopiclone			S				Not Reported	
	Fluoxetine			S	Unknown			Barr	
	Fluoxetine			S				Barr	
	Fluoxetine			S				Barr	
	Aripiprazole			S	Unknown	Only Prescribed For Short Time		Teva	
	Aripiprazole			S				Teva	
	Olanzapine			S	Unknown	Only Prescribed For Short Time		Teva	
	Quetiapine			S	Unknown	Only Prescribed For Short Time		Teva	
	Quetiapine			S				Teva	
	Duloxetine			S	Unknown	Only Prescribed For Short Time		Teva	
	Duloxetine			S				Teva	
	Clozapine			S	Unknown	75 Mg		Ivax	
	Clozapine			S				Ivax	
	Escitalopram			S	Unknown	20 Mg		Ivax	
	Escitalopram			S				Ivax	
	Bupropion			S	Unknown			Teva	
	Bupropion			S				Teva	

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Mirtazapine	S	Unknown		Teva
Mirtazapine	S			Teva
Venlafaxine	S	Unknown		Teva
Venlafaxine	S			Teva
Amisulpride	S	Unknown		Not Reported
Amisulpride	S			Not Reported
Risperidone	S	Unknown		Pliva
Risperidone	S			Pliva
Promethazine	S	Unknown	Only Prescribed For Short Time	Not Reported
Promethazine	S			Not Reported
Biperiden	S	Unknown		Not Reported
Biperiden	S			Not Reported
Oxazepam	C	Unknown	At Different Doses	Not Reported
Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year	Not Reported
Brivaracetam	C	Unknown	200-250mg; Received Over One Year	Not Reported
Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported
Zonisamide	C	Unknown	Up To 100mg	Not Reported
Clobazam	C	Unknown	Up To 20mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15208691	DIRECT		OT			21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cold Sweat; Nightmare; Poor Quality Sleep; Rapid Eye Movements Sleep Abnormal	Escitalopram Tablets			S	Oral	Quantity:1 Tablet(S);	90 DAY	Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2018	15094292	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2018-032854		86 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Duoplavin			S	Oral	75 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2018	15049241	EXPEDITED (15-DAY)		OT	US-TORRENT-00006261		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Disturbance In Attention; Fatigue; Lethargy; Mental Impairment; Product Substitution Issue; Wrong Technique In Product Usage Process	Escitalopram			S		Half A Pill Two Times A Day		Unknown	
	Armour Thyroid			S		Unknown		Unknown	
	Escitalopram			C		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2018	15094833	NON-EXPEDITED			US-AMGEN-USASP2018086560			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen	
	Morphine			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Nucynta			S	Unknown	Unk		Not Reported	
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	14777871	NON-EXPEDITED			US-PFIZER INC-2018161286		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Abnormal; Drug	Azithromycin			S		Unk		Pfizer	
	Lexapro			S		20 Mg, 1x/Day		Not Reported	

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Interaction; Heart Rate
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15095115	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-917495		52 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Loss Of Consciousness; Malaise	Escitalopram			S	Oral	20 Milligram Daily;		Ivax	
	Carbolithium 300 Mg Capsule Rigide			S	Oral	900 Milligram Daily;		Not Reported	
	Frontal 1 Mg Compresse			S	Oral	2 Milligram Daily;		Not Reported	
	Depakin			S	Oral	1000 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15095849	EXPEDITED (15-DAY)		HO	FR-ZYDUS-020027		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia	Risperidone			S	Oral	In Total		Zyklus Pharm	
	Escitalopram			S	Oral	In Total		Not Reported	
	Theralene			C	Oral	Unspecified Dosage		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15096105	EXPEDITED (15-DAY)		OT	SE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014524			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ecchymosis; Erythema	Escitalopram Oxalate 5mg Tablet			S	Oral	5 Milligram, Qd		Macleods	
	Aclasta			C	Unknown	Unk		Not Reported	
	Kalcipos-D			C	Unknown	Unk		Not Reported	
	Zopiklon			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15097191	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2018261366		56 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cadasil; Cerebrovascular Accident; Dysphagia; Hemiplegia; Mutism	Aspavor			S		Unk		Pfizer	
	Epanutin			S		Unk		Pfizer	
	Pearinda			S		Unk		Not Reported	
	Zytomil			S		Unk		Not Reported	
	Epilim			S		Unk		Not Reported	
	Plagrol			S		Unk		Not Reported	
	Glucophage Xr			S		Unk		Not Reported	
	Puricos			S				Not Reported	
	Uromax /00538902/			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15098250	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1832875US		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan	
	Folio			C	Transplacental	0.4 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15099059	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018265045		79 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Accumax			S		Unk		Pfizer	
	Euthyrox			S		Unk		Not Reported	
	Carloc			S		Unk		Not Reported	

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Lexamil	S	Unk	Not Reported
Amiloretic /00206601/	S	Unk	Not Reported
Rivotril	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	14720369	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1816988US		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome; Drug Interaction	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Dexamethasone			S	Oral	0.25 Mg, Qd		Not Reported	
	Hidroaltesona			S	Oral	20 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	14839201	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1823790US		37 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Delirium; Drug Ineffective; Haematoma; Insomnia; Menorrhagia; Off Label Use; Respiratory Tract Infection; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Pregabalin			S	Oral	100 Mg, Qpm		Not Reported	
	Risperidon			S	Oral	Unk, Unknown		Not Reported	
	Risperidon			S	Oral	Unk		Not Reported	
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15060600	NON-EXPEDITED			US-PFIZER INC-2018256690		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	

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	Lexapro		S			Unk			Not Reported
	Nucynta		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15104238	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-919514		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Ivax	
	Paroxetina Ratiopharm 20 Mg Comprime Rivestite Con Film			S	Oral			Teva	
	Minias 2,5 Mg/ML Gocce Orali, Soluzione			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	13546885	EXPEDITED (15-DAY)		HO	IT-TEVA-764815ACC		51 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self-Injury	Escitalopram			S	Oral			Ivax	
	Xanax - 0,25 Mg Comprime - Pharmacy Value S.R.L			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	14754324	EXPEDITED (15-DAY)		HO	IT-TEVA-768699ACC		19 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Abnormal; Intentional Overdose; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105170	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		46 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	Unk		Not Reported
	Ibuprofene		Y	S	Oral	Unk		Ranbaxy
	Atarax			S	Oral	Unk		Not Reported
	Coltramyl			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Cefuroxime			C	Oral	Unk		Not Reported
	Brexin			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105526	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-919441		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Oral	10 Milligram Daily;		Not Reported
	Indapamide			S	Oral	2.5 Milligram Daily;		Actavis
	Lactulose			C				Not Reported
	Perindopril			C				Not Reported
	Enoxaparin Sodium			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105910	EXPEDITED (15-DAY)		OT	FR-ZYDUS-018686		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Interaction; Formication; Hyperkalaemia; Myalgia;	Escitalopram			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Pravastatin			C	Unknown			Not Reported

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Testicular Pain	Pregabalin		C	Oral					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	13134800	EXPEDITED (15-DAY)		DS, HO, OT	US-JAZZ-JPI-P-008801			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Exposure During Pregnancy; Fatigue; Feeling Abnormal; Hallucination; Intervertebral Disc Protrusion; Mental Disorder; Mood Swings; Morning Sickness; Nausea; Personality Disorder; Somnolence	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	3 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Lexapro			S				Not Reported	
	Citalopram Hydrobromide			S				Not Reported	
	Escitalopram Oxalate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	14869141	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-024552		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Learning Disorder; Mental Impairment	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Brintellix			S	Unknown	10 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15043885	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1831187US		26 YR	Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Decreased	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Zopitan			C	Oral	3.75 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15082189	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-033048		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Feeling Abnormal; Panic Attack	Escitalopram Film-Coated Tablets			S	Unknown	15 Milligram, Once A Day		Aurobindo	
	Escitalopram Film-Coated Tablets			S				Aurobindo	
	Ciprallex /01588501/			S	Unknown	Unk		Not Reported	
	Ciprallex /01588501/			S	Unknown	15 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15109252	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-919804		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Ivax	
	Xanax			S	Oral	12 Df Units In Total		Not Reported	
	Haldol /00027401/			S	Oral	15 MI In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15109357	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018014634			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram Tablet			S	Oral	280 Milligram, Drug Abuse		Macleods	
	Delorazepam Gtt			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15109850	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-033975		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bradycardia; Somnolence;	Alprazolam	S	Oral	(1)In Total	Aurobindo
Toxicity To Various Agents	Seroplex	S	Oral	(1)In Total	Not Reported

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05-Jul-2018	15110124	EXPEDITED (15-DAY)		HO, OT	ZA-DRREDDYS-SAF/SAF/18/0101743			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hip Arthroplasty; Post Procedural Complication	Dopaquel			S	Oral			Not Reported	
	Sereflo			S	Oral			Not Reported	
	Alchera			S	Oral			Not Reported	
	Mylan Alprazolam			S	Oral			Mylan	
	Lexamil			S	Oral			Not Reported	
	Amiloretic			S	Oral			Not Reported	
	Nexiam			S	Oral			Not Reported	
	Avamys			S	Oral			Not Reported	
	Dormonoc			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15110310	EXPEDITED (15-DAY)		HO	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-04727		47 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Henoch-Schonlein Purpura; Lymphoedema; Product Use In Unapproved Indication	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin	
	Neurontin			S	Oral	600 Mg, Unk		Not Reported	
	Macrochantin			S	Oral	100 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15110991	EXPEDITED (15-DAY)		HO	IE-IMPAX LABORATORIES, INC-2018-IPXL-02283		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine Odt	S	Unknown	Unk	Impax
	Lamotrigine Odt	S	Unknown	Unk, Evening Dose Held	Impax
	Escitalopram	S	Unknown	5 Mg, 1 /Day	Not Reported
	Escitalopram	S	Unknown	10 Mg, 1 /Day	Not Reported
	Clobazam	C	Unknown	10 Mg, Bid	Not Reported
	Clobazam	C	Unknown	10 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15111018	NON-EXPEDITED			US-SA-2018SA168629			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Fatigue; Miliaria; Oropharyngeal Pain; Paraesthesia	Praluent			S		Unk		Sanofi	
	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15111384	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2017-033083		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Major Depression; Sexual Dysfunction; Weight Increased	Lorazepam			S	Unknown	At Bed Time		Not Reported	
	Duloxetine			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Ciprallex			S	Unknown			Not Reported	
	Ramipril/Idroclorotiazide			C				Not Reported	
	Warfarin			C				Not Reported	
	Ezetimibe			C				Not Reported	
	Lansoprazole			C				Not Reported	
	Simvastatin			C				Not Reported	
	Amiodarone			C				Not Reported	
	Alprazolam			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15111796	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-018066		45 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	In Total		Not Reported
	Tachipirina			S	Oral	In Total		Not Reported
	Cipralext			S	Oral	In Total		Not Reported
	Tolep			S	Oral	In Total		Not Reported
	Brintellix			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15112925	EXPEDITED (15-DAY)		OT	PHEH2018US026950			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Cancer; Drug Interaction; Musculoskeletal Chest Pain; Nausea; Second Primary Malignancy	Votrient			S	Oral	4 Df, Qd		Novartis
	Lexapro			S	Unknown			Not Reported
	Glipizide			C	Unknown			Not Reported
	Hydrocodone/Acetaminophen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	14444737	EXPEDITED (15-DAY)		HO	DE-TORRENT-00007662		42 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 30 Mg		Unknown
	Lorazepam			C	Unknown	0.5 Mg, Unk		Unknown
	Olanzapine			C	Unknown	10 Mg, Qd		Unknown
	Pangrol			C	Unknown	2 In 1 Day, Dose 1, 2 Ot, Qd		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	14585022	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010176		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hepatitis Cholestatic; Intentional Product Use Issue; Off Label Use	Prednisolone	S	Oral	Concordia
	Seroplex	S	Unknown	Not Reported
	Avastin	S	Intravenous (not otherwise specified)	Not Reported
	Belustine	S	Oral	Not Reported
	Silodyx	C		Not Reported
	Xanax	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	14948754	EXPEDITED (15-DAY)		DE	JP-PFIZER INC- 2018216975			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Effexor			S	Oral	Unk		Pfizer	
	Lexapro			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15074064	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE- 915283		37 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Escitalopram			S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg		Ivax	
	Escitalopram			S	Unknown	15 Milligram Daily; Reduced To 15 Mg/Day		Ivax	
	Escitalopram			S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily		Ivax	
	Risperidone			S	Unknown	0.5 Mg		Pliva	
	Risperidone			S				Pliva	
	Aripiprazole			S	Unknown	5 Milligram Daily;		Teva	
	Atorvastatin			C	Unknown			Not Reported	
	Promethazine			C	Unknown			Not Reported	

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Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Pregabalin	C	Unknown	100 Milligram Daily; Evening Dose Of 100 Mg	Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15113721	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-920994		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole			S	Oral			Teva	
	Alprazolam			S	Oral			Actavis	
	Escitalopram Oxalate			S	Oral			Ivax	
	Zitromax 500 Mg Compresse			S	Oral			Not Reported	
	Rivestite Con Film								
	Prozin 25 Mg Compresse			S	Oral			Not Reported	
	Rivestite								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15114472	EXPEDITED (15-DAY)		DE	ZA-CIPLA LTD.-2018ZA19814			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram			S	Unknown	5 Mg, Unk		Invagen	
	Aspavor			S	Unknown	20 Mg, Unk		Not Reported	
	Zanidip			S	Unknown	10 Mg, Unk		Not Reported	
	Lasix /00032601/			S	Unknown	20 Mg, Unk		Not Reported	
	Spiractin /00006201/			S	Unknown	25 Mg, Unk		Not Reported	
	Ganfort			S	Unknown	5 Mg, Unk		Not Reported	
	Ecotrin			S	Unknown	81 Mg, Unk		Not Reported	

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	Glucophage	S	Unknown	500 Mg, Unk		Not Reported			
	Stilpane /01152401/	S	Unknown	Unk		Not Reported			
	Bilocor	S	Unknown	5 Mg, Unk		Not Reported			
	Epleptin	S	Unknown	100 Mg, Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15115274	NON-EXPEDITED			US-ALLERGAN-1831294US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Vraylar			S	Unknown	Unk		Allergan	
	Viibryd			S	Unknown	Unk		Allergan	
	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15115907	EXPEDITED (15-DAY)		HO, OT	IE-GLAXOSMITHKLINE-IE2018119739		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	5 Mg, Qd		Glaxosmithkline	
	Escitalopram			S	Unknown	10 Mg, Qd		Glaxosmithkline	
	Clobazam			C		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15115976	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-919		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Twitching; Tremor	Maximum Strength Mucinex Dm Tablets			S	Unknown	1200 Mg, Bid, Took About 4-5 Doses Of Product		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116482	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-922283		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia	Escitalopram			S	Oral			Not Reported	
	Naproxene			S	Oral			Not Reported	
	Bromazepam			S	Oral			Not Reported	
	Irbesartan			S	Oral			Teva	
	Fenofibrate			S	Oral			Not Reported	
	Pregabalin			S	Oral			Not Reported	
	Levothyroxine Sodique			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116495	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922287		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	
	Aldactazine, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116838	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-922238		16 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hypotension; Loss Of Consciousness	Escitalopram Arrow 20 Mg, Comprimé Pelliculé Sécable			S	Oral	20 Milligram Daily;		Ivax	
	Tercian 40 Mg/ML, Solution Buvable En Gouttes			S	Oral	25 Gtt Daily;		Not Reported	

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	Alprazolam Mylan 0,50 Mg, Comprimé Sécable	S	Oral	1.5 Milligram Daily;	Mylan				
	Diane 35 Microgrammes, Comprimé Enrobé	C	Unknown		Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116848	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20180222203		13 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute; Somnolence	Tramadol Biogaran			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Atarax			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Stresam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116938	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20180637447		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Risperidone			S	Oral	In The Morning And Evening		Not Reported	
	Loxapine Succinate			S	Oral	5 Drops As Required		Not Reported	
	Escitalopram Arrow			S	Oral	In The Evening		Not Reported	
	Olanzapine Mylan			S	Oral	In The Evening		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15116939	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 922239		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Mirtazapine			S	Oral			Teva	
	Bisoprolol (Fumarate Acide De)			S	Oral			Teva	

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	Modopar (Benserazide Hydrochloride, Levodopa)	S	Oral	Not Reported
	Risperdal 1 Mg, Comprimé Pelliculé Sécable	S	Oral	Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable	S	Oral	Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15117421	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1834021US		31 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15117568	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1834025US		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperleukocytosis; Intentional Overdose; Pancreatitis; Renal Failure	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan	
	Atarax			S	Oral	750 Mg, Unk		Not Reported	
	Ibuprofene			S	Oral	6 G, Unk		Not Reported	
	Coltramyl			S	Oral	48 Mg, Unk		Not Reported	
	Paracetamol			S	Unknown	8.8 G, Unk		Not Reported	
	Alprazolam			C	Oral	5 Mg, Unk		Not Reported	
	Cefuroxime			C	Oral	Unk		Not Reported	
	Brexin			C	Oral	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	12981326	EXPEDITED (15-DAY)		HO, OT	PHHY2016FR155274		42 YR	Female	FRA

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Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Overdose; Suicide Attempt; Toxicity To Various Agents	Bromazepam			S	Unknown	180 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	840 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	7875 Mg, Unk		Novartis
	Lormetazepam			S	Unknown	14 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	14573366	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SA-2017SA116590		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Zolpidem Tartrate			S	Oral	10 Mg,Hs		Sanofi
	Sertraline			S	Unknown	50 Mg,Hs		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk Unk,Unk		Not Reported
	Venlafaxine Hydrochloride			S	Oral	150 Mg,Qd		Not Reported
	Moclobemide			S	Unknown	150 Mg,Hs		Not Reported
	Trazodone			S				Not Reported
	Escitalopram			S				Not Reported
	Warfarin			C				Not Reported
	Ginkgo Biloba Extract			C				Not Reported
	Sotalol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	14976711	EXPEDITED (15-DAY)			FI-ALLERGAN-1829278US		37 YR	Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Voxra			S	Oral	450 Mg, Qd		Not Reported
	Triptyl			C	Unknown	Unk		Not Reported

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09-Jul-2018	15027889	EXPEDITED (15-DAY)		OT	GB-TORRENT-00016655		53 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Mood Altered; Suicidal Ideation	Escitalopram 10 Mg Film-Coated Tablets			S				Unknown	
	Gaviscon			C		Unknown		Unknown	
	Lansoprazole			C		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15118767	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-921548		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Olanzapine			S	Oral			Not Reported	
	Ciprallex			S	Oral			Not Reported	
	Delorazepam			S	Oral			Not Reported	
	Venlafaxine			S	Oral	1 Dosage Forms Daily;		Teva	
	Donepezil			C	Unknown			Not Reported	
	Bisoprolol Fumarate			C	Unknown			Not Reported	
	Madopar			C	Unknown			Not Reported	
	Terazosin Hydrochloride			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15118899	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922496		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	
	Omeprazole Mylan 20 Mg, Gélule Gastro-Résistante			S	Oral	20 Milligram Daily;		Not Reported	
	Ramipril Mylan 5 Mg, Comprimé Sécable			S	Oral	5 Milligram Daily;		Not Reported	

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Acide Alendronique	C	Oral	1 S	Not Reported
Icaz Lp 2,5 Mg, Gélule À Libération Prolongée	C	Oral	2.5 Milligram Daily;	Not Reported
Sodium Alginate Sodium Bicarbonate Mylan	C	Oral	4 Dosage Forms Daily;	Not Reported
Ceris 20 Mg, Comprimé Enrobé	C	Oral	40 Milligram Daily;	Not Reported
Calperos D3, Comprimé À Sucrer	C	Oral	500 Milligram Daily;	Not Reported
Lactulose Mylan 10 G/15 Ml, Solution Buvable En Sachet	C	Oral	10 Gram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15119179	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-033189		71 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Escitalopram Arrow			S	Oral	10 Milligram, Daily		Aurobindo
	Risperidone			S	Oral	1 Milligram, Daily		Aurobindo
	Loxapine Succinate			S	Oral	5 Gtt, As Necessary		Not Reported
	Olanzapine Mylan			S	Oral	5 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15119638	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014658			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Medication Error	Escitalopram			S	Oral	35 Drop, Single, Total		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15121251	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2018271818		74 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Thrombosis	Celebrex			S		200 Mg, Unk		Pfizer

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Disprin Cardiacare	S	100 Mg, Unk	Not Reported
Adco-Zolpidem	S	10 Mg, Unk	Not Reported
Biotech Trazodone	S	50 Mg, Unk	Not Reported
Cipla-Simvastatin	S		Not Reported
Citraz	S	10 Mg, Unk	Not Reported
Ziabeta	S	2.5/6.25mg	Not Reported

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09-Jul-2018	15121860	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1834013US		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Fatigue; Fear; Feeding Disorder; Hallucination; Hospitalisation; Off Label Use; Pain; Panic Attack; Post-Traumatic Stress Disorder; Suicidal Ideation; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	
	Lysanxia			S	Unknown	10 Df, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15122091	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1834012US		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Diarrhoea	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	
	Meteospasmyl [Alverine Citrate;DI-Methionine			C	Unknown			Not Reported	
	Copper Iud			C	Unknown			Not Reported	

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09-Jul-2018	15122825	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1833645US		86 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage Intracranial	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Duoplavin			S	Oral	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15122884	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1048184		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Abnormal;	Enalapril			S	Oral	2 Df, Qd		Not Reported	
Depression; Diabetic	Escitalopram			S	Oral	1 Df, Qd		Not Reported	
Neuropathy;	Lantus			S	Subcutaneous	30 lu, Qd		Mylan	
Hyperglycaemia;	Seguril			S	Oral	1 Df, Qd		Mylan	
Hypoglycaemia; Influenza;	Carvedilol			S	Oral	1 Df, Qd		Mylan	
Myocardial Infarction	Orvatez			S	Oral	1 Df, Qd		Mylan	
	Toujeo			C	Subcutaneous	32 lu, Qd		Mylan	
	Lyxumia			C	Subcutaneous	Dose:20 Unit(S)		Mylan	
	Novorapid			C	Subcutaneous			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15123055	EXPEDITED (15-DAY)		HO	PHHY2018DE036797		65 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower;	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd (1-0-0-0)		Not Reported	
Dizziness; Dyspnoea;	Cipralax			S	Unknown	10 Mg, Qd (1-0-0-0)		Not Reported	
Haematochezia; Pain	Simvastatin			C	Unknown	20 Mg, Qd (0-1-0-0)		Not Reported	
	Ramipril			C	Unknown	2.5 Mg, Qd (0-1-0-0)		Not Reported	

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Spiriva	C	Unknown	18 Ug, Qd (1-0-0-0)	Not Reported
Pantoprazol	C	Unknown	40 Mg, Qd (0-0-1-0)	Not Reported
Euthyrox	C	Unknown	50 Ug, Qd (1-0-0-0)	Not Reported
Allopurinol	C	Unknown	5 Df, Qd (0-0-5-0)	Not Reported
Metamizol	C	Unknown	15 Gtt, Tid (1-1-1-0)	Not Reported
Metoprolol	C	Unknown	47.5 Mg, Bid (1-0-1-0)	Not Reported
Alna	C	Unknown	4 Mg, Qd (0-0-1-0)	Not Reported
Torasemid	C	Unknown	10 Mg, Qd (0-1-0-0)	Not Reported
Tramal Long	C	Unknown	Unk Mg, Unk (Bedarf)	Not Reported
Symbicort	C	Unknown	Unk Ug, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15123460	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018014655			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Disinhibition; Suicidal Ideation	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	13333566	EXPEDITED (15-DAY)		HO	IT-TEVA-749190ACC		74 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	1 Mg, Total		Actavis
	Entact			S	Oral			Not Reported
	Clozapine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	14357041	EXPEDITED (15-DAY)		HO	DE-MYLANLABS- 2018M1000859		42 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	40 Mg, Qd		Not Reported	
	Lorazepam			C		0.5 Mg, Unk		Mylan	
	Pangrol			C		Unk, Qd		Mylan	
	Olanzapine			C		10 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15107424	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1833492US		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Esidrex			S	Oral	0.5 Df, Qd		Not Reported	
	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported	
	Ramipril			C	Unknown			Not Reported	
	Dafalgan			C	Unknown	Unk G, Unk		Not Reported	
	Aspirin			C	Unknown	Unk		Not Reported	
	Acebutolol			C	Unknown	Unk		Not Reported	
	Seresta			C	Unknown	Unk		Not Reported	
	Mediatusyl			C	Unknown	Unk		Not Reported	
	Procoralan			C	Unknown	Unk		Not Reported	
	Pravastatine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15122077	EXPEDITED (15-DAY)		OT	IL-ALLERGAN-1834004US		65 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	

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Product Use In Unapproved Indication	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Unk	Allergan
	Levetiracetam	C	Unknown	1000 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Omeprazole	C	Unknown	20 Mg, Qd	Not Reported
	Alprazolam	C	Unknown	0.5 Mg, Qd	Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15123890	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922565		79 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Somnolence	Bisoprolol			S	Oral	1 Dosage Forms Daily;		Teva
	Escitalopram Arrow 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Arrow
	Pravastatine Biogaran 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Biogaran
	Zolpidem Sandoz 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Sandoz
	Rilmenidine Sandoz 1 Mg, Compressed			S	Oral	2 Dosage Forms Daily;		Sandoz
	Paracetamol			C	Unknown			Not Reported
	Aerius (Desloratadine)			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15124468	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/18/0101650		79 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Gait Disturbance; Hallucination; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1, Tabletten		Not Reported
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tabletten		Not Reported
	Cipralext 10mg			S	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Levothyroxine Sodium			C	Oral	75 Ug, 1-0-0-0, Tabletten		Not Reported

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Torasemid	C	Oral	10 Mg, 1-0-0-0, Tabletten	Not Reported
Felodipine	C		10 Mg, 1-0-0-0, Tabletten	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15124508	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MACLEODS PHARMACEUTICALS US LTD- MAC2018014671			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Venlafaxine 150 Mg			S	Oral	150 Milligram, Qd, In The Morning, In The Afternoon		Macleods
	Metoprolol			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Sertraline			S	Oral	50 Milligram, Qd, At Night		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd, At Bedtime		Not Reported
	Moclobemide			S	Oral	150 Milligram, Qd, In Afternoon		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Ginkgo Biloba Extract			C	Unknown	Unk		Not Reported
Sotalol			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15124525	EXPEDITED (15-DAY)		OT	HK-ACCORD-069588		43 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S		5 Mg Nocte In First Week		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125412	EXPEDITED (15-DAY)		DS	AU-ALLERGAN-			Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125436	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1048076		41 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Misuse; Intentional Self-Injury; Sluggishness; Sopor	Escitalopram			S	Oral	3 Df, Total		Not Reported
	Ethanol			S	Unknown	Dosage Form: Unspecified		Mylan
	Lyrica			S	Oral			Mylan
	Rezolsta			S	Oral			Mylan
	Tavor /00273201/			S	Unknown	3 Df, Total		Mylan
	Minias			S	Unknown	40 Gtt, Total		Mylan
	Kivexa			S	Unknown	4 Df, Total		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125449	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1048071		14 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Not Reported
	Haldol			S	Oral	15 MI In Total		Mylan
	Xanax			S	Oral	12 Df Units In Total		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125540	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-923609		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blood Glucose Abnormal; Depression; Diabetic Neuropathy; Hyperglycaemia; Hypoglycaemia; Influenza; Myocardial Infarction	Enalapril	S	Oral	2 Dosage Forms Daily;	Teva
	Escitalopram	S	Oral	1 Dosage Forms Daily;	Ivax
	Lantus (Insulin Glargine)	S	Subcutaneous	30 Iu (International Unit) Daily;	Not Reported
	Seguril	S	Oral	1 Dosage Forms Daily;	Not Reported
	Carvedilol	S	Oral	1 Dosage Forms Daily;	Not Reported
	Orvatez	S	Oral	1 Dosage Forms Daily;	Not Reported
	Toujeo	C			Not Reported
	Lyxumia	C			Not Reported
	Novorapid	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125640	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018273649		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperleukocytosis; Pancreatitis; Renal Failure	Atarax			S	Oral	750 Mg, Unk		Pfizer	
	Ibuprofen			S	Oral	6 G, Unk		Pfizer	
	Escitalopram			S	Oral	140 Mg, Unk		Not Reported	
	Coltramy			S	Oral	48 Mg, Unk		Not Reported	
	Paracetamol			S		8.8 G, Unk		Not Reported	
	Alprazolam			C	Oral	5 Mg, Unk		Not Reported	
	Cefuroxime			C	Oral	Unk		Not Reported	
	Brexin			C	Oral	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15125844	EXPEDITED (15-DAY)		OT	CH-ALLERGAN- 1834009US			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Prescribed Overdose; Short-Bowel Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127280	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1834026US		76 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Angle Closure Glaucoma; Eye Pain; Gastric Ph Decreased; Hypertension; Intentional Dose Omission; Prescription Drug Used Without A Prescription; Visual Acuity Reduced	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	0.25 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df (10 Mg), Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	1.5 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
	Alprazolam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127363	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1048357		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome; Drug Interaction	Escitalopram			S	Oral			Not Reported	
	Dexametasona /00016001/			S	Oral	0.25 Mg, Qd		Mylan	
	Hidroaltesona			S	Oral	20 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127578	EXPEDITED (15-DAY)		OT	CN-PRINSTON PHARMACEUTICAL INC.-2018PRN00371		43 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	5 Mg, 1x/Day		Prinston Pharmaceutical	
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Prinston Pharmaceutical	

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Escitalopram			S		Unknown		5 Mg, 1x/Day		Prinston Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127587	EXPEDITED (15-DAY)		HO, OT		IE-PRINCSTON PHARMACEUTICAL INC.-2018PRN00368		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram				S	Oral	5 Mg, 1x/Day		Prinston Pharmaceutical	
	Escitalopram				S	Oral	10 Mg, 1x/Day		Prinston Pharmaceutical	
	Lamotrigine				S	Unknown			Not Reported	
	Clobazam				C	Unknown	10 Mg, 2x/Day		Not Reported	
	Clobazam				C	Unknown	10 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127598	EXPEDITED (15-DAY)		HO		FR-ALLERGAN- 1834665US		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp				S	Oral	Unknown; In Total		Allergan	
	Alprazolam				S	Oral	Unknown; In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15055075	EXPEDITED (15-DAY)		OT		CN-ALLERGAN- 1831836US			Male	CHN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Mood Altered; Suicidal Ideation	Escitalopram Oxalate - Bp				S	Oral	Unk Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15117007	EXPEDITED (15-DAY)		HO, LT, OT		CH-JNJFOC- 20180705628		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Delirium; Disturbance In Attention	Haldol	S	Oral		Not Reported
	Tramal	S	Oral		Not Reported
	Morphin Hcl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Morphin Hcl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Quetiapin Sandoz	S	Oral		Not Reported
	Quetiapin Sandoz	S	Oral		Not Reported
	Quetiapin Sandoz	S	Oral	At Night	Not Reported
	Valium	S	Oral		Not Reported
	Pramipexol	S	Oral	(Once In Evening)	Not Reported
	Cipralex	S	Oral	Once In Morning	Not Reported
	Pantoprazol Sandoz	S	Oral	Once In Morning	Not Reported
	Allopurinol	S	Oral	Once In Morning And Evening	Not Reported
	Allopurinol	S	Oral	Once In Morning	Not Reported
	Lisitril	S	Oral	Once In Morning	Not Reported
	Meto Zerok	S	Oral	Once In Morning	Not Reported
	Plavix	S	Oral	Once In Morning	Not Reported
	Plavix	S	Oral		Not Reported
	Spiricort	S	Unknown	0.75 In The Morning And 0.25 In The Evening	Not Reported
	Oxynorm	S	Oral		Not Reported
	Fentanyl Sintetica	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin Cardio	C	Oral	In Morning	Not Reported
	Atorvastatin Pfizer	C	Oral	In Morning	Not Reported
	Dafalgan	C	Oral	In Morning, Midday And Evening	Not Reported
	Spiriva	C	Respiratory (inhalation)	In Morning	Not Reported

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Torem	C	Unknown	In Morning	Not Reported
Novalglin (Metamizole Sodium)	C	Oral		Not Reported

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11-Jul-2018	15129360	EXPEDITED (15-DAY)		HO	IT-MERCK KGAA-2051719		83 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Novothyrox			S	Oral			Merck Kgaa
	Cipralext			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lansox			C				Not Reported
	Folina [Folic Acid]			C				Not Reported
	Torvast			C				Not Reported
	Allopurinol			C				Not Reported
	Luvion			C				Not Reported
	Bisoprolol Hemifumarate			C				Not Reported
Amiodar			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15129980	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1834376US		35 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Abilify			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Noctran			C	Unknown	Unk		Not Reported
	Tercian			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15130016	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1833595US			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Platelet Count Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15130886	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018271166		58 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Aspavor			S		20 Mg, Unk		Pfizer	
	Prexum Plus /01421201/			S		5/1.25 Mg		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
	Trepiline /00002201/			S		25 Mg, Unk		Not Reported	
	Wellbutrin XI			S		150 Mg, Unk		Not Reported	
	Glucophage Xr			S		1000 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15130888	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018276979		59 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Seizure	Aldactone (Spironolactone)			S				Pfizer	
	Lancap			S				Not Reported	
	Duovent			S				Not Reported	
	Rivotril			S				Not Reported	
	Mylan Furosemide			S				Not Reported	
	Plenish-K			S				Not Reported	
	Lexamil			S				Not Reported	
	Euthyrox			S				Not Reported	
	Redilev			S				Not Reported	
	Epilim Cr			S				Not Reported	
	Symbicord			S				Not Reported	
	Ipvent			S				Not Reported	
	Nexipraz			S				Not Reported	
	Venteze (Salbutamol)			S				Not Reported	
	Beceze			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15130890	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018276759		53 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure	Aspavor			S		40 Mg, Unk		Pfizer	
	Furosemide			S		40 Mg, Unk		Not Reported	
	Purgoxin			S		0.25 Mg, Unk		Not Reported	
	Clopiwin			S		75 Mg, Unk		Not Reported	
	Disprin Cardiocare			S		100 Mg, Unk		Not Reported	
	Zetomax			S		5 Mg, Unk		Not Reported	
	Carloc			S		6.25 Mg, Unk		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	14528961	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00009875		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Digoxin			S	Unknown	Unk		Not Reported	
	Amiodarone (Ngx)			S	Unknown	Unk		Not Reported	
	Bisoprolol (Ngx)			S	Unknown	Unk		Not Reported	
	Domperidone (Ngx)			S	Unknown	Unk		Not Reported	
	Escitalopram (Ngx)			S	Unknown	10 Mg, Unk		Not Reported	
	Escitalopram (Ngx)			S	Unknown	5 Mg, Unk		Not Reported	
	Aliskiren			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15017552	NON-EXPEDITED			US-JNJFOC-20180604319			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Asthenia; Fatigue; Feeling Abnormal; Somnolence	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Xarelto	S	Oral	Not Reported
	Lexapro	S	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Promeprazole	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15132870	EXPEDITED (15-DAY)		HO	IE-UNICHEM PHARMACEUTICALS (USA) INC-UCM201807-000		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Drug Level Increased; Toxicity To Various Agents	Lamotrigine			S				Unichem	
	Clobazam			S				Not Reported	
	Clobazam			S				Not Reported	
	Escitalopram			S				Not Reported	
	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15132936	EXPEDITED (15-DAY)		HO, LT, OT	CH-TEVA-2018-CH-922614		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenocorticotrophic Hormone Deficiency; Aspiration; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Allopurinol Mepha			S	Oral	200 Milligram Daily;		Actavis	
	Allopurinol Mepha			S	Oral	100 Milligram Daily;		Actavis	
	Pramipexol Helvepharm			S	Oral	.125 Milligram Daily;		Not Reported	
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported	
	Pantoprazol Sandoz			S	Oral	40 Milligram Daily;		Not Reported	
	Lisitril			S	Oral	20 Milligram Daily;		Not Reported	
	Meto Zerok			S	Oral	50 Milligram Daily;		Not Reported	
	Plavix			S	Oral	75 Milligram Daily;		Not Reported	

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Plavix	S	Oral	75 Milligram Daily;	Not Reported
Spiricort	S		Spiricort, Film-Coated Tablets, 20 Mg (Prednisolone); 0.75-0-0.25-0, Until 2 June 2018	Not Reported
Tramal	S	Oral	Tramal® Tropfen (100 Mg = 40 Gtt) 100 Mg/1 Ml ; As Necessary	Not Reported
Fentanyl Sintetica	S	Intravenous (not otherwise specified)	In Total	Not Reported
Haldol	S	Oral	In Total	Not Reported
Oxynorm	S	Oral	As Necessary	Not Reported
Morphin Hcl Sintetica	S	Oral	In Total	Not Reported
Morphin Hcl Sintetica	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	In Total	Not Reported
Quetiapin Sandoz	S	Oral	25 Milligram Daily;	Not Reported
Valium	S	Oral	As Necessary	Not Reported
Aspirin Cardio	C	Oral	100 Milligram Daily;	Not Reported
Atorvastatin Pfizer	C	Oral	20 Milligram Daily;	Not Reported
Dafalgan	C	Oral	1500 Milligram Daily;	Not Reported
Spiriva	C		18 Microgram Daily;	Not Reported
Torem	C		5 Milligram Daily;	Not Reported
Novalgine (Metamizole Sodium)	C	Oral	As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15133134	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-924309		31 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	

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12-Jul-2018	15134094	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-034849		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo	
	Zopiclone			S	Oral	7.5 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15135999	NON-EXPEDITED			US-APOTEX-2018AP016806		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Gastritis; Hyperchlorhydria	Fluoxetine			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15136225	NON-EXPEDITED			JP-ALLERGAN-1835035US		45 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Convulsions Local	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Gasmotin			C	Oral	Unk		Not Reported	
	Domperidone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15136957	EXPEDITED (15-DAY)		HO	PHHY2018TR039251		52 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion; Paranoia; Speech Disorder	Quetiapine			S	Unknown	200 Mg, Unk		Novartis	
	Quetiapine			S	Unknown	25 Mg, Unk		Novartis	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Aripiprazole			S	Unknown	30 Mg, Unk		Not Reported	

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Carbamazepine			S	Unknown	400 Mg, Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15137862	EXPEDITED (15-DAY)		HO	IL-ALLERGAN-1834976US		78 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unk		Allergan	
	Stator			C	Unknown			Not Reported	
	Sterocort			C	Unknown			Not Reported	
	Insulin Degludec			C	Unknown			Not Reported	
	Normiten			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15137912	EXPEDITED (15-DAY)		OT	AT-ELI_LILLY_AND_COMP ANY-AT201807002331		21 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Zyprexa Velotab			S	Unknown	2.5 Mg, Unknown		Not Reported	
	Zyprexa Velotab			S	Unknown	5 Mg, Unknown		Not Reported	
	Seroquel			S	Unknown	75 Mg, Unknown		Not Reported	
	Seroquel			S	Unknown	100 Mg, Unk		Not Reported	
	Ciprallex /01588501/			S	Unknown	5 Mg, Unknown		Not Reported	
	Ciprallex /01588501/			S	Unknown	10 Mg, Unk		Not Reported	
	Lamictal			S	Unknown	25 Mg, Unknown		Not Reported	
	Lamictal			S	Unknown	50 Mg, Unk		Not Reported	
	Lamictal			S	Unknown	100 Mg, Unk		Not Reported	
	Gewacalm			S	Unknown	5 Mg, Unk		Not Reported	
	Gewacalm			S	Unknown	10 Mg, Unknown		Not Reported	
	Gewacalm			S	Unknown	15 Mg, Unk		Not Reported	
	Trittico			S		50 Mg, Unk		Not Reported	

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Trittico	S	Unknown	100 Mg, Unknown	Not Reported
Trittico	S	Unknown	150 Mg, Unknown	Not Reported
Dominal /00018902/	S	Unknown	80 Mg, Unknown	Not Reported
Dominal /00018902/	S	Unknown	40 Mg, Unknown	Not Reported
Dominal /00018902/	S		80 Mg, Unk	Not Reported
Temesta /00273201/	S	Unknown	Unk Unk, Unknown	Not Reported
Zoldem	C	Unknown	10 Mg, Unknown	Not Reported
Quilonorm /00033702/	C	Unknown	225 Mg, Unknown	Not Reported
Halcion	C	Unknown	.25 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15242922	DIRECT		DS, HO			81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Pneumonia	Imitrex			S	Oral			Not Reported
	Imitrex			S				Not Reported
	Patanol			S				Not Reported
	Lorsartan			S				Not Reported
	Aggrenox			S				Not Reported
	Atenolol			S				Not Reported
	Tramadol			S				Not Reported
	Levothyronine			S				Not Reported
	Lyrica			S				Not Reported
	Escitalopram			S				Not Reported
	Trazodone			S				Not Reported
	Dok			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Fiber Ion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	12773443	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2016SE99839		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Cough;	Inexium			S	Oral			Astrazeneca	

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Interstitial Lung Disease	Triatec (Ramipril)	S	Oral		Not Reported
	Seroplex	S	Oral		Not Reported
	Stilnox	S	Oral		Not Reported
	Cellcept	S	Oral		Not Reported
	Cortancyl	S	Oral		Not Reported
	Tahor	S	Oral		Not Reported
	Theralene	S	Oral		Not Reported
	Ixprim	S	Oral	37,5 Mg / 325 Mg Coated Tablet	Not Reported
	Seresta	C			Not Reported
	Lasilix	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14252402	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017513653		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradypnoea; Bundle Branch Block Right; Diarrhoea; Electrocardiogram Qrs Complex Prolonged; Haematuria; Hyperkalaemia; Intentional Overdose; Sinus Bradycardia; Somnolence; Vomiting	Tahor			S	Oral	40 Mg, Daily		Pfizer	
	Tahor			S	Oral	40 Mg, Daily		Pfizer	
	Triatec (Ramipril)			S	Oral	2.5 Mg, 2x/Day		Pfizer	
	Bisoprolol Fumarate			S	Oral	2 Df, Daily (3.25 Mg In The Morning And 2.5 Mg In The Evening)		Not Reported	
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported	
	Diffu-K			S	Oral	Unk		Not Reported	
	Brilique			S	Oral	90 Mg, 2x/Day		Not Reported	
	Brilique			S	Oral	90 Mg, 2x/Day		Not Reported	
	Seroplex			S	Oral	5 Mg, Daily		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Lactibiane (Probiotic)			S	Unknown	Unk		Not Reported	
	Inexium			C		20 Mg, Daily		Not Reported	
	Kardegic			C		75 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14281931	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-17P-144-2191476-00		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Intentional Overdose	Valproate Sodium			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Antabus			S	Oral			Not Reported	
	Abilify			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14816351	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1027581		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Aripiprazole			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Norset			S	Oral	Unk		Mylan	
	Lexapro			S		Unk		Mylan	
	Seroplex			S	Oral	Unk		Mylan	
	Inipomp			C		Unk		Mylan	
	Aprovel			C		Unk		Mylan	
	Kardegic			C		Unk		Mylan	
	Irbesartan			C	Oral	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14931584	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-896822		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cushing'S Syndrome; Drug Interaction	Escitalopram	S	Oral	10 Milligram Daily;	Ivax
	Dexametasona (722a)	S	Oral	.25 Milligram Daily;	Not Reported
	Hidroaltesona Tablets, 10 Tablets	S	Oral	20 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14978716	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-028985		21 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sopor	Aripiprazole Tablets			S	Oral	210 Milligram, In Total		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	140 Milligram, In Total		Aurobindo
	Alprazolam			S	Oral	15 Milliliter, In Total		Not Reported
	Prozin /00011902/			S	Oral	1200 Milligram, In Total		Not Reported
	Zitromax			S	Oral	1500 Milligram,In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15100193	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT- 918561		46 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram Oxalate			S	Oral			Ivax
	Lexotan 2,5 Mg/Ml Gocce Orali Soluzione			S	Oral			Not Reported
	Efexor 37,5 Mg Capsule Rigide A Rilascio Prolungato			S	Oral			Not Reported
	Lamictal 100 Mg Compresse			S	Oral			Not Reported
	Masticabili/Dispersibili							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15138704	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 924521		46 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperleukocytosis;	Escitalopram			S	Oral			Ivax

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Pancreatitis; Renal Failure	Ibuprofene	S	Oral	Actavis
	Paracetamol	S	Unknown	Not Reported
	Atarax	S	Oral	Not Reported
	Coltramyl	S	Oral	Not Reported
	Alprazolam	C	Oral	Not Reported
	Cefuroxime	C	Oral	Not Reported
	Brexin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15138918	EXPEDITED (15-DAY)	CA		DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00013750			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect;	Prednisolone			S				Concordia
Autism Spectrum	Lorazepam			S				Not Reported
Disorder; Camptodactyly	Fosfomycin			S				Not Reported
Congenital; Clinodactyly;	Valaciclovir			S				Not Reported
Congenital Arterial	Abatacept			S				Not Reported
Malformation; Congenital	Ursodeoxycholic Acid			S				Not Reported
Central Nervous System	Mycophenolate Mofetil			S				Not Reported
Anomaly; Congenital	Tacrolimus			S				Not Reported
Renal Cyst; Dysplasia;	Acebutolol			S				Not Reported
External Auditory Canal	Prednisone			S				Not Reported
Atresia; Foetal Exposure	Colchicine			S				Not Reported
During Pregnancy; Foetal	Cyclosporine			S				Not Reported
Malformation;	Methyldopa			S				Not Reported
Hydronephrosis;	Azathioprine			S				Not Reported
Meningocele; Microtia;	Naproxen			S				Not Reported
Oesophageal Atresia;	Zolpidem			S				Not Reported
Premature Baby	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139196	NON-EXPEDITED			US-PFIZER INC- 2018280417			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Atenolol	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Doxepin Hcl	S	Unk	Pfizer
	Spironolactone	S	Unk	Pfizer
	Vancomycin Hcl	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Zoloft	S	Unk	Pfizer
	Arimidex	S	Unk	Not Reported
	Ceftin	S	Unk	Not Reported
	Ethacrynic Acid	S	Unk	Not Reported
	Januvia	S	Unk	Not Reported
	Lasix	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Lisinopril	S	Unk	Not Reported
	Losartan	S	Unk	Not Reported
	Lovenox	S	Unk	Not Reported
	Mavik	S	Unk	Not Reported
	Metformin Hcl	S	Unk	Not Reported
	Prandin	S	Unk	Not Reported
	Topamax	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139387	EXPEDITED (15-DAY)		OT	FR-ACCORD-069429		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition	Escitalopram			S	Oral			Not Reported	
Aggravated; Formication; Hyperkalaemia; Myalgia; Off Label Use; Testicular	Inexium			S	Oral			Not Reported	

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Pain	Pravastatin	C	Oral	Not Reported
	Pregabalin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139588	EXPEDITED (15-DAY)	DE		AT-ASTRAZENECA-2018SE87806		36 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Seroquel			S	Oral	100.0mg Unknown		Zeneca	
	Seroquel			S	Oral	50.0mg Unknown		Not Reported	
	Cipralex			S	Oral	10.0mg Unknown		Not Reported	
	Cipralex			S	Oral	20.0mg Unknown		Not Reported	
	Mirtazapine			S	Unknown	30.0mg Unknown		Not Reported	
	Mirtazapine			S	Unknown	15.0mg Unknown		Not Reported	
	Inderal			C	Unknown	10.0mg Unknown		Not Reported	
	Inderal			C	Unknown	20.0mg Unknown		Not Reported	
	Zoldem			C	Unknown	5.0mg Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139597	EXPEDITED (15-DAY)	OT		DE-HETERO CORPORATE-HET2018DE00646		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inhibitory Drug Interaction; Psychotic Disorder	Escitalopram			S	Unknown	Unk		Hetero	
	Lixiana			S	Unknown	60 Mg, Qd		Not Reported	
	Olanzapin			S	Unknown	Unk		Not Reported	
	Cortisone			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15141879	EXPEDITED (15-DAY)	OT		DE-AUROBINDO-AUR-APL-2018-035860		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram	S	Oral	Unk, Once A Day In The Morning	Aurobindo

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13-Jul-2018	15142312	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE- IT2018120525		24 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperreflexia; Intentional Self-Injury; Loss Of Consciousness; Mydriasis; Nystagmus; Overdose; Tachycardia	Lamictal			S	Oral	In Total		Glaxosmithkline
	Cipralext			S	Unknown	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15143094	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC- 2018279087		78 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphasia	Amlodipine Besilate			S		5 Mg, Unk		Pfizer
	Xalatan			S		50 Ug, Unk		Pfizer
	Lancap			S		30 Mg, Unk		Not Reported
	Tesar			S		80 Mg, Unk		Not Reported
	Clopidogrel			S		75 Mg, Unk		Not Reported
	Glucophage Xr			S		500 Mg, Unk		Not Reported
	Rivotril			S		0.5 Mg, Unk		Not Reported
	Lexamil			S		10 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Diagluclide			S		30 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15145573	EXPEDITED (15-DAY)		HO, LT, OT	CH-ALLERGAN- 1835159US		83 YR	Male	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Aspiration; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Pantoprazol Sandoz			S	Oral	40 Mg, Qd		Not Reported
	Allopurinol Mepha			S	Oral	100 Mg, Bid		Not Reported
	Allopurinol Mepha			S	Oral	100 Mg, Qd		Not Reported
	Lisitril			S	Oral	20 Mg, Qd		Not Reported
	Meto Zerok			S	Oral	50 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Not Reported
	Spiricort			S	Unknown	15 Mg - 0 - 5 Mg, Bis Am		Not Reported
	Tramal			S	Oral	10 Gtt, Prn		Not Reported
	Fentanyl Sintetica			S	Intravenous (not otherwise specified)	25 Mg, Single		Not Reported
	Haldol			S	Oral	10 Gtt, Single		Not Reported
	Oxynorm			S	Oral	5 Mg, Prn		Not Reported
	Morphin Hcl Sintetica			S	Oral	7.5 Mg, Single		Not Reported
	Morphin Hcl Sintetica			S	Oral	2.5 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	125 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	200 Mg, Single		Not Reported
	Quetiapin Sandoz			S	Oral	25 Mg, Qd		Not Reported
	Valium			S	Oral	5 Mg, Prn		Not Reported
	Pramipexol Helvepharm			S	Oral	0.125 Mg, Qd		Not Reported
	Aspirin Cardio			C	Oral	100 Mg, Qd		Not Reported
	Atorvastatin Pfizer			C	Oral	20 Mg, Qd		Not Reported
	Dafalgan			C	Oral	500 Mg, Q8hr		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Torem			C	Unknown	5 Mg, Qd		Not Reported
	Novalglin (Metamizole Sodium)			C	Oral	As Necessary		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2018	15145974	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-925219		86 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Duoplavin			S	Oral	75 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2018	15146120	EXPEDITED (15-DAY)		DE, HO	GB-TORRENT-00016874		88 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid			S	Oral	Unknown		Unknown	
	Dihydrocodeine			C	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	13330395	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1015247		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral	100 Mg, Once		Not Reported	
	Clozapine			S		Unk		Not Reported	
	Lorazepam			S	Oral	1 Mg, Once		Not Reported	
	Entact			S	Oral	20 Mg, Once		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	14445008	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20180119290		59 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Not Reported	

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Motilium		S	Oral	Start Unspecified Might Be Between 15-Sep Of An Unspecified Year And 02-Oct Of An Unspecified Year	Not Reported
Motilium		S	Oral		Not Reported
Imodium	Y	S	Oral		Not Reported
Imodium		S	Oral		Not Reported
Ondansetron		S	Oral		Not Reported
Nexium		S	Oral		Not Reported
Faslodex		S	Intramuscular		Not Reported
Ibrance		S	Oral	Interrupted From 19-Sep-Of An Unspecified Year To 12-Nov Of An Unspecified Year	Not Reported
Ibrance		S	Oral		Not Reported
Escitalopram		S	Oral		Not Reported
Escitalopram		S	Oral		Not Reported
Imovane		C	Unknown		Not Reported
Calcimagon		C	Unknown		Not Reported
Condrosulf		C	Unknown		Not Reported
Euthyrox		C	Unknown		Not Reported
Dafalgan		C	Unknown		Not Reported
Irfen		C	Unknown		Not Reported
Diclofenac Epolamine		C	Unknown		Not Reported
Diclofenac Epolamine		C	Unknown	Interrupted From 02-Oct Of An Unspecified Year To 01-Dec Of An Unspecified Year	Not Reported
Temgesic		C	Unknown		Not Reported
Targin		C	Unknown		Not Reported
Oxynorm		C	Unknown		Not Reported

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Sodium Bicarbonate	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Clexane	C	Unknown	Not Reported
Mycostatine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	14868033	EXPEDITED (15-DAY)		LT, OT	US-JNJFOC-20180505018		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Overdose; Syncope	Loperamide Hydrochloride		Y	S	Unknown			Not Reported
	Loperamide Hydrochloride			S	Unknown			Not Reported
	Quetiapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15104037	EXPEDITED (15-DAY)		HO	DE-OTSUKA-2018_017640		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole			S	Unknown	5 Mg, Qd		Otsuka
	Escitalopram			S	Unknown	20 Mg, Qd (Increased To A Dose Of 20 Mg)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd (In A Morning Target Dose Of 20 Mg)		Not Reported
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Opipramol			C	Unknown	Unk (In Crisis Situations With Temporary Effect)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lorazepam	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
Pregabalin	C	Unknown	100 Mg, Qd (Evening Dose Of 100 Mg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15139598	EXPEDITED (15-DAY)		OT	IN-HETERO LABS LIMITED- HET2018IN00641		72 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Speech Disorder; Suicidal Ideation; Tremor	Escitalopram			S	Oral	Unk, Qd		Hetero	
	Rescue			C	Unknown	Unk Unk, Qd		Not Reported	
	Bupropion			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15146865	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE- HET2018DE00650		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dyspepsia	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Neupro			S	Transdermal	14 Mg, Qd		Not Reported	
	Ibuprofen /00109205/			S	Unknown	Unk		Not Reported	
	Amantadin /00055901/			S	Unknown	100 Mg, Bid		Not Reported	
	Amitriptylin			S	Unknown	75 Mg, Qd		Not Reported	
	Bornaprine			S	Unknown	4 Mg (1-0.5-1-0)		Not Reported	
	Madopar Depot			C	Unknown	100/25 Mg		Not Reported	
	Madopar Depot			C	Unknown	100/25 Mg, 1.5-1.5-1.5-1.5		Not Reported	
	Madopar Depot			C	Unknown	100/25 Mg, 1-0-0-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15147045	EXPEDITED (15-DAY)		HO, OT	IE-CIPLA LTD.- 2018IE19846			Unknown	IRL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebellar Syndrome; Drug Interaction; Nausea; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	5 Mg, Once Daily		Invagen
	Escitalopram			S	Oral	10 Mg, Once Daily		Invagen
	Lamotrigine			S	Unknown	Unk		Not Reported
	Clobazam			S	Unknown	10 Mg, Twice Daily		Not Reported
	Clobazam			S	Unknown	10 Mg, Thrice Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15147143	EXPEDITED (15-DAY)		DE, OT	ZA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-064580		83 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Glucophage Xr			S	Unknown	500 Mg, Unk		Bristol Myers Squibb
	Aspavor			S	Unknown	20 Mg, Unk		Not Reported
	Zanidip			S	Unknown	10 Mg, Unk		Not Reported
	Lasix /00032601/			S	Unknown	20 Mg, Unk		Not Reported
	Spiractin /00006201/			S	Unknown	25 Mg, Unk		Not Reported
	Ganfort			S	Unknown	5 Mg, Unk		Not Reported
	Ecotrin			S	Unknown	81 Mg, Unk		Not Reported
	Stilpane /01152401/			S	Unknown			Not Reported
	Lexamil			S	Unknown	5 Mg, Unk		Not Reported
	Bilocor			S	Unknown	5 Mg, Unk		Not Reported
	Epleptin			S	Unknown	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15147295	EXPEDITED (15-DAY)		OT	IL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-178413		65 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported

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Inappropriate Antidiuretic Hormone Secretion	Alprazolam	S	Unknown	1 Mg, Daily	Sun
	Zopiclone	C	Unknown	7.5 Mg, Daily	Not Reported
	Levetiracetam	C	Unknown	1000 Mg, Daily	Not Reported
	Omeprazole	C	Unknown	20 Mg, Daily	Not Reported
	Prednisone	C	Unknown	10 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15147899	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-178496		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	0.5 Mg Matin Et Soir		Ranbaxy	
	Loxapine (Succinate De)			S	Oral	5 Gouttes Si Besoin ; As Necessary		Not Reported	
	Escitalopram Arrow			S	Oral	10 Mg Le Soir		Not Reported	
	Olanzapine Mylan			S	Oral	5 Mg Le Soir		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15148219	EXPEDITED (15-DAY)		HO	LU-TEVA-2018-LU- 923654		47 YR	Female	LUX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Actin Antibody Positive; Gamma- Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral			Ivax	
	Gilenya 0,5 Mg, Gélule			S	Oral			Not Reported	
	Lyrica			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15148645	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2018M1050420		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt	Amiodarone			S	Unknown	Unk		Not Reported	

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Prolonged	Bisoprolol	S	Unknown	Unk	Not Reported
	Domperidone	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
	Escitalopram	S	Unknown	5 Mg, Unk	Not Reported
	Digoxin	S	Unknown	Unk	Not Reported
	Aliskiren	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15148801	EXPEDITED (15-DAY)		HO	IE-MYLANLABS-2018M1051409		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Toxicity To Various Agents	Lamotrigine			S	Unknown			Not Reported	
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Clobazam			C	Unknown	10 Mg, Unk		Mylan	
	Clobazam			C	Unknown	10mg Three Times Daily		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149008	EXPEDITED (15-DAY)		CA, HO, OT	IT-TEVA-2018-IT-926354			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome; Live Birth	Carbolithium			S	Transplacental	The Treatment Was Continued Till 39 Weeks Of Gestation		Barr	
	Escitalopram			S	Transplacental	The Treatment Was Continued Until Six Weeks Of Gestation		Not Reported	
	Lorazepam			C	Transplacental	The Treatment Was Continued Until 38 Weeks Of Gestation		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149124	EXPEDITED (15-DAY)		OT	CN-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00276		43 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	5 Mg,		Jubilant	
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Jubilant	
	Escitalopram			S	Unknown	5 Mg, 1x/Day		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149129	EXPEDITED (15-DAY)		HO, OT	IE-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00272		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram			S	Oral	5 Mg, 1x/Day		Jubilant	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Jubilant	
	Lamotrigine			S	Unknown	Unk		Jubilant	
	Clobazam			C	Unknown	10 Mg, 2x/Day		Not Reported	
	Clobazam			C	Unknown	10 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149133	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CH044268		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Disturbance In Attention	Pantoprazole Sandoz			S	Oral	40 Mg, Qd		Novartis	
	Quetiapine Sandoz			S	Oral	125 Mg, Total		Not Reported	
	Quetiapine Sandoz			S	Oral	200 Mg, Total		Not Reported	
	Quetiapine Sandoz			S	Oral	25 Mg, Qd		Not Reported	
	Lisitril			S	Oral	20 Mg, Qd		Not Reported	
	Meto Zerok			S	Oral	50 Mg, Qd		Not Reported	

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Pramipexole Helvepharm	S	Oral	0.125 Mg, Qd	Not Reported
Cipralex	S	Oral	10 Mg, Qd	Not Reported
Plavix	S	Oral	75 Mg, Qd	Not Reported
Spiricort	S	Unknown	20 Mg, Qd	Not Reported
Tramal	S	Oral	10 Gtt, Prn	Not Reported
Fentanyl Sintetica	S	Intravenous (not otherwise specified)	25 Ug, Total	Not Reported
Haldol	S	Oral	10 Gtt, Total	Not Reported
Oxynorm	S	Oral	5 Mg, Prn	Not Reported
Morphin Hcl Sintetica	S	Oral	7.5 Mg, Total	Not Reported
Morphin Hcl Sintetica	S	Oral	2.5 Mg, Total	Not Reported
Valium	S	Oral	5 Mg, Prn	Not Reported
Aspirin Cardio	C	Oral	100 Mg, Qd	Not Reported
Atorvastatin Pfizer	C	Oral	20 Mg, Qd	Not Reported
Dafalgan	C	Oral	500 Mg, Q8h	Not Reported
Spiriva	C	Unknown	Unk	Not Reported
Torem	C	Unknown	5 Mg, Qd	Not Reported
Novalgine (Metamizole Sodium)	C	Oral	500 Mg, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149389	EXPEDITED (15-DAY)		CA, OT	IT-MYLANLABS-2018M1051505			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Lithium			S	Transplacental	The Treatment Was Continued Till 39 Weeks Of Gestation		Not Reported
	Escitalopram			S	Transplacental	The Treatment Was Continued Until Six Weeks Of Gestation		Not Reported
	Lorazepam			C	Transplacental	The Treatment Was Continued Until 38 Weeks		Mylan

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Of Gestation									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150310	EXPEDITED (15-DAY)		HO	PHHY2018FR044748		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia;	Risperidone			S	Oral	36 Mg, Total		Novartis	
Extrapyramidal Disorder;	Escitalopram			S	Oral	9 Mg, Total		Not Reported	
Mydriasis; Sinus	Theralene			C	Oral	Unk		Not Reported	
Tachycardia									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150474	EXPEDITED (15-DAY)		OT	AT-MYLANLABS-2018M1051115		38 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Autonomic	Escitalopram			S	Unknown	Unk		Not Reported	
Nervous System	Escitalopram			S	Unknown	Doubled Dosage		Not Reported	
Imbalance; Cognitive	Dextromethorphan			S	Oral	Unk		Mylan	
Disorder; Hyperhidrosis;	Hydrobromide W/Dox/01062901/								
Hyperreflexia; Labelled									
Drug-Drug Interaction									
Medication Error;									
Restlessness; Serotonin									
Syndrome; Tachypnoea;									
Tremor									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15151310	EXPEDITED (15-DAY)		HO	TR-LANNETT COMPANY, INC.-TR-2018LAN000806		34 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sinus Bradycardia	Cetirizine Hydrochloride			S	Oral	10 Mg, Qd		Lannett	
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett	
	Enoxaparin			C		60 Mg, Qd		Not Reported	

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Pantoprazole	C	40 Mg, Qd	Not Reported
Aspirin /00002701/	C	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	13078794	EXPEDITED (15-DAY)		HO, OT	IT-ABBVIE-17P-083-1827084-00		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Feeling Of Despair; Insomnia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation; Treatment Noncompliance	Valproic Acid			S	Unknown			Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Oral			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Clonazepam			S	Oral			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
Trazodone Hydrochloride			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15009685	EXPEDITED (15-DAY)		HO	US-VIVIMED-2018SP004473			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Electrocardiogram Qrs Complex Prolonged; Overdose; Seizure	Amlodipine			S	Oral	Unk		Vivimed Labs
	Escitalopram			S	Oral	Unk		Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported
	Buspirone			S	Oral	Unk		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Amphetamine W/Dexamphetamine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Fluoxetine			S	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15137865	EXPEDITED (15-DAY)		HO, OT	IE-ALLERGAN-1835047US		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Lamotrigine			S	Unknown	Unk		Not Reported	
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported	
	Clobazam			C		10 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15152209	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-926895		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral			Actavis	
	Seroplex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15152580	EXPEDITED (15-DAY)		HO, OT	IE-ACCORD-069538		42 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction	Escitalopram			S		Dose Increase To 10mg Od		Accord	
	Lamotrigine			S				Not Reported	
	Clobazam			C				Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15153490	EXPEDITED (15-DAY)		HO	PHHY2018IT047245		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam	S	Oral			Not Reported
	Alprazolam	S	Oral	1.5 Mg, Unk		Novartis
	Escitalopram	S	Oral			Not Reported
	Quetiapine	S	Oral			Not Reported
	Venlafaxine	S	Oral			Not Reported
	Valproic Acid	S	Oral	300 Mg, Unk		Not Reported
	Trazodone	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15153578	EXPEDITED (15-DAY)		HO	PHHY2018IE038978		42 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Ataxia; Cerebellar Syndrome; Coordination Abnormal; Drug Interaction; Drug Level Increased; Dyskinesia; Moaning; Nausea; Nystagmus; Tardive Dyskinesia; Vomiting	Lamotrigine			S	Unknown			Novartis
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15153596	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1050724		66 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Haldol /00027401/			S	Oral	20 Gtt, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15154141	EXPEDITED (15-DAY)		HO	FR-B. BRAUN MEDICAL INC.-2052230		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Confusional State; Hyponatraemia	Dextrose Injections Usp 0264- 7510-00 0264-7510-20	S			B Braun
	Escitalopram	S	Oral		Not Reported
	Glucose	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15154872	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00008916		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inhibitory Drug Interaction; Psychotic Disorder	Lixiana			S		60 Mg, Qd		Unknown	
	Olanzapin			S		Unknown		Unknown	
	Escitalopram			S		Unknown		Unknown	
	Cortisone			S		Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15155365	EXPEDITED (15-DAY)		HO, LT, OT	CH-JNJFOC- 20180718159		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Delirium; Disturbance In Attention; Haemodynamic Instability; Pyrexia	Tramal			S	Oral			Not Reported	
	Fentanyl Sintetica			S	Intravenous (not otherwise specified)			Not Reported	
	Haldol			S	Oral			Not Reported	
	Pantoprazol Sandoz			S	Oral			Not Reported	
	Allopurinol Mepha			S	Oral			Not Reported	
	Allopurinol Mepha			S	Oral			Not Reported	
	Lisitril			S	Oral			Not Reported	
	Meto Zerok			S	Oral			Not Reported	
	Plavix			S	Oral			Not Reported	
	Plavix			S	Oral			Not Reported	
	Spiricort			S	Unknown			Not Reported	

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Pramipexol Helvepharm	S	Oral	Not Reported
Cipralex	S	Oral	Not Reported
Oxynorm	S	Oral	Not Reported
Morphin Hcl Sintetica	S	Oral	Not Reported
Morphin Hcl Sintetica	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Quetiapin Sandoz	S	Oral	Not Reported
Valium	S	Oral	Not Reported
Aspirin Cardio	C	Oral	Not Reported
Atorvastatin Pfizer	C	Oral	Not Reported
Dafalgan	C	Oral	Not Reported
Spiriva	C	Unknown	Not Reported
Torem	C	Unknown	Not Reported
Novalgin (Metamizole Sodium)	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15155570	EXPEDITED (15-DAY)	HO		PHHY2018DE042979		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Lamotrigine			S	Unknown	100 Mg, Tid (1-1-1-0)		Novartis
	Mirtazapine			S	Unknown	15 Mg, Qd ((0-0-1) At Night)		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Qd (At Night)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd ((20mg-0mg-0mg-0mg) In The Morning)		Not Reported
	Milnacipran			S	Oral	50 Mg, Bid		Not Reported
	Milnacipran			S	Oral	200 Mg, Qd		Not Reported
	Levothyroxine			C	Unknown	100 Ug, Qd ((1-0-0-0) In The Morning)		Not Reported

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17-Jul-2018	15156197	EXPEDITED (15-DAY)		HO	PHHY2018IT047136		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Quetiapine			S	Oral	200 Mg, Qd		Novartis	
	Clonazepam			S	Oral	0.5 Mg, Qd		Not Reported	
	Valproic Acid Sandoz			S	Oral	300 Mg, Qd		Not Reported	
	Alprazolam			S	Oral	1.5 Mg, Qd		Not Reported	
	Venlafaxine			S	Oral	300 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Trazodone			S	Oral	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15255262	DIRECT					72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Interest; Fatigue; Impaired Quality Of Life; Nightmare	Escitalopram 20mg			S	Oral			Not Reported	
	Xanax			C				Not Reported	
	Clonidine			C				Not Reported	
	Metoprolol			C				Not Reported	
	Escilopram			C				Not Reported	
	B			C				Not Reported	
	E			C				Not Reported	
	D			C				Not Reported	
	Fish Oil			C				Not Reported	
	Calcium			C				Not Reported	
	Magnesium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15104827	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1833200US		47 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Activation Syndrome	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd	Allergan
	Trazodone Hydrochloride	C	Oral	25 Mg, Unk	Not Reported
	Brotizolam	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15157078	EXPEDITED (15-DAY)		HO, OT	IE-LUPIN PHARMACEUTICALS INC.-2018-05061		42 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Lupin
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15157466	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 927565		42 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Zopiclone			S	Oral	7.5 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15158944	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018282912		19 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral	Unk (Reported As 1, Unit Unspecified), Single		Pfizer
	Seroplex			S	Oral	Unk (Reported As 1, Unit Unspecified), Single		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160115	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1835512US		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Disinhibition; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160452	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20180713334		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State	Ibuprofeno (1769a)		Y	S	Oral			Not Reported	
	Ibuprofeno (1769a)			S	Oral	400 Mg X 7 Counts Per Second (Cps); In Total		Not Reported	
	Exforge			S	Oral	5 Counts Per Second (Cps); In Total		Not Reported	
	Escitalopram			S	Oral	5 Counts Per Second (Cps)		Not Reported	
	Paracetamol			S	Oral	12gr Day; In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160633	EXPEDITED (15-DAY)		HO, LT	ES-ALLERGAN-1835767US		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hepatitis; Hypocoagulable State	Escitalopram Oxalate - Bp			S	Oral	5 Capsules In Total		Allergan	
	Paracetamol			S	Oral	12 G In Total		Not Reported	
	Exforge			S	Oral	5 Capsules In Total		Not Reported	
	Ibuprofeno			S	Oral	2800 Mg In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160878	EXPEDITED (15-DAY)		CA	PHHY2018IT043014			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Escitalopram			S	Transplacental	Unk		Not Reported	
	Lorazepam			S	Transplacental	Unk		Novartis	
	Carbolithium			S	Transplacental	Maternal Dose: 750 Mg/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160943	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1835503US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unknown		Allergan	
	Xanax			S	Unknown	0.25 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160946	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1835913US		33 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15257766	DIRECT		DS, HO			36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder; Refusal Of Treatment By Patient; Schizophrenia	Lexapro			S	Oral	Quantity:1 Tablet(S);		Unknown	
	Risperdal			C				Not Reported	
	Celexa			C				Not Reported	
	Klonopin			C				Not Reported	

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Lipitor	C	Not Reported
Levothyroxine	C	Not Reported
Benadryl	C	Not Reported
Dulera	C	Not Reported

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19-Jul-2018	13035561	EXPEDITED (15-DAY)	CA		DE-ALLERGAN-1680905US			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect;	Escitalopram Oxalate Unk			S	Transplacental			Allergan
Autism Spectrum	Lorazepam			S	Transplacental			Not Reported
Disorder; Camptodactyly	Mycophenolate			S	Transplacental	Unk		Not Reported
Congenital; Clinodactyly;	Zolpidem			S	Transplacental			Not Reported
Congenital Arterial	Fosfomycin			S	Transplacental	Unk		Not Reported
Malformation; Congenital	Valaciclovir			S	Transplacental			Not Reported
Central Nervous System	Abatacept			S	Transplacental			Not Reported
Anomaly; Congenital	Ursodeoxycholic Acid Unk			S	Transplacental			Allergan
Renal Cyst; Dysplasia;	Tacrolimus			S	Transplacental			Not Reported
External Auditory Canal	Acebutolol			S	Transplacental			Not Reported
Atresia; Foetal Exposure	Prednisone			S	Transplacental			Not Reported
During Pregnancy; Foetal	Colchicine			S	Transplacental			Not Reported
Malformation;	Cyclosporine Unk			S	Transplacental	Unk		Allergan
Hydronephrosis;	Methyldopa			S	Transplacental			Not Reported
Meningocele; Microtia;	Prednisolone			S	Transplacental			Not Reported
Oesophageal Atresia;	Azathioprine			S	Transplacental			Not Reported
Premature Baby	Naproxen			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15163303	EXPEDITED (15-DAY)	HO, OT		IE-MACLEODS PHARMACEUTICALS US LTD-MAC2018015081			Unknown	IRL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods	
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Macleods	
	Lamotrigine			S	Unknown	Unk		Not Reported	
	Clobazam			C	Unknown	10 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15163427	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-927635		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Milligram Daily; 0.5 Mg Morning And Evening		Pliva	
	Loxapine (Succinate De)			S	Oral	Drops If Necessary		Not Reported	
	Escitalopram Arrow			S	Oral	10 Milligram Daily; 10 Mg In The Evening		Not Reported	
	Olanzapine Mylan			S	Oral	5 Milligram Daily; 5 Mg In The Evening		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15163662	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018015178			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness	Escitalopram Tablet			S	Oral	15 Milligram, Qd, Tablet		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15164180	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US19932			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stress Cardiomyopathy	Escitalopram			S	Unknown	Unk		Invagen	

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19-Jul-2018	15164890	EXPEDITED (15-DAY)		HO, LT, OT	CH-NAPPMUNDI-GBR-2018-0057594		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Disturbance In Attention	Oxynorm			S	Oral	5 Mg, Prn		Purdue	
	Morphine Hydrochloride			S	Intravenous (not otherwise specified)	2.5 Mg, Prn		Not Reported	
	Morphine Hydrochloride			S	Intravenous (not otherwise specified)	75 Mg, Prn		Not Reported	
	Tramal			S	Oral	10 Drop, Prn (100 Mg/1ml; 100 Mg = 40 Drops)		Not Reported	
	Pramipexole Dihydrochloride			S	Oral	0.125 Mg, Daily		Not Reported	
	Cipralex			S	Oral	10 Mg, Daily		Not Reported	
	Pantoprazol			S	Oral	40 Mg, Daily		Not Reported	
	Allopurinol			S	Oral	100 Mg, Daily		Not Reported	
	Allopurinol			S	Oral	100 Mg, Bid		Not Reported	
	Lisitril			S	Oral	20 Mg, Daily		Not Reported	
	Meto Zerok			S	Oral	50 Mg, Daily		Not Reported	
	Plavix			S	Oral	75 Mg, Daily		Not Reported	
	Plavix			S	Oral	75 Mg, Daily		Not Reported	
	Spiricort			S	Unknown	20mg, Daily (0.75 - 0 - 0.25 - 0 Dosage)		Not Reported	
	Fentanyl /00174602/			S	Intravenous (not otherwise specified)	25 Mcg, Unk		Not Reported	
	Haldol /00027401/			S	Oral	10 Drop, Single		Not Reported	
	Quetiapine Fumarate			S	Oral	25 Mg, Daily		Not Reported	
	Quetiapine Fumarate			S	Oral	200 Mg, Daily		Not Reported	
	Quetiapine Fumarate			S	Oral	125 Mg, Daily (100 Mg And 25 Mg = 125 Mg)		Not Reported	
	Valium /00017001/			S	Oral	5 Mg, Prn		Not Reported	

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Aspirin Cardio	C	Oral	100 Mg, Daily	Not Reported
Atorvastatin	C	Oral	20 Mg, Daily	Not Reported
Dafalgan	C	Oral	500 Mg, Tid	Not Reported
Spiriva	C	Oral	18 Mcg, Daily	Not Reported
Torem /01036501/	C	Oral	5 Mg, Daily	Not Reported
Novalgin /00169801/	C	Oral	500 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15166054	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-927070		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Medication Error	Escitalopram Oxalate			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15168198	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1835908US		83 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Lasix			S	Oral	Unk		Not Reported	
	Eutirox			S	Oral	50 Mg, Qd		Not Reported	
	Lansox			C	Unknown			Not Reported	
	Folina [Folic Acid]			C	Unknown			Not Reported	
	Torvast			C	Unknown			Not Reported	
	Allopurinol			C	Unknown			Not Reported	
	Luvion			C	Unknown			Not Reported	
	Bisoprolol Hemifumarate			C	Unknown			Not Reported	
	Amiodar			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15168221	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1835884US		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram Oxalate - Bp			S	Oral	Unk, Qam		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15168845	EXPEDITED (15-DAY)		HO, LT, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018015180			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State	Escitalopram Oxalate			S	Oral	5 Cps		Macleods	
	Paracetamol			S	Oral	12 Gram, Qd, 1 Total		Not Reported	
	Exforge			S	Oral	5 Dosage Form, Qd, 1 Total, 5 Cps		Not Reported	
	Ibuprofen			S	Oral	2800 Milligram, Qd, 1 Total, 400 Mg X 7 Cps		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15168848	EXPEDITED (15-DAY)		DS, HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018015184			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Milligram		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15169321	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00670		77 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Unk		Hetero
	Metoprolol /00376902/			C	Unknown	47.5 Mg, Q.D.		Not Reported
	Metamizole /06276704/			C	Unknown	500 Mg, Tid		Not Reported
	Valsartan			C	Unknown	80 Mg, B.I.D.		Not Reported
	Simvastatin			C	Unknown	40 Mg, Q.D.		Not Reported
	Eferox			C	Unknown	50 Mcg, Qd		Not Reported
	Hct			C	Unknown	12.5 Mg, Qd		Not Reported
	Ventolair			C	Unknown	250 Mcg, Qid		Not Reported
	Ass			C	Unknown	100 Mg, Qd		Not Reported
	Pantoprazol			C	Unknown	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15169786	EXPEDITED (15-DAY)		OT	PE-TEVA-2018-PE-926755		86 YR	Female	PER

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Constipation; Renal Disorder	Azilect			S		1 Milligram Daily;		Teva
	Madopar			S	Unknown			Not Reported
	Bivadin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15170161	EXPEDITED (15-DAY)		HO	DE-TORRENT-00008996		77 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Eferox			C		50 G, 1-0-0-0		Unknown
	Hct			C		12.5 Mg, 1-0-0-0		Unknown
	Metoprolol			C		47.5 Mg, 1-0-0-0		Unknown
	Escitalopram			S	Unknown	Nk		Unknown
	Ventolair			C		250 G, 2-0-0-2		Unknown

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Metamizole	C	500 Mg, 1-1-1-0	Unknown
Valsartan	C	80 Mg, 0.5-0-0-1	Unknown
Ass 100	C	100 Mg, 0-1-0-0	Unknown
Simvastatin	C	40 Mg, 0-0-0-1	Unknown
Pantoprazol	C	20 Mg, 1-0-0-0	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15170486	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-036606		47 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Microscopic; Diarrhoea	Escitalopram			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Seroplex			S	Unknown	10 Milligram, Daily		Not Reported
	Meteospasmyl /01017401/			C	Unknown	Unk		Not Reported
	Meteospasmyl /01017401/			C	Unknown	Unk		Not Reported
	Copper Iud			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15170505	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-036549		23 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Loss Of Consciousness	Escitalopram (Escitalopram)			S	Oral	15 Milligram, Daily		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15171348	EXPEDITED (15-DAY)		OT	HK-TEVA-2018-HK-929621		43 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S	Unknown	5 Milligram Daily; At Night, In The First Week; Dose Was Increased To 10mg At Night		Ivax

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Escitalopram	S	Unknown	10 Milligram Daily; At Night. Dose Reduced And Finally Stopped	Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15171574	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201807949		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hyponatraemia	Glucose (Not Specified)			S	Subcutaneous			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172063	EXPEDITED (15-DAY)		OT	IT-ASTRAZENECA-2018SE89867		35 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Apathy; Asthenia	Seroquel			S	Oral			Zeneca
	Seroquel			S	Oral			Zeneca
	Escitalopram Oxalate			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172185	EXPEDITED (15-DAY)		OT	HK-MYLANLABS-2018M1052929		43 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram			S	Unknown	5 Mg, Qd, At Night, In The First Week; Dose Was Increased To 10mg At Night		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd, At Night		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172372	EXPEDITED (15-DAY)		HO	ZA-MERCK KGAA-2052473		87 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Fall	Novothyrox			S				Merck Kgaa	
	Cardugen			S				Not Reported	
	Halcion			S				Not Reported	
	Spiractin (Spironolactone)			S				Not Reported	
	Dopaquel			S				Not Reported	
	Zytomil			S				Not Reported	
	Vesicare			S				Not Reported	
	Macrochantin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172385	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-929675		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	1x Täglich Morgens		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15173392	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1053143		20 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S		15 Mg, Nk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15175685	NON-EXPEDITED			US-TEVA-2018-US-927920			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Emotional Disorder; Irritability; Nausea; Tremor		Escitalopram		S	Unknown		Ivax		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2018	15178264	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2018-036261		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State	Escitalopram			S	Oral	5 Cps, Unk		Aurobindo	
	Ibuprofen			S	Oral	2800 Milligram (400 Mg X 7 Cps ; In Total)		Aurobindo	
	Paracetamol			S	Oral	12 Gram,In Total		Aurobindo	
	Exforge			S	Oral	5 Dosage Form In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2018	15178615	EXPEDITED (15-DAY)		DE	US-TORRENT- 00006338		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingestion		Unknown	
	Vitamin B1			S	Oral	Ingestion		Unknown	
	Loratadine			S	Oral	Ingestion		Unknown	
	Furosemide			S	Oral	Ingestion		Unknown	
	Levothyroxine			S	Oral	Ingestion		Unknown	
	Folic Acid			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2018	15178616	EXPEDITED (15-DAY)		DE	US-TORRENT- 00006337		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Alprazolam			S	Oral	Unknown		Unknown	
	Aciclovir			S	Oral	Unknown		Unknown	
	Lamotrigine			S	Oral	Unknown		Unknown	

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Escitalopram	S	Oral	Unknown	Unknown
Oxycodone And Acetaminophen	S	Oral	Unknown	Unknown
Ibuprofen	S	Oral	Unknown	Unknown
Propranolol	S	Oral	Unknown	Unknown
Ondansetron	S	Oral	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	14351768	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2018-000315		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Sopor; Suicide Attempt	Venlafaxine Hydrochloride			S	Oral	525 Mg In Total		Not Reported	
	Escitalopram Oxalate			S	Oral	400 Mg In Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	14923543	EXPEDITED (15-DAY)			DE-PFIZER INC-2018203881		37 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Insomnia	Pregabalin			S	Oral	100 Mg, 1x/Day (Evening Dose)		Pfizer	
	Pregabalin			S	Oral	Reduced Gradually/Tapered Off		Pfizer	
	Escitalopram			S	Oral	20 Mg, 1x/Day (Morning)		Not Reported	
	Escitalopram			S	Oral	15 Mg, Daily		Not Reported	
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported	
	Escitalopram			S	Oral	Half Dose		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15077223	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-MYLANLABS-2017M1077087		7 DAY	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death Neonatal; Foetal Exposure During Pregnancy; Foetal Malformation; Maternal Drugs Affecting Foetus; Trisomy 18	Levocetirizine	S	Transplacental	5 Mg, Qd	Not Reported
	Pantoprazole	S	Transplacental	Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S	Transplacental	Unk	Mylan
	Nucala	S	Transplacental	100 Mg, Qw	Mylan
	D-Cure	S	Transplacental	25 Kiu, Unk	Mylan
	Flixotide	S	Transplacental	250 Mg, Bid	Mylan
	Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd	Mylan
	Ventolin	S	Transplacental	100 Ug, Unk	Mylan
	Relvar Ellipta	S	Transplacental	1 Df, Qd	Mylan
	Sipralexa	S	Transplacental	10 Mg, Z	Mylan
	Avamys	S	Transplacental	2 Df, Qd	Mylan
	Fluticasone Furoate	S	Transplacental	Unk, Qd	Mylan
	Seretide	S	Transplacental	Unk	Mylan
	Theophylline	S	Transplacental	Unk	Mylan
	Vilanterol Trifenatate	S	Transplacental	1 Df, Qd	Mylan
	Xyzall	S	Transplacental	5 Mg, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15167208	EXPEDITED (15-DAY)		OT	HK-ALLERGAN-1835768US		43 YR	Male	HKG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qpm		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qpm		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qpm		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15179179	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00680		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram	S	Unknown	20 Mg, Q.D.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15179663	EXPEDITED (15-DAY)		OT	HK-LUPIN PHARMACEUTICALS INC.-2018-05096		43 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram			S	Unknown	5 Mg, Qd (Nocte In The First Week)		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd (Increased On Day 8-Finally Stopped On Day 80)		Lupin
	Escitalopram			S	Unknown	5 Mg, Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15179665	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES- 874355		87 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Hyponatraemia	Enalapril 20 Mg 28 Tablets			S	Oral	20 Milligram Daily;		Teva
	Heipram 10 Mg Tablets Film- Coated Tablets, 56 Tablets			S	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15180312	EXPEDITED (15-DAY)		OT	US-ACCORD-069693		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Akathisia; Amnesia; Bone Pain; Chills; Diarrhoea; Disorganised Speech; Feeling Abnormal;	Aripiprazole			S		Q.H.S		Not Reported
	Buspirone			S				Not Reported
	Escitalopram			S				Not Reported
	Lorazepam			C				Not Reported
	Testosterone			C				Not Reported

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Gynaecomastia;	Benzatropine	C	B.I.D. P.R.N	Not Reported
Headache; Hyperhidrosis;	Lithium	C	Q.H.S.	Not Reported
Pain; Piloerection;	Amfetamine	C	Q.A.M	Not Reported
Pyrexia; Restlessness;	Lurasidone	C	40 Mg Q. Dinner	Not Reported
Withdrawal Syndrome	Lamotrigine	C		Not Reported
	Bupropion/Bupropion	C	150 Mg Q.A.M.	Not Reported
	Hydrochloride			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15180539	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018015505			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia;	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
Apathy; Asthenia	Seroquel			S	Oral	1 Dosage Form, Qd		Not Reported
	Seroquel			S		Unk		Not Reported
	Lamotrigine			S	Oral	100 Milligram, Qd		Not Reported
	Seroquel			S	Oral	1 Dosage Form, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15180546	EXPEDITED (15-DAY)		OT	HK-MACLEODS PHARMACEUTICALS US LTD- MAC2018015526			Unknown	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Function Abnormal; Somnolence	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd, 5 Mg Nocte In The First Week		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd (Increased On Day 8- Finally Stopped On Day 80)		Macleods
	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15180901	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1836282US		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Loss Of Libido; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Lexomil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14360294	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-000763		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Sopor; Suicide Attempt	Escitalopram Film-Coated Tablets			S	Oral	In Total		Aurobindo	
	Venlafaxine			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14959411	EXPEDITED (15-DAY)		HO	US-OTSUKA-2018_013254		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Body Mass Index Abnormal; Disease Recurrence; Drug Ineffective; Food Craving; Hunger; Hyporesponsive To Stimuli; Increased Appetite; Obesity; Somnolence; Thinking Abnormal; Tooth Disorder; Treatment Noncompliance; Weight Increased	Abilify Maintena			S	Unknown	400 Mg, Qm		Otsuka	
	Abilify			S	Unknown	10mg To 15mg		Otsuka	
	Lexapro			S	Unknown	5 Mg, Unk		Not Reported	

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24-Jul-2018	15041374	EXPEDITED (15-DAY)		HO, LT	US-CIPLA LTD.- 2017US14107			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Decreased Appetite; Drug Interaction; Electrocardiogram Qt Prolonged; Poor Quality Sleep; Serotonin Syndrome; Sleep Talking	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen	
	Dextromethorphan W/Promethazine			S	Unknown	Unk, 5 Days		Not Reported	
	Dextromethorphan W/Promethazine			S				Not Reported	
	Labetalol			C	Unknown	100 Mg, Per Day		Not Reported	
	Amlodipine			C	Unknown	5 Mg, Bid		Not Reported	
	Naltrexone			C	Intramuscular	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15056337	EXPEDITED (15-DAY)		OT	JP-ALLERGAN- 1831979US		44 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Pr Prolongation; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Cymbalta			C	Oral			Not Reported	
	Abilify			C	Oral			Not Reported	
	Risperdal			C	Oral	1 MI, Q8hr		Not Reported	
	Noritren			C	Oral	50 Mg, Q12h		Not Reported	
	Rize			C	Oral	8 G, Q8hr		Not Reported	
	Akineton			C	Oral	1.67 Mg, Q8hr		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15187710	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-05986			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pain; Vomiting	Escitalopram Oxalate Tablets			S	Unknown			Lupin	

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Usp, 20 Mg

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15187835	EXPEDITED (15-DAY)		HO, LT	CH-ROCHE-2157082		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Disturbance In Attention	Valium			S	Oral			Not Reported	
	Allopurinol			S	Oral			Not Reported	
	Allopurinol			S	Oral			Not Reported	
	Pramipexole Dihydrochloride			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Pantoprazole Sodium Sesquihydrate			S	Oral			Not Reported	
	Lisitril			S	Oral			Not Reported	
	Meto Zerok			S	Oral			Not Reported	
	Plavix			S	Oral			Not Reported	
	Plavix			S	Oral			Not Reported	
	Spiricort			S	Unknown	15 Mg - 0 - 5 Mg - 0		Not Reported	
	Tramal			S	Oral	10 Gtt (100 Mg = 40 Gtt) 100 Mg/1 Ml As Required		Not Reported	
	Fentanyl Citrate			S	Intravenous (not otherwise specified)			Not Reported	
	Haldol			S	Oral			Not Reported	
	Oxynorm			S	Oral			Not Reported	
	Morphin Hcl			S	Oral			Not Reported	
	Morphin Hcl			S	Oral			Not Reported	
	Quetiapine Fumarate			S	Oral			Not Reported	
	Quetiapine Fumarate			S	Oral			Not Reported	
	Quetiapine Fumarate			S	Oral			Not Reported	
	Aspirin Cardio			C	Oral			Not Reported	
	Atorvastatin Pfizer			C	Oral			Not Reported	

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		Dafalgan	C	Oral				Not Reported	
		Spiriva	C	Unknown				Not Reported	
		Torem	C	Unknown				Not Reported	
		Novalglin (Switzerland)	C	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15189050	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006453		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingestion		Unknown	
	Bupropion			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15189053	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006433		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Losartan Potassium			S	Oral	Ingestion		Unknown	
	Amlodipine			S	Oral	Ingestion		Unknown	
	Bupropion			S	Oral	Ingestion		Unknown	
	Escitalopram			S	Oral	Ingestion		Unknown	
	Levothyroxine Sodium			S	Oral	Ingestion		Unknown	
	Ethanol			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15189793	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-036786		35 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo	
	Lamotrigine			S	Oral	100 Milligram, Daily		Aurobindo	
	Seroquel			S	Oral	1 Dosage Form, Daily		Not Reported	

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Seroquel			S		Oral		1 Dosage Form, Daily		Not Reported	
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24-Jul-2018	15190297	EXPEDITED (15-DAY)		HO	PHHY2018DE049223		79 YR	Female	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, Qd (0-0-0-1)		Novartis		
	Valproate Sodium			S	Oral	500 Mg, Qd (0-0-0-1)		Not Reported		
	Cipralext			S	Oral	10 Mg, Qd (1-0-0-0)		Not Reported		
	Torasemid			C	Oral	10 Mg, Qd (1-0-0-0)		Not Reported		
	Felodipine			C	Oral	10 Mg, Qd (1-0-0-0)		Not Reported		
	Levothyroxin			C	Oral	75 G, Qd (1-0-0-0)		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Jul-2018	15190636	EXPEDITED (15-DAY)		DE	AT-TEVA-2018-AT-930210		36 YR	Male	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Mirtazapine			S				Teva		
	Mirtazapine			S				Teva		
	Cipralext			S				Not Reported		
	Cipralext			S				Not Reported		
	Seroquel			S				Not Reported		
	Seroquel			S				Not Reported		
	Inderal			C				Not Reported		
	Inderal			C				Not Reported		
	Zoldem			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Jul-2018	15192026	EXPEDITED (15-DAY)		HO	PHHY2018DE048929		81 YR	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Decreased Appetite	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported		
	Nitrofurantoin			S	Unknown	100 Mg, 1-1-1-0		Novartis		

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Metoprolol	C	Unknown	47.5 Mg, 0.5-0-0-0	Not Reported
Ass	C	Unknown	100 Mg, 1-0-0-0/Alle 2 Tage	Not Reported
Simvastatin	C	Unknown	20 Mg, 0-0-1-0	Not Reported
Metamizol	C	Unknown	500 Mg, 0-0-1-0	Not Reported
Allopurinol	C	Unknown	150 Mg, 1-0-0-0	Not Reported

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25-Jul-2018	14532005	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1806967US		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Cystitis; Disorientation; Frontotemporal Dementia	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	
	Qizenday			S	Oral	300 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15128884	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-034561		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam Tablets			S	Oral	20 Milligram (In Total)		Aurobindo	
	Paracetamol			S	Oral	2 G, Unk		Aurobindo	
	Tachipirina			S	Oral	2 Gram (In Total)		Not Reported	
	Cipralext /01588502/			S	Oral	15 Milliliter (In Total)		Not Reported	
	Tolep			S	Oral	In Total		Not Reported	
	Brintellix			S	Oral	15 MI, Unk		Not Reported	
	Oxcarbazepine			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15130470	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1834616US		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Erythema; Intentional Overdose; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp	S	Oral	15 MI, Unk	Allergan
	Vortioxetine	S	Oral	15 MI, Unk	Not Reported
	Paracetamol	S	Oral	2 G, Unk	Not Reported
	Lorazepam	S	Oral	20 Mg, Unk	Not Reported
	Oxcarbazepine	S	Oral	Unk	Not Reported

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25-Jul-2018	15169230	EXPEDITED (15-DAY)		HO	IE-TEVA-2018-IE-926303		42 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebellar Syndrome; Toxicity To Various Agents	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Lamotrigine			S	Unknown			Not Reported
	Clobazam			C	Unknown			Not Reported
	Clobazam			C	Unknown	10mg Three Times Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15192472	EXPEDITED (15-DAY)		HO	ES-ROCHE-2157455			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Obinutuzumab			S	Intravenous (not otherwise specified)			Not Reported
	Cotrimoxazole			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Incb050465			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

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25-Jul-2018	15193061	EXPEDITED (15-DAY)		HO	IE-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00484			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	Unk		Sciegen	
	Escitalopram			S	Unknown	5 Mg Daily		Not Reported	
	Escitalopram			S	Unknown	10 Mg Daily		Not Reported	
	Clobazam			C	Unknown	Unk		Not Reported	
	Clobazam			C	Unknown	10 Mg, Bid		Not Reported	
	Clobazam			C	Unknown	10 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15193451	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00006351		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Clonazepam			S		Ingst Plus Aspir		Unknown	
	Escitalopram			S		Ingst Plus Aspir		Unknown	
	Buspirone Hydrochloride			S		Ingst Plus Aspir		Unknown	
	Propranolol Hydrochloride			S		Ingst Plus Aspir		Unknown	
	Lamotrigine			S		Ingst Plus Aspir		Unknown	
	Mirtazapine			S		Ingst Plus Aspir		Unknown	
	Activated Charcoal			S		Ingst Plus Aspir		Unknown	
	Cyclobenzaprine			S		Ingst Plus Aspir		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15193452	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00006396		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Escitalopram			S	Oral	Ingestion		Unknown	

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Toxicity To Various Agents		Lamotrigine		S	Oral	Unknown		Unknown	
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25-Jul-2018	15193495	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006539		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Diphenhydramine Hydrochloride			S	Oral	Ingestion		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Fluoxetine			S	Oral	Ingestion		Unknown	
	Risperidone			S	Oral	Ingest		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15193497	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006542		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Verapamil			S	Oral	Ingestion		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Flecainide Acetate			S	Oral	Ingestion		Unknown	
	Alprazolam			S	Oral	Ingest		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15193508	EXPEDITED (15-DAY)		DE	US-TORRENT-00006565		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Sitagliptin			S	Oral	Ingest		Unknown	
	Mirtazapine			S	Oral	Ingest		Unknown	
	Phenytoin			S	Oral	Ingestion		Unknown	
	Primidone			S	Oral	Ingest		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Carvedilol			S	Oral	Ingest		Unknown	

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Valproic Acid			S		Oral		Ingestion		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #		503B Facility	Age	Sex	Country
25-Jul-2018	15194421	EXPEDITED (15-DAY)		HO	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-05158			87 YR	Female	ZAF
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dehydration; Fall	Zytomil 20 Mg				S	Unknown	Unk		Lupin	
	Halcion				S	Unknown	Unk		Not Reported	
	Spiractin /00006201/				S	Unknown	Unk		Not Reported	
	Dopaquel				S	Unknown	Unk		Not Reported	
	Vesicare				S	Unknown	Unk		Not Reported	
	Macrochantin				S	Unknown	Unk		Not Reported	
	Euthyrox				S	Unknown	Unk		Not Reported	
	Cardugen				S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #		503B Facility	Age	Sex	Country
25-Jul-2018	15194782	NON-EXPEDITED			US-LANNETT COMPANY, INC.-US- 2017LAN001289				Unknown	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Apathy; Depression; Drug Ineffective; Malaise	Escitalopram Oxalate				S	Oral	15 Mg, Qd		Lannett	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #		503B Facility	Age	Sex	Country
25-Jul-2018	15196102	EXPEDITED (15-DAY)		OT	SG-ALLERGAN- 1836480US			83 YR	Male	SGP
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Urticaria	Escitalopram Oxalate - Bp				S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #		503B Facility	Age	Sex	Country
25-Jul-2018	15196823	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20180726701			83 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Zopiclone			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15198352	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1836435US		23 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	14360187	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-000641		36 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Escitalopram Tablets			S	Oral	1x Daags 1 Tablet		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	14526724	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1805717US		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Baclofen			S	Oral	Unk		Not Reported	
	Baclofen			S				Not Reported	
	Dextropropoxyphene			S	Oral	Unk		Not Reported	
	Valpromide			S	Oral	Unk		Not Reported	
	Paracetamol			S	Oral	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	14701459	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1816524US		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aptyalism; Drug Ineffective; Off Label Use; Overdose; Panic Disorder	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan	
	Amitriptyline			S	Oral	20 Mg, Qd		Not Reported	
	Apo-Buspirone			S	Oral	5 Mg, Qd		Not Reported	
	Zyprexa			S	Unknown	2.5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	14790084	EXPEDITED (15-DAY)		HO, LT, OT	DE-AUROBINDO-AUR-APL-2018-021415		21 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S	Unknown	Unknown		Aurobindo	
	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Aurobindo	
	Esomeprazole			S	Unknown	Unknown		Aurobindo	
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported	
	Ivabradin Sandoz			C	Unknown	Daily Dose: 15 Mg Milligram(S) Every Days		Not Reported	
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported	
	Naloxone W/Tilidine			C	Unknown	Unknown		Not Reported	
	Scopolamin			C	Unknown	Unknown		Not Reported	
	Baclofen			C	Unknown	Unknown		Not Reported	
	Prednisolon /00016201/			C	Unknown	Unknown		Not Reported	
	Lorazepam			C		Daily Dose: 1 Mg Milligram(S) Every Days		Not Reported	
	L-Thyroxin /00068001/			C	Unknown	Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15200140	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ASTRAZENECA-2018SE92978		40 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Tooth Injury	Cipralelex			S	Unknown			Not Reported	
	Cipralelex			S	Unknown	Increased Dose		Not Reported	
	Quetiapine			S	Unknown	25 Mg, Every 12 Hours, Non-Az (Sandoz)		Zeneca	
	Quetiapine			S	Unknown	Increased Dose		Zeneca	
	Calcigran Forte Sitron			S	Unknown			Not Reported	
	Calcigran Forte Sitron			S	Unknown	Reduced Dose		Not Reported	
	Calcium Etalpa			C	Oral			Not Reported	
	Zopiclone			C				Not Reported	
	Multiminerals			C				Not Reported	
	Vitamins Nos			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15200596	EXPEDITED (15-DAY)		OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018010797			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram Oxalate			S	Unknown	10 Milligram		Macleods	
	Irbesartan			S	Unknown			Macleods	
	Paracetamol			S	Unknown			Not Reported	
	Diuretics			S	Unknown			Not Reported	
	Galantamine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201297	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD-			Unknown	ITA

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MAC2018015682

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Sopor; Therapy Change	Escitalopram			S	Oral	Overdose		Macleods
	Anafranil			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201306	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE- HET2018DE00708		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported
	Mirtazapine			S	Unknown	At Night		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Qd		Not Reported
	Milnacipran			S	Oral	200 Milligram, Qd		Not Reported
	Milnacipran			S	Oral	50 Milligram		Not Reported
	Levothyroxine /00068002/			C	Unknown	(1-0-0-0) In The Morning		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201310	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE- HET2018DE00709		45 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache;	Escitalopram			S	Unknown	10 Milligram, Qd		Hetero
	Escitalopram			S	Unknown	Unk		Hetero
	Amlodipin			C	Unknown	10 Milligram, Qd		Not Reported

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Therapeutic Product Effect
Incomplete

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201379	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006549		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Alprazolam			S	Oral	Ingest		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Naproxen			S	Oral	Ingestion		Unknown	
	Glucophage			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201380	EXPEDITED (15-DAY)		DE	US-TORRENT-00006552		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Ethanol			S	Oral	Ingest +Aspir		Unknown	
	Escitalopram			S	Oral	Ingest +Aspir		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201382	EXPEDITED (15-DAY)		DE	US-TORRENT-00006554		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingest		Unknown	
	Amitriptyline			S	Oral	Ingest		Unknown	
	Lorazepam			S	Oral	Ingest		Unknown	
	Lithium Carbonate			S	Oral	Ingest		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201386	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006558		14 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Ingest		Unknown	
	Diphenhydramin Hcl			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201391	EXPEDITED (15-DAY)		DE	US-TORRENT-00006568		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Levothyroxine			S	Oral	Ingest		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Diltiazem			S	Oral	Ingest		Unknown	
	Propranolol			S	Oral	Ingestion		Unknown	
	Metformin			S	Oral	Ingest		Unknown	
	Glyburide			S	Oral	Ingest		Unknown	
	Losartan			S	Oral	Ingestion		Unknown	
	Lorazepam			S	Oral	Ingest		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201400	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006560		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Ingestion (Extended Release)		Unknown	
	Escitalopram			S	Oral	Ingestion		Unknown	
	Venlafaxine			S	Oral	Ingestion		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201459	EXPEDITED (15-DAY)		HO	FR-ACCORD-070136		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dysphagia; Sedation	Escitalopram	S	Oral						Not Reported
	Risperdal	S	Oral						Not Reported
	Alprazolam	S	Oral	Alprazolam 0,25 1/2 Cp/J					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201631	EXPEDITED (15-DAY)		OT	FR-BAYER-2018-136304		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Ciflox			S	Oral	Unk		Bayer	
	Voriconazole			S	Intravenous drip	600 Mg, Qd		Not Reported	
	Seroplex			S	Oral	20 Mg, Qd		Not Reported	
	Flecaine			S	Oral	200 Mg, Qd		Not Reported	
	Roalcyte			C	Oral	450 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201858	EXPEDITED (15-DAY)		HO	ZA-MYLANLABS-2018M1052484		87 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Fall	Cardugen 1mg			S		Unk		Mylan	
	Halcion			S		Unk		Mylan	
	Spiractin /00006201/			S		Unk		Mylan	
	Dopaquel			S		Unk		Mylan	
	Zytomil			S		Unk		Mylan	
	Vesicare			S		Unk		Mylan	
	Macrochantin			S		Unk		Mylan	
	Euthyrox			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15202641	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-037566		75 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Sopor; Therapy Change	Escitalopram Film-Coated Tablets			S	Oral	3 Dosage Form, In Total		Aurobindo	
	Anafranil			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15204185	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1837115US		41 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Attention Deficit/Hyperactivity Disorder; Bipolar Disorder; Disturbance In Attention; Fatigue; Fibromyalgia; Hypomania; Memory Impairment; Obsessive-Compulsive Disorder; Psychotic Disorder; Sensory Disturbance; Social Anxiety Disorder; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	Most Of The Time In Treatment She Used 20 Mg		Allergan	
	Efexor Depot			S	Oral	75 Mg		Not Reported	
	Alopam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15204271	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-929851		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Escitalopram			S	Oral			Ivax	
	Amiodarona. Hidrocloruro (392ch)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15205575	NON-EXPEDITED			US-TEVA-2018-US-930837			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity;	Escitalopram	S	Unknown	Ivax
Rash	Escitalopram	S		Ivax

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27-Jul-2018	13428367	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-028140		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Atrial Fibrillation; Fall;	Coumadine			S	Oral	1 Df, Unk		Bristol Myers Squibb
Haematoma Muscle;	Seroplex			S	Unknown	1 Df, Unk		Not Reported
Haemoglobin Decreased;	Bisoprolol			C	Unknown	2.5 Mg, Qd		Not Reported
International Normalised Ratio Abnormal; Labelled	Allopurinol			C	Unknown	100 Mg, Qd		Not Reported
Drug-Drug Interaction	Dafalgan			C	Unknown	3 G, Qd		Not Reported
Medication Error;	Lasilix /00032601/			C	Unknown	(Half Tablet Daily)		Not Reported
Overdose; Packed Red	Modopar			C	Unknown	4 Tab, Qd		Not Reported
Blood Cell Transfusion;	Skenan			C	Unknown	5 Mg, Qd		Not Reported
Spontaneous Haematoma;	Vogalene			C	Unknown	3 Tab, Qd		Not Reported
Subdural Haematoma	Macrogol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	13901387	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-APOTEX- 2017AP017265		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria;	Amlodipine			S	Oral	150 Mg, Unk		Apotex
Blindness; Blindness	Amlodipine			S	Oral	Unk		Apotex
Cortical; Cardiogenic Shock; Cerebral Infarction;	Amlodipine			S	Unknown	150 Unk, Unk Every One Day		Apotex
Circulatory Collapse;	Escitalopram			S	Unknown	60 Mg, Unk Every One Day		Apotex
Colour Blindness;	Escitalopram			S	Oral	60 Unk, Unk		Apotex
Condition Aggravated; Csf Pressure Increased;	Risperidone			S	Unknown	6 Mg, Unk Every One Day		Apotex
Cytotoxic Oedema;								
Depressed Level Of								

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Consciousness;	Risperidone	S	Oral	Unk	Apotex
Electrocardiogram P Wave Abnormal;	Risperidone	S	Oral	6 Mg, Unk	Apotex
Electrocardiogram ST Segment Depression;	Potassium Chloride	S	Oral	Unk	Not Reported
Electrocardiogram T Wave Amplitude Decreased;	Potassium Chloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
Electrocardiogram T Wave Inversion;	Epinephrine	S	Unknown	30 Mg, Unk	Not Reported
Electrocardiogram U Wave Present; Embolism;	Vasopressin	S	Unknown	Unk	Not Reported
Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia;	Norepinephrine Bitartrate	S	Unknown	30 Mg, Unk	Not Reported
Hypokalaemia; Hypotension;	Glucose	S	Unknown	Unk	Not Reported
Hypothermia; Intentional Overdose; Ischaemia;	Escitalopram Mylan	S	Oral	Unk	Not Reported
Optic Atrophy; Optic Nerve Injury; Overdose;	Escitalopram	C	Unknown	60 Mg, Unk	Not Reported
Pulmonary Oedema; Renal Tubular Necrosis;	Activated Charcoal	C	Unknown	50 G, Unk	Not Reported
Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock;	Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tachycardia; Toxicity To Various Agents; Visual Impairment	Potassium Chloride	C	Oral	Unk	Not Reported
	Risperidone	C	Unknown	6 Mg, Unk	Not Reported
	Risperidone	C	Oral	Unk	Not Reported
	Insulin	C	Intravenous bolus	70 Iu, Unk	Not Reported
	Insulin	C	Intravenous (not otherwise specified)	70 Df, Unk One Every One Hour	Not Reported
	Amlodipine	C	Unknown	150 Mg, Unk	Not Reported
	Calcium Gluconate	C	Intravenous (not otherwise specified)	2 G, Unk	Not Reported
	Dextrose	C	Intravenous (not otherwise specified)	1 Df, Unk	Not Reported
	Epinephrine	C	Unknown	25 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	10 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	40 Mg, Unk	Not Reported
	Epinephrine	C	Unknown	30 Mg, Unk	Not Reported
	Glucagon	C	Intravenous (not	5 Mg, Unk	Not Reported

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					otherwise specified)				
	Norepinephrine	C	Unknown	40 Mg, Unk				Not Reported	
	Norepinephrine	C	Unknown	30 Mg, Unk				Not Reported	
	Vasopressin	C	Unknown	2.4 Df, Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	14607779	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1812096US		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Somnolence; Sopor; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	400 Mg In Total		Allergan	
	Venlafaxine Hydrochloride			S	Oral	525 Mg In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	14651856	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2018-015388		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Furosemide			S	Oral	Unk		Not Reported	
	Meropenem			S	Intravenous drip	Unk		Aurobindo	
	Bromazepam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Aurobindo	
	Escitalopram			S	Unknown	()		Aurobindo	
	Ondansetron			S	Oral	Unk		Aurobindo	
	Valaciclovir			S	Oral	Unk		Aurobindo	
	Doxorubicin			S	Intravenous drip	Unk		Not Reported	
	Bisoprolol			S	Oral	Unk		Aurobindo	
	Pantoprazole			S	Intravenous drip	Unk		Not Reported	
	Prednisone			S	Intravenous drip	Unk		Not Reported	
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported	
	Fungizone			S	Buccal	Unk		Not Reported	

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Exacyl	S	Intravenous drip	Unk	Not Reported
Eporex	S	Subcutaneous	Unk	Not Reported
Zarzio	S	Subcutaneous	Unk	Not Reported
Hextril	S	Buccal	Unk	Not Reported
Lidocaine	S	Buccal	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Calciparine	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Voraxaze	S	Intravenous drip	Unk	Not Reported
Voraxaze	S			Not Reported
Cyclophosphamide	S	Intravenous drip	Unk	Not Reported
Cyclophosphamide	S	Intravenous drip	()	Not Reported
Cyclophosphamide	S	Unknown	()	Not Reported
Cyclophosphamide	S	Unknown	()	Not Reported
Vincristine	S	Intravenous drip	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	14881674	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2018-025444		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder With	Quetiapine			S	Oral	200 Milligram, Once A Day		Aurobindo	
Mixed Anxiety And	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo	
Depressed Mood;	Alprazolam			S	Oral	1.5 Milligram, Once A Day		Aurobindo	
Anhedonia; Drug	Alprazolam			S	Unknown	1 Mg		Aurobindo	
Ineffective; Drug	Alprazolam			S	Unknown	1.5 Mg,Unk		Aurobindo	
Interaction; Feeling Of	Venlafaxine			S	Oral	300 Milligram, Once A Day		Aurobindo	
Despair; Insomnia;	Valproic Acid			S	Oral	300 Milligram, Once A Day		Not Reported	
Labelled Drug-Drug	Valproic Acid			S		600 Unk		Not Reported	
Interaction Medication									
Error; Suicidal Ideation;									
Treatment Noncompliance									

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Valproic Acid	S		300 Mg,Unk	Not Reported
Clonazepam	S	Oral	0.5 Milligram, Once A Day	Not Reported
Trazodone	S	Oral	75 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15107801	EXPEDITED (15-DAY)		HO, OT	IT-TAKEDA-2018TUS021150		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Brintellix			S	Oral	15 MI, Unk		Takeda	
	Paracetamol			S	Oral	2 G, Unk		Not Reported	
	Lorazepam			S	Oral	20 Mg, Unk		Not Reported	
	Cipralex /01588501/			S	Oral	15 MI, Unk		Not Reported	
	Oxcarbazepine			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15166602	NON-EXPEDITED			US-TEVA-2018-US-927913			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain; Tetany	Escitalopram			S				Not Reported	
	Escitalopram			S		Decreased From 10 Mg To 5 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15205668	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018015681			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuser	Escitalopram			S	Oral	15 Milliliter, Single Abuse / Misuse		Macleods	
	Delorazepam			S	Oral	10 Milliliter, Single Abuse / Misuse		Not Reported	

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27-Jul-2018	15205960	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-931018		23 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15206408	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-03046		19 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Emotional Poverty; Hyperhidrosis; Libido Decreased; Off Label Use; Sexual Dysfunction; Sleep Disorder; Weight Increased	Escitalopram			S	Unknown	30 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Venlafaxine			S	Unknown	150 Mg, Unk		Not Reported	
	Venlafaxine			S	Unknown	225 Mg, Unk		Not Reported	
	Quetiapine			S	Unknown	12.5 Mg, Qd, At Night		Not Reported	
	Bupropion			S	Unknown	150 Mg, Qd		Lupin	
	Bupropion			S	Unknown	300 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15207121	EXPEDITED (15-DAY)		OT	SI-ACCORD-070038		49 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Kidney Disease; Left Ventricular Hypertrophy	Escitalopram			S				Not Reported	
	Rosuvastatin			S				Not Reported	
	Perindopril/Perindopril Erbumine			S				Not Reported	
	Indapamide/Indapamide			S				Not Reported	
	Hemihydrate								
	Alprazolam			S		Unk Unk, Prn		Not Reported	

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27-Jul-2018	15207474	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018015691			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor; Suicidal Ideation	Escitalopram			S	Oral	50 Milligram, Single, Total, Abuse / Misuse		Macleods	
	Olanzapine			S	Oral	20 Milligram, Single, Total, Abuse / Misuse		Macleods	
	Tavor (Lorazepam)			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15207865	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00006561		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amitriptyline			S	Oral	Ingestion		Unknown	
	Escitalopram			S	Oral	Ingest		Unknown	
	Propranolol			S	Oral	Ingestion		Unknown	
	Alprazolam			S	Oral	Ingest		Unknown	
	Acetaminophen			S	Oral	Ingest		Unknown	
	Ethanol			S	Oral	Ingest		Unknown	
	Cocaine			S	Oral	Ingest		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15208012	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2018-ES- 930899		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State	Ibuprofeno (1769a)			S	Oral	400 Mg X 7 Cps		Actavis	
	Paracetamol			S	Oral	12gr Dia		Not Reported	
	Escitalopram			S	Oral	5 Cps		Ivax	

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Exforge 10 Mg/160 Mg
Comprimidos Recubiertos Con
Película 28

S Oral 5 Cps

Not Reported

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27-Jul-2018	15208459	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1837127US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram T Wave Inversion	Lexapro			S	Unknown	Unk		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208910	EXPEDITED (15-DAY)		OT	US-TAKEDA-2018TUS023063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irritability; Major Depression; Nausea; Paraesthesia; Suicidal Ideation	Vortioxetine			S	Unknown	5 Mg, Unk		Takeda
	Vortioxetine			S	Unknown	10 Mg, Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208972	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1837069US			Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prescribed Underdose; Somnolence; Suicidal Ideation; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15210332	EXPEDITED (15-DAY)			CA-TEVA-2018-CA-933316		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Amnesia; Condition Aggravated; Mydriasis; Somnambulism	Escitalopram Ativan	S C	Oral					Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2018	15073980	EXPEDITED (15-DAY)		HO	DE-TORRENT-00008683		44 YR	Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Akathisia; Paraesthesia; Prescribed Underdose	Aripiprazole			S	Oral	10 Mg, Qd		Unknown	
	Escitalopram			S	Oral	20 Mg, Qd		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2018	15211911	EXPEDITED (15-DAY)		CA, OT	IT-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000536			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Lithium Carbonate			S	Transplacental	Unk		Alembic	
	Lithium Carbonate			S			Alembic		
	Escitalopram			S		Unk	Not Reported		
	Lorazepam			S		Unk	Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	14323704	EXPEDITED (15-DAY)		OT	PHHY2017ES192734			Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence	Amlodipine			S	Unknown	1 Df, Qd (1 Ug/Litre)		Not Reported	
	Simvastatin			S	Unknown	Unk, Qd		Not Reported	
	Simvastatin			S	Unknown	1 Df, Qd (1 Ug/Litre)		Not Reported	
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported	
	Omeprazole			S	Unknown	1 Df, Qd (1 Ug/Litre)		Novartis	
	Topiramate			S	Unknown	0.5 Df, Qd (0.5 Ug/Litre)		Not Reported	

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Topiramate	S	Unknown	1 Df, Qd (1ug/Litre)	Not Reported
Paracetamol	S	Unknown	3 Df, Qd (3 Ug/Litre)	Not Reported
Paracetamol	S	Unknown	1 Df, Tid (3 Ug/Litre)	Not Reported
Escitalopram	S	Unknown	Unk, Qd (1ug/Litre)	Not Reported
Escitalopram	S	Unknown	1 Df, Qd (1 Ug/Litre)	Not Reported
Tramadol+Paracetamol	S	Unknown	3 Df, Qd (3 Ug/Litre)	Not Reported
Tramadol+Paracetamol	S	Unknown	1 Df, Tid (5/325 Mg)	Not Reported
Enalapril Hydrochlorothiazide Bc	S	Unknown	1 Df, Qd (20/12.5 Mg)	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd (1 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	2 Df, Qd (2 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	1 Df, Bid (2 Ug/Litre)	Not Reported
Glibenclamide	S	Unknown	Unk	Not Reported
Diazepam	S	Unknown	1 Ot, Qd	Not Reported
Diazepam	S	Unknown	0.5 Df, Qd (0.5 Ug/Litre)	Not Reported
Diazepam	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	5 Mg, Qd	Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
Naproxen	S	Unknown	2 Df, Qd (2 Ug/Litre)	Not Reported
Naproxen	S	Unknown	1 Df, Bid (2 Ug/Litre)	Not Reported
Tepazepam	S	Unknown	Unk Unk, Qd	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	14640887	EXPEDITED (15-DAY)		DE, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2018VAL000511		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Furosemide	S	Oral	Unk	Validus
	Pantoprazole	S	Intravenous drip	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported
	Ciprofloxacin /00697202/	S	Intravenous drip	Unk	Not Reported
	Exacyl	S	Intravenous drip	Unk	Not Reported
	Exacyl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Prednisone	S	Intravenous drip	Unk	Not Reported
	Ondansetron	S	Oral	Unk	Not Reported
	Bromazepam	S	Oral	Unk	Not Reported
	Bromazepam	S	Unknown	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Unknown	Unk	Not Reported
	Fungizone	S	Buccal	Unk	Not Reported
	Eprex	S	Subcutaneous	Unk	Not Reported
	Zarzio	S	Subcutaneous	Unk	Not Reported
	Meropenem	S	Intravenous drip	Unk	Not Reported
	Hextril	S	Buccal	Unk	Not Reported
	Hextril	S	Buccal	Unk	Not Reported
	Hextril	S	Unknown	Unk	Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Calciparine	S	Subcutaneous	Unk	Not Reported
	Calciparine	S	Subcutaneous	Unk	Not Reported
	Bisoprolol	S	Oral	Unk	Not Reported
	Doxorubicin	S	Intravenous drip	Unk	Not Reported

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	Voraxaze	S	Intravenous drip	Unk	Not Reported
	Valaciclovir	S	Oral	Unk	Not Reported
	Valaciclovir	S	Unknown	Unk	Not Reported
	Valaciclovir	S	Oral	Unk	Not Reported
	Cyclophosphamide	S	Intravenous drip	Unk	Not Reported
	Vincristine	S	Intravenous drip	Unk	Not Reported
	Bactrim	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15084348	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018261695		87 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Dementia; Fall	Halcion			S		Unk		Pfizer	
	Spiractin /00006201/			S		Unk		Not Reported	
	Dopaquel			S		Unk		Not Reported	
	Zytomil			S		Unk		Not Reported	
	Vesicare			S		Unk		Not Reported	
	Macrochantin			S		Unk		Not Reported	
	Euthyrox			S		Unk		Not Reported	
	Cardugen			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15213470	NON-EXPEDITED			US-PFIZER INC-2018304914			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Gabapentin			S		Unk		Pfizer	
	Ativan			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15213583	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-037813		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram			S	Oral	50 Milligram, In Total		Aurobindo	
	Olanzapine			S	Oral	In Total		Aurobindo	
	Tavor /00273201/			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15213925	EXPEDITED (15-DAY)		HO	PHHY2018FR056263		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Amiodarone			S	Oral	200 Mg, Unk		Novartis	
	Allopurinol			S	Oral	100 Mg, Unk		Not Reported	
	Seroplex			S	Oral	1 Df, Unk		Not Reported	
	Topalgic Lp			S	Oral	3 Df, Unk		Not Reported	
	Oxynormoro			S	Oral	5 Mg, Unk		Not Reported	
	Xanax			S	Oral	0.38 Mg, Unk		Not Reported	
	Kardegic			S	Oral	1 Df, Unk		Not Reported	
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df, Unk		Not Reported	
	Ciclosporine			C	Oral	100 Mg, Unk		Not Reported	
	Mycophenolate			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15214249	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004502		34 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Dyspepsia; Eructation;	Espran			S	Oral	One Tablet Daily		Torrent	

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Haemangioma Of Liver; Varices Oesophageal		Pantoprazol	C	Oral	Unknown				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	14617659	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-011773		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Prescribed Overdose	Bisoprolol			S	Unknown	Unk		Aurobindo	
	Escitalopram			S	Unknown	5 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	14922162	EXPEDITED (15-DAY)		OT	ES-ACCORD-064898			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amitriptyline			S				Accord	
	Paracetamol			S	Unknown	1 Df, Tid		Accord	
	Simvastatin			S				Accord	
	Topiramate			S		1 Df, Qd		Accord	
	Diazepam			S		0.5 Df, Qd		Not Reported	
	Amlodipine			S		1 Df, Qd		Accord	
	Escitalopram			S		1 Df, Qd		Not Reported	
	Omeprazole			S		1 Df, Qd		Not Reported	
	Lormetazepam			S		1 Df, Qd		Not Reported	
	Tepazepam			S		Unk, Qd Dose: 1		Not Reported	
	Paracetamol/Tramadol			S		1 Df, Tid		Not Reported	
	Naproxen			S		1 Df, Bid		Not Reported	
	Enalapril/Hydrochlorothiazide			S		1 Df, Qd		Not Reported	
	Glibenclamide			S		1 Df, Bid		Not Reported	
	Metoclopramide			C		1 Week Treatment		Not Reported	

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31-Jul-2018	15196136	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1836461US		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperreflexia; Intentional Self-Injury; Loss Of Consciousness; Mydriasis; Nystagmus; Overdose; Product Use In Unapproved Indication; Tachycardia	Escitalopram Oxalate - Bp			S	Unknown	5 Df; In Total		Allergan	
	Lamictal			S	Oral	2800 Mg; In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220201	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018015718			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods	
	Risperdal			S	Oral	1 Unk, Divisible Coated Tablet		Not Reported	
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221356	EXPEDITED (15-DAY)		OT	PHHY2018BR060405		85 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Application Site Pruritus; Deafness; Depression	Exelon Patch			S	Unknown			Novartis	
	Espran			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221946	EXPEDITED (15-DAY)		HO, LT, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-069137		82 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Eliquis			S	Oral	1 Df, Daily		Bristol Myers Squibb	
	Seroplex			S	Oral	10 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221980	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837302US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Ethyl Loflazepate			C	Unknown	Unk, Unknown		Not Reported	
	Alprazolam			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221985	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1837326US		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Tooth Infection	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15222705	EXPEDITED (15-DAY)		OT	PHEH2018US030749			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Urticaria	Ilevro			S	Ophthalmic	Unk		Novartis	
	Durezol			S	Ophthalmic	Unk		Not Reported	
	Meloxicam			S	Unknown			Not Reported	
	Celexa			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	

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01-Aug-2018	12763589	EXPEDITED (15-DAY)		HO	FR-SA-2016SA172334		35 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Interstitial Lung Disease	Cortancyl			S	Oral	5 Mg,Bid		Not Reported
	Triatec (Ramipril)			S	Oral	5 Mg,Qd		Sanofi
	Stilnox			S	Oral	10 Mg,Qd		Sanofi
	Mycophenolate Mofetil			S	Oral	Unk Unk,Bid		Not Reported
	Atorvastatin Calcium			S	Oral	10 Mg,Qd		Not Reported
	Theralene			S	Oral	5 Mg,Bid		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg,Bid		Not Reported
	Ixprim			S	Oral	Unk Unk,Unk,37,5 Mg / 325 Mg Coated Tablets		Not Reported
	Esomeprazole Magnesium			S	Oral	20 Mg,Qd		Not Reported
	Seresta			C		Strength: 50 Mg		Not Reported
	Lasilix [Furosemide]			C		Strength: 40 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	14133044	NON-EXPEDITED			JP-ALLERGAN-1750665US		22 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affect Lability	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan
	Paxil Cr			S	Oral	37.5 Mg, Qd		Not Reported
	Meilax			C	Unknown			Not Reported
	Meilax			C	Oral			Not Reported
	Akineton			C	Unknown			Not Reported
	Akineton			C	Oral			Not Reported
	Abilify			C	Unknown			Not Reported

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Abilify	C	Oral	Not Reported
Constan [Alprazolam]	C	Unknown	Not Reported
Constan	C	Oral	Not Reported
Methycobal	C	Unknown Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	14472465	EXPEDITED (15-DAY)	HO		DE-TEVA-2018-DE-850996		42 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Level Decreased; Hospitalisation; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram			S	Oral	30 Milligram Daily;		Ivax
	Escitalopram			S	Oral			Ivax
	Pangrol			C	Unknown	2 Unk, Unk		Not Reported
	Lorazepam			C	Unknown			Not Reported
	Olanzapine			C	Unknown	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	14775852	EXPEDITED (15-DAY)			FR-JNJFOC-20180406793		47 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Tramadol Hydrochloride			S	Oral			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Seroplex			S	Oral			Not Reported
	Bilaska			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Nocertone			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15013981	NON-EXPEDITED			PHEH2018US023706		40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Erythema;	Cosentyx	S	Subcutaneous	300 Mg, Qw	Novartis
Hypersensitivity; Pain Of	Cosentyx	S			Novartis
Skin; Pruritus; Rash; Rash	Lexapro	S	Oral	20 Mg, Qd	Not Reported
Erythematous; Skin					
Exfoliation; Skin Irritation;					
Skin Oedema; Urticaria					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15049790	EXPEDITED (15-DAY)		HO	PHHY2018FR025250		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Esidrex			S	Oral	0.5 Df, Qd		Novartis
Hemianopia;	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported
Hyponatraemia; Language	Seroplex			S	Oral	1 Df, Qd		Not Reported
Disorder	Procoralan			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Breackable		Not Reported
	Dafalgan			C	Unknown	Unk		Not Reported
	Pravastatine			C	Unknown			Not Reported
	Mediatensyl			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown			Not Reported
	Ramipril			C				Not Reported
	Acebutolol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15160037	EXPEDITED (15-DAY)		HO, LT	DE-FRESENIUS KABI-FK201807869		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Linezolid 600mg Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Esomeprazole			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram	S	Unknown	Unk	Not Reported
Levothyroxine Sodium	C			Not Reported
Lorazepam	C		Daily Dose: 1 Mg Milligram(S) Every Days	Not Reported
Hyoscine Hydrobromide	C	Transdermal		Not Reported
Levetiracetam	C		Daily Dose: 2 Df Dosage Form Every Days	Not Reported
Prednisolone	C			Not Reported
Ivabradine	C		Daily Dose: 15 Mg Milligram(S) Every Days	Not Reported
Naloxone/Tilidine	C			Not Reported
Sulfamethoxazole/Trimethoprim	C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
Baclofen	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15191730	EXPEDITED (15-DAY)	CA		DE-PFIZER INC- 2018292736			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Oesophageal Atresia; Premature Baby	Lorazepam			S	Transplacental	Unk		Pfizer
	Mycophenolate Mofetil			S	Transplacental	Unk		Not Reported
	Zolpidem			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15226032	EXPEDITED (15-DAY)	DE, HO		US-TORRENT- 00006634		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Drug Abuse; Toxicity To Various Agents	Bupropion			S	Unknown	Unknown		Unknown
	Escitalopram			S	Unknown	Unknown		Unknown
	Alprazolam			S	Unknown	Unknown		Unknown
	Ethanol			S	Unknown	Unknown		Unknown

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Cocaine			S		Unknown		Unknown		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes		Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15226956	EXPEDITED (15-DAY)		HO		PHHY2018LU061172		47 YR	Female	LUX
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Gilenya				S	Oral	1 Df, Qd		Novartis	
	Escitalopram				S	Oral			Not Reported	
	Lyrica				C	Oral	100 Mg, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes		Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227112	EXPEDITED (15-DAY)		OT		HR-ALLERGAN-1837818US		50 YR	Female	HRV
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chromaturia; Constipation; Urinary Retention	Escitalopram Oxalate - Bp				S	Oral	10 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes		Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227132	EXPEDITED (15-DAY)		HO		IT-ALLERGAN-1837820US		75 YR	Female	ITA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Asthenia; Overdose; Sopor; Therapy Change	Escitalopram Oxalate - Bp				S	Oral	3 Df, Total		Allergan	
	Anafranil				C	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes		Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227540	EXPEDITED (15-DAY)		HO		ZA-PFIZER INC-2018304932		67 YR	Female	ZAF
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cystitis; Gastric Disorder	Aspavor				S		Unk		Pfizer	
	Ecotrin				S		Unk		Not Reported	

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	Bilacor	S	Unk	Not Reported
	Clopiwin	S	Unk	Not Reported
	Zytomil	S	Unk	Not Reported
	Trustan	S	Unk	Not Reported
	Zartan Co	S	Unk	Not Reported
	Humalog Mix	S	Unk	Not Reported
	Diaphage	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15227602	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2018298726			Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Cyanosis; Syncope	Acetylsalicylic Acid			S		Unk		Pfizer	
	Amlodipine Besilate			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Insulin			S		Unk		Not Reported	
	Polmatine			S		Unk		Not Reported	
	Metoprolol			S		Unk		Not Reported	
	Perindopril			S		Unk		Not Reported	
	Rivastigmine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15228713	EXPEDITED (15-DAY)		HO	PHHY2017FR204444		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged; Haematuria;	Bisoprolol Fumarate			S	Oral	2 Ot, Qd (3.25 Mg In The Morning And 2.5 Mg In The Evening)		Novartis	
Hyperkalaemia; Intentional Overdose; Sinus	Bisoprolol Fumarate			S	Oral	Unk		Novartis	
	Tahor			S	Oral	Unk		Not Reported	

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Bradycardia; Somnolence	Tahor	S	Oral	40 Mg, Qd ((40 Mg/Day)	Not Reported
	Diffu-K	S	Oral	Unk	Not Reported
	Diffu-K	S	Oral	Unk	Not Reported
	Triatec (Ramipril)	S	Oral	Unk	Not Reported
	Triatec (Ramipril)	S	Oral	2.5 Mg, Bid (2.5 Mg 2/Day)	Not Reported
	Brilique	S	Oral	90 Mg, Bid (90 Mg 2/Day)	Not Reported
	Brilique	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	5 Mg, Qd (5 Mg/Day)	Not Reported
	Inexium	C	Unknown	20 Mg, Qd (20 Mg/Day)	Not Reported
	Kardegic	C	Unknown	75 Mg, Qd (75 Mg/Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15285175	DIRECT	Y				25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15120524	EXPEDITED (15-DAY)		HO	PHHY2018ES065501		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Condition Aggravated; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Mental Disorder; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	Unk		Novartis
	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15178796	EXPEDITED (15-DAY)		DS	PHHY2018DE050632			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Gait	Escitalopram			S	Oral	1 Df, Qd (10 Mg)		Not Reported	
Disturbance;	Escitalopram			S	Oral	1 Df, Qd (20 Mg)		Not Reported	
Hyperhidrosis;	Oxazepam			S	Oral	10 Mg, Qd		Novartis	
Hypoaesthesia; Insomnia;	Monostep			C	Oral			Not Reported	
Malaise; Muscle									
Twitching; Off Label Use;									
Palpitations; Paraesthesia;									
Tremor									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15229691	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-038517		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
System Imbalance;	Zopiclone			S	Oral	7.5 Milligram, Daily		Not Reported	
Malaise; Orthostatic	Risperdal			S	Oral	Unk		Not Reported	
Hypotension									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15230581	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2018DE00737			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15230844	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00009105			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Renal Failure	Escitalopram	S	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15231786	EXPEDITED (15-DAY)		OT	CH-SA-2018SA197380		83 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Disturbance In Attention	Pramipexole Hydrochloride			S	Oral	0.125 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Allopurinol			S	Oral	100 Mg, Bid		Not Reported
	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
	Metoprolol Succinate			S	Oral	50 Mg, Qd		Not Reported
	Plavix			S	Oral	75 Mg, Qd		Sanofi
	Plavix			S	Oral	75 Unk		Sanofi
	Prednisolone			S	Unknown	Spiricort® Filmtabl 20 Mg (Prednisolon); 15 Mg - 0 - 5 Mg - 0, Bis Am 02.06.2018		Not Reported
	Tramadol Hydrochloride			S	Oral	Tramal® Tropfen (100 Mg = 40 Gtt) 100 Mg/1 MI ; As Necessary		Not Reported
	Oxycodone Hydrochloride			S	Oral	As Necessary		Not Reported
	Morphine Hydrochloride			S	Oral	In Total		Not Reported
	Morphine Hydrochloride			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	In Total		Not Reported
	Quetiapine Fumarate			S	Oral	25 Mg, Qd		Not Reported
	Diazepam			S	Oral	As Necessary		Not Reported
	Haloperidol			S	Oral	In Total		Not Reported
	Fentanyl Citrate			S	Intravenous (not otherwise specified)	25 Mg, Qd		Not Reported

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Lisitril	S	Oral	20 Mg, Qd	Not Reported
Aspirin Cardio	C	Oral	100 Mg, Qd	Not Reported
Atorvastatin Pfizer	C	Oral	20 Mg, Qd	Not Reported
Dafalgan	C	Oral	500 Mg, Tid	Not Reported
Spiriva	C			Not Reported
Torem	C	Unknown	5 Mg, Qd	Not Reported
Novalglin (Metamizole Sodium)	C	Oral	As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15232044	EXPEDITED (15-DAY)		DS, HO, LT, OT	NO-ALLERGAN-1838278US		40 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Product Use Issue; Tooth Injury	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Q12h		Allergan
	Quetiapin Sandoz			S	Unknown	25 Mg, Q12h		Not Reported
	Calcigran Forte			S	Unknown	4 lu, Q12h		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Etalpa			C	Oral			Not Reported
	Zopiklon Mylan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15232552	EXPEDITED (15-DAY)		OT	PHHY2018CA001594			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Drug Ineffective; Fatigue; Lip Swelling; Sleep Deficit	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
	Metformin			S	Oral	2 Df, Bid		Not Reported
	Clonazepam			S	Oral	1 Df, Bid		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Candesartan			S	Oral	1 Df, Qd		Not Reported

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	Candesartan	S	Unknown	16 Mg, Unk	Not Reported
	Simvastatin	S	Oral	2 Df, Qd	Not Reported
	Prednisone	C	Oral	1 Df, Qd	Not Reported
	Abilify	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15233301	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2018M1057404		37 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Mental Disorder; Persecutory Delusion	Escitalopram			S	Unknown	7 Months Prior To The Commencement Of Ademetonine.		Not Reported	
	S-Adenosyl-L-Methionine			S	Unknown	She Started Ademetonine In Conjunction With An Ssri, Eight Months Prior To Hospitalisation		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15233629	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2018IN20392			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Per Day		Invagen	
	Amisulpride			S	Unknown	100 Mg, Per Day		Not Reported	
	Amisulpride			S	Unknown	400 Mg, Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	13937162	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL129784			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Condition Aggravated;	Bisoprolol			S	Unknown	Unk		Not Reported	
Depression; Drug Abuse; Drug Ineffective; Impaired	Bisoprolol			S	Unknown	Unk		Not Reported	

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Work Ability; Insomnia;	Atorvastatin	S	Unknown	Unk	Novartis
Intentional Overdose;	Atorvastatin	S	Oral	B/D	Novartis
Intentional Product	Atorvastatin	S	Oral	Unk, Qhs	Novartis
Misuse; Loss Of	Zolpidem	S	Unknown	10 Mg, Qhs	Not Reported
Consciousness; Loss Of	Zolpidem	S	Oral	B/D	Not Reported
Personal Independence In	Zolpidem	S	Oral	10 Mg, Qhs	Not Reported
Daily Activities; Overdose;	Zolpidem	S	Oral	10 Mg, Qhs	Not Reported
Product Use In	Clarithromycin	S	Unknown	Two 10 Day Courses	Not Reported
Unapproved Indication;	Clarithromycin	S	Unknown	Unk	Not Reported
Suicide Attempt; Tinnitus	Clarithromycin	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Oral	Two 10 Day Cycles.	Not Reported
	Sertraline	S	Unknown	50 Mg, Qd	Not Reported
	Sertraline	S	Unknown	50 Mg In The Morning	Not Reported
	Sertraline	S	Oral	50 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
	Escitalopram	S	Oral	10 Mg, Before Sleeping	Not Reported
	Escitalopram	S	Unknown	Doctor Switched The Patient From Sertraline To Escitalopram	Not Reported
	Escitalopram	S	Oral	10 Mg, Hs (Doctor Switched The Patient From Sertraline To Escitalopram)	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported

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Meloxicam	S	Oral	B/D	Not Reported
Meloxicam	S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
Perindopril	S	Unknown	Unk	Not Reported
Perindopril	S	Unknown	Unk	Not Reported
Doxepin	S	Unknown	25 Mg, Qhs	Not Reported
Doxepin	S			Not Reported
Troscicam	S	Unknown	Unk	Not Reported
Atoris	S	Unknown		Not Reported
Atoris	S			Not Reported
Polisen	S	Unknown	10 Mg, (Od At Bed Time)	Not Reported
Polisen	S	Oral	10 Mg, (Od At Bedtime)	Not Reported
Concor	S	Unknown		Not Reported
Concor	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	14772761	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-850962		36 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling Face	Escitalopram Tablet, 5 Mg (Milligram)			S	Unknown	5 Milligram Daily; 1x Daily 1 Tablet		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	14818901	EXPEDITED (15-DAY)		HO, LT, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018012786			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram Oxalate			S	Unknown	5 Milligram		Macleods
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd, Linezolid 600 Mg		Not Reported
	Esomeprazol			S	Unknown	40 Milligram		Not Reported

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Prednisolone 10 Mg	C	Unknown	10 Milligram	Not Reported
Levetiracetam	C	Unknown	2 Dosage Form, Qd, 1.5g	Not Reported
L-Thyroxin	C	Unknown	75 Microgram	Not Reported
Ivabradine	C	Unknown	15 Milligram, Qd	Not Reported
Cotrimoxazol	C	Intravenous (not otherwise specified)	2 Dosage Form, Qd (Cotrimoxazol 960mg)	Not Reported
Naloxone, Tilidine	C	Unknown	10 Drop, 25/2mg	Not Reported
Scopolamin	C	Transdermal	Unk, Scopolamine Plaster	Not Reported
Baclofen	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	14917979	EXPEDITED (15-DAY)		DE, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-167094		69 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Pantoprazole			S	Intravenous drip	Unk		Sun
	Valaciclovir			S	Oral	Unk		Sun
	Escitalopram			S	Oral	Unk		Not Reported
	Fungizone			S	Buccal	Unk		Not Reported
	Exacyl			S	Intravenous drip	()		Not Reported
	Eprex			S	Subcutaneous	Unk		Not Reported
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported
	Zarzio			S	Subcutaneous	Unk		Not Reported
	Meropenem Anhydride			S	Intravenous drip	Unk		Not Reported
	Hextril			S	Buccal	Unk		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Lidocaine			S	Buccal	Unk		Not Reported
	Rituximab ((Mammifere/Hamster/Cellules Cho))			S	Intravenous drip	Unk		Not Reported

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Calciparine	S	Subcutaneous	Unk	Not Reported
Bisoprolol (Fumarate Acide De)	S	Oral	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Doxorubicine (Chlorhydrate De)	S	Intravenous drip	Unk	Not Reported
Voraxaze	S	Intravenous drip	Unk	Not Reported
Cyclophosphamide	S	Intravenous drip	Unk	Not Reported
Prednisone	S	Intravenous drip	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Vincristine (Sulfate De)	S	Intravenous drip	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15192711	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US20222			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Deafness; Depression; Dyspnoea; Hallucination; Insomnia; Panic Attack; Somnambulism; Somnolence; Thought Blocking	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Escitalopram			S				Invagen	
	Benazepril			C	Unknown	10 Mg, Unk		Not Reported	
	Allopurinol			C	Unknown	100 Mg, Bid		Not Reported	
	Lasix /00032601/			C	Unknown	Unk, Bid		Not Reported	
	Novolin			C	Unknown	50 Units, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15234231	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE- HET2018DE00741		55 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia; Product Used For Unknown Indication	Escitalopram			S	Unknown	Nk		Hetero	
	Acetylsalicylsaeure			C	Unknown	Nk		Not Reported	

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03-Aug-2018	15234423	EXPEDITED (15-DAY)		OT	BR-ROCHE-2147191		24 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ataxia; Balance Disorder; Coordination Abnormal; Dizziness; Multiple Sclerosis	Rivotril			S	Unknown			Not Reported	
	Rivotril			S				Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235479	EXPEDITED (15-DAY)		HO, OT	AT-ACCORD-070337		58 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Lethargy; Sedation; Social Avoidant Behaviour; Tremor	Topiramate			S	Oral			Accord	
	Pregabalin			S	Oral	375 Mg On 08-Feb-2016 300 Mg 09-Feb To 10-Feb-2016		Not Reported	
	Risperidone			S				Not Reported	
	Cipralex			S	Oral			Not Reported	
	Pantoprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235484	EXPEDITED (15-DAY)		DE	FR-ACCORD-070434		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyspnoea; Hyperhidrosis; Hyperthermia; Hypertonia	Escitalopram			S	Oral			Not Reported	
	Tiapridal			S	Oral			Not Reported	
	Orozamudol			S	Oral			Not Reported	
	Mirtazapine			S	Oral			Not Reported	

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03-Aug-2018	15236102	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018015964			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram Oxalate			S	Oral	15 Milligram, Qd		Macleods	
	Deniban			S	Oral	25 Milligram, Qd, Comprese		Not Reported	
	Valium			S	Oral	16 Drop, Qd		Not Reported	
	Leponex			S	Oral	150 Milligram, Qd Comprese		Not Reported	
	Arlevertan			S	Oral	3 Dosage Form, Qd, Compress		Not Reported	
	Resilient			S	Oral	1 Dosage Form, Qd, Prolonged Release Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15236286	EXPEDITED (15-DAY)		HO	US-APOTEX- 2018AP018543		29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Priapism; Treatment Noncompliance	Trazodone			S	Unknown	200 Mg, Qd		Apotex	
	Escitalopram			S	Unknown	20 Mg, Qd		Apotex	
	Valproic Acid			S	Unknown			Apotex	
	Buspirone			S	Unknown			Apotex	
	Duloxetine			S	Unknown			Apotex	
	Modafinil			S	Unknown			Apotex	
	Prazosin			S	Unknown	20 Mg, Qd		Not Reported	
	Nortriptyline			S	Unknown			Not Reported	
	Methylphenidate			S	Unknown	10 Mg, Qd		Not Reported	
	Methylphenidate			S				Not Reported	

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03-Aug-2018	15236778	EXPEDITED (15-DAY)		HO, OT	AU-TORRENT-00000275		44 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Olanzapine			S		Unknown		Unknown	
	Escitalopram Oxalate			S				Unknown	
	Quetiapine			S				Unknown	
	Risperidone			S		Unknown		Unknown	
	Clomipramine			S		Unknown		Unknown	
	Amisulpride			S		Unknown		Unknown	
	Clozapine			C		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15237197	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-038648			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer	Escitalopram			S	Unknown	Low Dose, At Last 10-15 Mg Qd ()		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15239002	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-934860		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Sopor; Therapy Change	Escitalopram Oxalate			S	Oral			Ivax	
	Anafranil			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2018	15067964	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	PHHY2017BE200004			Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death Neonatal; Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine	S	Transplacental	Maternal Dose: 5 Mg Qd	Not Reported
	Pantoprazole	S	Transplacental		Novartis
	Ventolin (Salbutamol Sulfate)	S	Transplacental	Maternal Dose: 100 Ug Unk	Not Reported
	Avamys	S	Transplacental	Maternal Dose: 2 Ot Bid	Not Reported
	Seretide	S	Transplacental	Unk	Not Reported
	Sipralexa	S	Transplacental	Maternal Dose: 10 Mg Unk	Not Reported
	Relvar Ellipta	S	Transplacental	Maternal Dose: 1 Ot, Qd	Not Reported
	Flixotide	S	Transplacental	Maternal Dose: 250 Ug, Bid	Not Reported
	D-Cure	S	Transplacental	Maternal Dose: 25 Kiu, Unk	Not Reported
	Pantomed (Pantoprazole Sodium Sesquihydrate)	S	Transplacental		Not Reported
	Nucala	S	Transplacental	Maternal Dose: 100 Mg, Unk	Not Reported
	Xanthium (Theophylline)	S	Transplacental	Maternal Dose: 200 Mg, Qd	Not Reported
	Fluticasone Furoate	S	Transplacental	Maternal Dose: 1 Ot, Qd	Not Reported
	Vilanterol Trifenatate	S	Transplacental	Maternal Dose: 1 Df, Qd	Not Reported
	Xyzall	S	Transplacental	Maternal Dose: 5 Mg, Qd	Not Reported
	Theophylline	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2018	15241436	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-038935		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence	Escitalopram			S	Oral	28 Dosage Form		Aurobindo	
	Paroxetine			S	Oral	12 Dosage Form		Aurobindo	
	Ibuprofen			S	Oral	20 Dosage Form		Aurobindo	
	Havlane			S	Oral	20 Dosage Form		Not Reported	

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Dafalgan			S		Oral		8 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
05-Aug-2018	15241670	NON-EXPEDITED			US-JNJFOC-20180730788		71 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Dizziness; Oedema Peripheral; Weight Increased	Xarelto			S	Oral				Not Reported	
	Lexapro			S	Unknown				Not Reported	
	Spironolactone			C	Unknown				Not Reported	
	Remeron			C	Unknown				Not Reported	
	Digestive Enzyme			C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
05-Aug-2018	15290650	DIRECT		OT			44 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Disease Recurrence; Mental Disorder; Product Substitution Issue	Escitalopram		Y	S	Oral	Quantity:1 Tablet(S);	2 YR		Unknown	
	Clonazepam			C					Not Reported	
	Omega 3 Fish Oil			C					Not Reported	
	Magnesium			C					Not Reported	
	Vitamin D3			C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Aug-2018	15218734	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US20404			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Treatment Noncompliance	Escitalopram			S	Unknown	10 Mg, Daily			Invagen	
	Escitalopram			S	Unknown	20 Mg, Per Day			Invagen	
	Escitalopram			S	Unknown	Unk			Invagen	
	Escitalopram			S	Unknown	20 Mg, Per Day			Invagen	
	Amlodipine			C	Unknown	2.5 Mg, Daily			Not Reported	

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Pantoprazole			C	Unknown	20 Mg, Daily	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15242258	EXPEDITED (15-DAY)		OT	PL-ACCORD-070421			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk;	Escitalopram			S				Not Reported	
Seizure	Bupropion/Bupropion Hydrochloride			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15243373	EXPEDITED (15-DAY)		OT	US-TORRENT-00006701		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia;	Aripiprazole			S		Unknown		Unknown	
Hyperkeratosis; Tardive	Lithium Citrate			S		Unknown		Unknown	
Dyskinesia	Escitalopram			S		Unknown		Unknown	
	Bupropion			S		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15243463	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837370US		63 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activation Syndrome;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
Restlessness; Suicidal Ideation	Amoban			C	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15244454	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMP ANY-FR201807012758		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hyponatraemia	Gemzar	S	Intravenous (not otherwise specified)	1.5 G, Unknown	Eli Lilly And Co
	Cisplatin	S	Intravenous drip	25 Mg/M2, Unk	Not Reported
	Escitalopram	S	Oral	10 Mg, Daily	Not Reported
	Alprazolam	C	Oral	.25 Mg, Daily	Not Reported
	Propranolol	C	Oral	Unk	Not Reported
	Fluconazole	C	Oral	100 Mg, Daily	Not Reported
	Coaprovel	C	Oral		Not Reported
	Levothyroxine Sodique	C	Oral	100 Mg, Daily	Not Reported
	Lansoprazole	C	Oral	30 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15244611	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2018137897		35 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Coma; Hypotension; Suicide Attempt	Propranolol			S	Oral	Unk		Glaxosmithkline
	Paracetamol			S	Oral	Unk		Glaxosmithkline
	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Alprazolam			S	Oral	Unk		Not Reported
	Ibuprofene			C	Unknown	Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245524	EXPEDITED (15-DAY)		HO	PHHY2018FR061608		46 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Ibuprofen			S	Oral	6 G, Unk		Novartis
	Paracetamol			S	Unknown	8.8 G, Unk		Not Reported

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Atarax	S	Oral	750 Mg, Unk	Not Reported
Cefuroxime	C	Oral	Unk	Not Reported
Alprazolam	C	Oral	5 Mg, Unk	Not Reported
Brexin	C	Oral	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245630	EXPEDITED (15-DAY)		HO	PHHY2018FR058677		84 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Mirtazapine			S	Oral	15 Mg, Unk		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Unk		Novartis
	Modopar			S	Oral	3 Df, Unk		Not Reported
	Risperdal			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Kardegic			C	Oral	1 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245646	EXPEDITED (15-DAY)		OT	PHHY2018FR059294		68 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Irbesartan			S	Oral	75 Mg, Unk		Novartis
	Fenofibrate			S	Oral	67 Mg, Unk		Not Reported
	Naproxene			S	Oral	1100 Mg, Unk		Not Reported
	Levothyroxine Sodique			S	Oral	75 Ug, Unk		Not Reported
	Pregabalin			S	Oral	150 Mg, Unk		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported

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06-Aug-2018	15245647	EXPEDITED (15-DAY)	Y	HO	PHHY2018FR059739		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Somnolence	Rilmenidine Sandoz 1 Mg, Compressed			S	Oral	2 Df, Qd		Not Reported	
	Zolpidem Sandoz			S	Oral	1 Df, Qd		Novartis	
	Bisoprolol Teva			S	Oral	1 Df, Qd		Not Reported	
	Escitalopram Arrow			S	Oral	1 Df, Qd		Not Reported	
	Pravastatine Biogaran 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Df, Qd		Not Reported	
	Inexium			C	Unknown	Unk		Not Reported	
	Aerius (Desloratadine)			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15246268	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1057981		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	13423965	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1713804US		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoglobin Decreased; Overdose; Spontaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Coumadine			S	Oral	2 Mg, Bid		Not Reported	
	Bisoprolol			C	Unknown	2.5 Mg, Qd		Not Reported	

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	Allopurinol	C	Unknown	100 Mg, Qd	Not Reported
	Dafalgan	C	Unknown	3 G, Qd	Not Reported
	Lasilix	C	Unknown	500 Mg, Qd	Not Reported
	Modopar	C	Unknown	500 Mg, Qid	Not Reported
	Skenan	C	Unknown	5 Mg, Qd	Not Reported
	Macrogol	C	Unknown		Not Reported
	Vogalene	C	Unknown	7.5 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	14347045	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018002426		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Somnolence; Sopor; Suicide Attempt	Venlafaxine Hcl			S	Oral	525 Mg, Single		Pfizer	
	Escitalopram			S	Oral	400 Mg, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	14944519	EXPEDITED (15-DAY)		OT	CA-MACLEODS PHARMACEUTICALS US LTD-MAC2018013744			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Rivaroxaban			S	Unknown	Unk		Not Reported	
	Rivaroxaban			S	Unknown	15 Milligram, Qd		Not Reported	
	Heparin			S	Subcutaneous	Unk Unk, 5000 U, 12 Hour		Not Reported	
	Heparin			S	Subcutaneous	Unk, Every 12 Hour		Not Reported	
	Bupivacaine			C	Intravenous (not otherwise specified)	1 Mg/MI, Infusion		Not Reported	
	Bupivacaine			C	Unknown	Unk		Not Reported	
	Epinephrine			C	Unknown	Q, A Test Dose Of 3 MI Of Lidocaine 2% With		Not Reported	

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Epinephrine	C	Unknown	Epinephrine 5 ?G/MI	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
			Unk,10 ?G/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion	
Hydromorphone	C	Unknown	Unk	Not Reported
Lidocaine	C	Unknown	3 Milliliter, A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI	Not Reported
Lidocaine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15133890	EXPEDITED (15-DAY)		HO, OT	AU-009507513-1807AUS002839		86 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Simvastatin			S		Unk		Merck
	Denosumab			S		Unk, Cyclical		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazole			S		Unk		Not Reported
	Naloxone Hydrochloride			S				Not Reported
	Oxybutynin			S		Unk		Not Reported
	Pregabalin			S		Unk		Not Reported
	Telmisartan			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15204218	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1055049		77 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown	Nk		Not Reported
	Eferox			C		50 Mg, 1-0-0-0		Mylan

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Hct	C	12.5 Mg, 1-0-0-0	Mylan
Metoprolol	C	47.5 Mg, 1-0-0-0	Mylan
Ventolair	C	250 Mg, 2-0-0-2	Mylan
Metamizole	C	500 Mg, 1-1-1-0	Mylan
Valsartan	C	80 Mg, 0.5-0-0-1	Mylan
Ass AI	C	100 Mg, 0-1-0-0	Mylan
Simvastatin	C	40 Mg, 0-0-0-1	Mylan
Pantoprazol /01263201/	C	20 Mg, 1-0-0-0	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15240166	NON-EXPEDITED			PHEH2018US031713		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Cold; Migraine; Pain; Tremor	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Lexapro			S	Unknown	Unk		Not Reported
	Topamax			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Sumatriptan			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Ketorolac Tromethamine			C	Unknown			Not Reported
	Zofran			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15247591	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-180698			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Sopor	Escitalopram			S	Oral	In Total		Not Reported

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Olanzapine	S	Oral	In Total	Sun
Tavor (Lorazepam)	S	Oral	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15248093	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018015986			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole 5 Mg			S	Unknown	5 Milligram, Qd		Macleods
	Escitalopram			S	Unknown	15 Milligram, Qd, 15 Milligram Daily; Reduced To 15 Mg/Day, Action Taken: Dose Halved And Withdrawn		Macleods
	Escitalopram			S	Unknown	20 Milligram, Qd, In A Morning Target Dose Of 20 Mg, Action Taken: Dose Halved And Withdrawn		Macleods
	Escitalopram			S	Unknown	Increased To A Dose Of 20 Mg Daily		Macleods
	Risperidone			S	Unknown	0.5 Milligram		Not Reported
	Risperidone			S				Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	100 Milligram, Qd, Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Evening Dose Of 100 Mg		Not Reported
	Opi Pramol			C	Unknown	Unk, In Crisis Situations With Temporary Effect		Not Reported
	Lorazepam			C	Unknown	Unk, In Crisis Situations With Temporary Effect		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported

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07-Aug-2018	15250121	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018271546		46 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity	Methotrexate			S		15 Mg, Weekly (6 Tablets A Week)		Pfizer	
	Arcoxia			S		90 Mg, Unk		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
	Adco Zopimed			S		7.5 Mg, Unk		Not Reported	
	Synaleve /01057301/			S		Unk		Not Reported	
	Lunar [Cyproterone Acetate\Ethinyl Estradiol]			S		20 Mg, Unk		Not Reported	
	Trepiline /00002201/			S		10 Mg, Unk		Not Reported	
	Stilpane /01152401/			S		Unk		Not Reported	
	Prednisone			S		5 Mg, Unk		Not Reported	
	Folic Acid			S		5 Mg, Unk		Not Reported	
	Eltroxin			S		100 Ug, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15296267	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Trintillex			S				Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	12786872	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1669849US		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Interstitial Lung Disease; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Q12h		Allergan	
	Cellcept			S	Oral	2 G, Bid		Not Reported	

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Cortancyl	S	Oral	10 Mg, Bid	Not Reported
Tahor	S	Oral	10 Mg, Qd	Not Reported
Theralene	S	Oral	5 Mg, Q12h	Not Reported
Triatec (Ramipril)	S	Oral	5 Mg, Qd	Not Reported
Stilnox	S	Oral	10 Mg, Qd	Not Reported
Ixprim	S	Oral	Unk	Not Reported
Inexium	S	Oral	20 Mg, Qd	Not Reported
Seresta	C	Unknown	Unk	Not Reported
Lasilix	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15014026	EXPEDITED (15-DAY)		HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-053358		90 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Eliquis			S	Unknown	5 Mg, Bid		Bristol Myers Squibb	
	Eliquis			S	Unknown	Unk		Bristol Myers Squibb	
	Escitalopram			S	Unknown	15 Mg, Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15234330	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US20359			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease	Escitalopram			S	Unknown	5 Mg, Qd (1 Each Every Morning)		Invagen	
	Escitalopram			S	Unknown	10 Mg, Qd (1 Each Every Morning)		Invagen	
	Motrin			C	Unknown	400 Mg, Evening		Not Reported	
	Centrum /02267801/			C	Unknown	Unk		Not Reported	
	Clobetasol			C	Topical	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15253988	EXPEDITED (15-DAY)		DS	FI-MACLEODS PHARMACEUTICALS US LTD- MAC2018016269			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram Oxalate			S	Oral	10 Milligram, Qd		Macleods	
	Cohemin Depot			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15254069	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2018-039199		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Paracetamol			S	Oral	Unk		Aurobindo	
	Lamotrigine			S	Oral	Unk		Aurobindo	
	Alprazolam			S	Oral	Unk		Aurobindo	
	Escitalopram			S	Oral	Unk		Aurobindo	
	Propranolol			S	Oral	Unk		Not Reported	
	Ibuprofene			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15254501	EXPEDITED (15-DAY)		HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018016259			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Escitalopram Oxalate			S	Oral	Unk		Macleods	
	Paracetamol			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	

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	Alprazolam		S	Oral	Unk			Not Reported	
	Lamotrigine		S	Oral	Unk			Not Reported	
	Ibuprofene		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15256165	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1839087US		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan	
	Tofranil			S	Unknown	Unk, Unknown		Not Reported	
	Coumadine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15256336	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1839058US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer	Escitalopram Oxalate - Bp			S	Unknown	Low Dose, At Last 10-15 Mg Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15256343	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1839101US		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Tramadol			S	Oral	Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	15257493	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1838288US		30 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion; Haemorrhage Subcutaneous	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Bid		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Bid		Allergan	
	Ibuprofen			C	Unknown	200 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15009479	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04093		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oromandibular Dystonia	Paroxetine			S	Unknown	Unk		Lupin	
	Paroxetine			S	Unknown	Unk		Lupin	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15093243	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN- 1832633US		58 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Seizure	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Asenapine Maleate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Dexamethasone			S	Oral	8 Mg, Qd		Not Reported	
	Pantozol			C	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15178047	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163- 2423037-00		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fluid Retention; Skin Fissures; Skin Odour Abnormal; Suicidal Ideation	Mavyret			S	Oral			Not Reported	
	Xarelto			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	

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Darvocet			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15258700	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-936341		69 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Trimethoprim			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Cabergoline			S	Unknown			Ivax	
	Carbidopa			S	Unknown			Not Reported	
	Septrin			S	Unknown			Not Reported	
	Stalevo			S	Unknown			Not Reported	
	Entacapone			S	Unknown			Not Reported	
	Levodopa			S	Unknown			Not Reported	
	Co-Beneldopa Capsules			C	Unknown			Not Reported	
	Co-Beneldopa Capsules 50 Mg/12.5 Mg			C	Unknown			Not Reported	
	Macrogol			C	Unknown			Not Reported	
	Duloxetine 90mg Capsule			C	Unknown			Not Reported	
	Co-Beneldopa Capsules			C	Unknown			Not Reported	
	Adcal D3			C	Unknown			Not Reported	
	Rivastigmine 4.6mg Patch - Transdermal Patch			C				Not Reported	
	Quetiapine 25 Mg			C	Unknown			Not Reported	
	Paracetamol - Tablet			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259085	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00006586		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide; Toxicity To Various Agents	Escitalopram	S	Oral	Ingestion	Unknown
	Ethanol	S	Oral	Ingestion	Unknown
	Amitriptyline Hydrochloride	S	Oral	Ingestion	Unknown
	Ibuprofen	S	Oral	Ingestion	Unknown
	Gabapentin	S	Oral	Ingestion	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259451	NON-EXPEDITED			US-PFIZER INC- 2018321178		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Cefepime Hcl			S		Unk		Unknown	
	Celexa			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259733	EXPEDITED (15-DAY)		HO	FR-APOTEX- 2018AP018506		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence; Toxicity To Various Agents	Paroxetine Tablet			S	Oral	12 Df, Unk		Apotex	
	Ibuprofene			S	Oral	20 Df, Unk		Not Reported	
	Escitalopram			S	Oral	28 Df, Unk		Not Reported	
	Dafalgan Codein			S	Oral	8 G, Unk		Not Reported	
	Havlane			S	Oral	20 Df, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259768	NON-EXPEDITED			US-MYLANLABS- 2018M1057473			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Fatigue; Fear; Heart Rate Decreased; Musculoskeletal Pain;	Nitroglycerin Transdermal System			S	Transdermal	Unk		Mylan	

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Night Sweats; Pharyngeal Swelling; Pollakiuria; Product Quality Issue; Sleep Disorder; Weight Decreased	Escitalopram	S	Unk	Mylan
	Advair	C	Unk, Bid	Mylan

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09-Aug-2018	15262062	EXPEDITED (15-DAY)		CA	FR-ELI_LILLY_AND_COMP ANY-FR201808001408			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Heart Disease Congenital	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Seroplex			S	Transplacental	5 Mg, Daily		Not Reported
	Seroplex			S	Transplacental	5 Mg, Daily		Not Reported
	Seroplex			S	Transplacental	10 Mg, Unk		Not Reported
	Seroplex			S	Transplacental	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15262169	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1839384US		82 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Eliquis			S	Oral	2 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	13077127	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1682625US		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Trazodone			S	Unknown	150 Mg, Unk		Not Reported
	Trazodone			S	Oral	75 Mg, Qd		Not Reported

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Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam	S	Oral	0.5 Mg, Qd	Not Reported
	Valproic Acid	S	Oral	300 Mg, Qd	Not Reported
	Valproic Acid	S	Unknown	600 Mg, Unk	Not Reported
	Venlafaxine	S	Oral	300 Mg, Qd	Not Reported
	Quetiapine	S	Oral	200 Mg, Qd	Not Reported
	Alprazolam	S	Oral	1.5 Mg, Qd	Not Reported
	Alprazolam	S	Oral	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	14633062	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-867819		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Pantoprazole			S	Oral	Unspecified		Teva
	Escitalopram			S	Oral	Unspecified		Ivax
	Xeloda			S	Oral	Unspecified		Not Reported
	Novorapid			S	Subcutaneous	Unspecified		Not Reported
	Primperan			S	Oral	Unspecified		Not Reported
	Lipanthyl			S	Oral	Unspecified		Not Reported
	Movicol			S	Oral	Unspecified		Not Reported
	Abasaglar			S	Subcutaneous	Unspecified		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Unspecified		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	14815226	EXPEDITED (15-DAY)		HO, LT	DE-ASTRAZENECA-2018SE51713		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazole			S	Oral	40.0mg Unknown		Astrazeneca
	Escitalopram			S	Unknown			Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported

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	Levetiracetam	C						Not Reported
	Ivabradine	C						Not Reported
	Cotrimoxazol	C		Intravenous (not otherwise specified)				Not Reported
	Naloxone, Tilidine	C			10 Drops			Not Reported
	Scopolamin	C						Not Reported
	Baclofen	C						Not Reported
	Prednisolon	C						Not Reported
	Lorazepam	C						Not Reported
	L-Thyroxin	C			75.0ug Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15262927	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-040535		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Incorrect Dose Administered	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	20 Milligram, Daily		Aurobindo
	Ramipril Mylan			C	Unknown	Unk		Not Reported
	Lexomil			C	Unknown	Unk		Not Reported
	Dulcolax /00064401/			C	Unknown	Unk		Not Reported
	Imovane			C	Unknown	Unk		Not Reported
	Macrogol 4000			C	Unknown	Unk		Not Reported
	Euthyrox			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15264244	EXPEDITED (15-DAY)		HO	PHHY2018FR069486		19 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Somnolence; Toxicity To Various Agents	Alprazolam			S	Oral	1 Df, (Total)		Novartis
	Seroplex			S	Oral	1 Df, (Total)		Not Reported

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10-Aug-2018	15265866	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2018318163		41 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Hypomania; Sensory Disturbance	Efexor Depot			S	Oral	75 Mg, Unk		Pfizer	
	Alopam			S	Oral			Not Reported	
	Cipralex /01588502/			S	Oral	Most Of The Time Treated With 20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15266054	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1061121		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Valproic Acid			S	Unknown	Unk		Not Reported	
	Levetiracetam			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Clobazam			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15266600	EXPEDITED (15-DAY)		HO	PHHY2018FR068608		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Mg, Qd (0.5 Mg Morning And Evening)		Novartis	
	Escitalopram			S	Oral	10 Mg, Qd (In The Evening)		Not Reported	
	Olanzapine			S	Oral	5 Mg, Qd (In The Evening)		Not Reported	
	Loxapine			S	Oral	5 Gtt, Prn (If Needed)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15266987	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-938484			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15267032	EXPEDITED (15-DAY)		HO	PHHY2018FR069546		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Pantoprazole			S	Oral	30 Mg, Qd		Novartis	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2018	15267533	EXPEDITED (15-DAY)		HO	DE-TORRENT-00009252		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Levothyroxin			C	Oral	75 G, 1-0-0-0		Unknown	
	Torasemid			C	Oral	10 Mg, 1-0-0-0		Unknown	
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1		Unknown	
	Quetiapine			S	Oral	100 Mg, 0-0-0-1		Unknown	
	Cipralelex			S	Oral	10 Mg, 1-0-0-0		Unknown	
	Felodipine			C	Oral	10 Mg, 1-0-0-0		Unknown	

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11-Aug-2018	15267534	EXPEDITED (15-DAY)		HO	IN-TORRENT-00001801		33 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram			S		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2018	14338214	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2017-FR-841886		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Diazepam			S	Oral	30 Milligram Daily;		Barr	
	Alprazolam			S	Oral	.75 Milligram Daily; 0.25 Mg, 3x/Day		Actavis	
	Mirtazapine			S	Oral	15 Milligram Daily;		Teva	
	Amlodipine			S	Oral	10 Milligram Daily;		Teva	
	Pantoprazole			S	Oral	20 Milligram Daily;		Teva	
	Bisoprolol Fumarate			S	Oral	1.25 Milligram Daily; 1.25 Mg, 1x/Day		Duramed	
	Furosemide			S	Oral	60 Milligram Daily; 30 Mg (2-1-0), 2x/Day		Ivax	
	Furosemide			S	Oral	2 Unk, Qd		Ivax	
	Irbesartan			S	Oral	300 Milligram Daily; 300mg, 1x/Day		Teva	
	Nefopam Hydrochloride			S	Oral	3 Dosage Forms Daily;		Not Reported	
	Diffu K			S	Oral	6 Dosage Forms Daily; 3 Df (2-1-0), 2x/Day		Not Reported	
	Colchicine Opocalcium			S	Oral	1 Dosage Forms Daily; 1df, 1x/Day		Not Reported	
	Colchicine Opocalcium			S	Oral			Not Reported	

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Xarelto	S	Oral	20 Milligram Daily;	Not Reported
Xarelto	S	Oral		Not Reported
Seroplex	S	Oral	1 Dosage Forms Daily; 1df, 1x/Day	Not Reported
Tavanic	S	Oral	500 Milligram Daily; 250 Mg, 2x/Day	Not Reported
Tavanic	S	Oral		Not Reported
Valium	S	Oral	3 Dosage Forms Daily; 3 Df, 1x/Day	Not Reported
Terbutaline Sulphate	S	Respiratory (inhalation)	1 Dosage Forms Daily; 1 Df, Unk	Not Reported
Dafalgan	S	Oral	3000 Milligram Daily; 1000 Mg, 3x/Day	Not Reported
Dafalgan	S	Oral		Not Reported
Metformine Pfizer	S	Oral	1000 Milligram Daily; 1000 Mg, 1x/Day	Not Reported
Metformine Pfizer	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2018	15309577	DIRECT		OT			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Confusional State; Depression; Dizziness; Nausea; Vomiting	Escitalopram, Generic For Lexapro			S	Oral	Quantity:1 Tablet(S);		Allergan
	Bentyl (Dicyclomine)			C				Not Reported
	Neurontin (Gabapentin)			C				Not Reported
	Toradol (Ketorolac)			C				Not Reported
	Ativan (Lorazepam)			C				Not Reported
	Lopressor (Metoprolol Tartrate)			C				Not Reported
	Zegerid (Omeprazole)			C				Not Reported
	Zofran (Ondansetron)			C				Not Reported
	Imitrex (Sumatriptan)			C				Not Reported
	Simethicone			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D3			C				Not Reported

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13-Aug-2018	14391026	NON-EXPEDITED			US-PFIZER INC-2018015994		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Hallucination; Hallucination, Auditory; Insomnia; Mydriasis; Therapeutic Product Effect Incomplete	Advil Congestion Relief			S	Oral	1 Df, Unk (One Tablet, Once At Around Noon And Again At Around 5 Pm)		Pfizer	
	Advil Congestion Relief			S				Pfizer	
	Escitalopram			S		10 Mg, Unk		Not Reported	
	Escitalopram			S	Oral	20 Mg, Daily(One A Day At Night When She Goes To Bed)		Not Reported	
	Escitalopram			S				Not Reported	
	Levothyroxine			C		0.112 Ug, Daily		Not Reported	
	Metoprolol			C		25 Ug, 3x/Day		Not Reported	
	Centrum Silver			C		Unk Unk, 1x/Day		Not Reported	
	Vitamin B			C		Unk Unk, 1x/Day		Not Reported	
	Fish Oil			C		Unk Unk, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	14598392	EXPEDITED (15-DAY)		HO, LT, OT	FR-TEVA-2018-FR-862991		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Hypotonia; Miosis	Zopiclone			S	Oral	210 Milligram Daily;		Not Reported	
	Olanzapine			S	Oral			Teva	
	Seroplex			S	Oral			Not Reported	
	Abilify			S	Oral	5 Milligram Daily;		Not Reported	
	Lysanxia			S	Oral			Not Reported	
	Zyprexa			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	

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13-Aug-2018	14665622	EXPEDITED (15-DAY)		LT	CA-ALLERGAN-1815261US		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	14670413	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1815473US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Depression; Emotional Disorder; Fatigue	Escitalopram Oxalate Unk Humira			S S	Oral Subcutaneous	10 Mg, Qd 40 Mg, Unknown		Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	14970621	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-901708		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Aripiprazole			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Unknown			Teva	
	Seroplex			S	Unknown	Unk		Not Reported	
	Seroplex			S	Oral			Not Reported	
	Norset			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Inipomp			C	Unknown			Not Reported	
	Aprovel			C	Unknown			Not Reported	
	Irbesartan			C	Oral			Not Reported	
	Kardegic			C	Unknown			Not Reported	

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13-Aug-2018	15269031	EXPEDITED (15-DAY)		OT	US-ACCORD-070714		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Irritable Bowel Syndrome	Escitalopram Accord			S	Oral	Strength: 20 Mg Took 1/2 Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15271908	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1839565US		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Propranolol			S	Oral	Unk		Not Reported	
	Paracetamol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Ibuprofene			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15271910	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1839570US		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Narcolepsy	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
	Xanax			C	Unknown	Unk, Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15271921	EXPEDITED (15-DAY)		DE, HO, LT	FR-ALLERGAN-1839573US		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Previscan (Fluindione)			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15272101	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2018SF01746			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; No Adverse Event; Suicide Attempt	Quetiapine			S	Oral			Not Reported	
	Citram			S	Oral			Not Reported	
	Ketonal			S	Oral			Not Reported	
	Aripiprazole			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15310017	DIRECT		OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Decreased Appetite; Hallucination; Influenza Like Illness; Insomnia; Mood Swings; Paranoia; Restlessness; Suicide Attempt; Taste Disorder; Thinking Abnormal	Lexipro-Escitalopram			S	Oral	Quantity:2 Tablet(S);		Unknown	
	Celexa Citalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Rosuvastatin			C				Not Reported	
	Bupropion XL			C				Not Reported	
	Hydroxyzined			C				Not Reported	
	Lamotrigine			C				Not Reported	
	Omeprazole			C				Not Reported	
	Naproxen			C				Not Reported	
	Tizanidine			C				Not Reported	
	Multi-Vitamin			C				Not Reported	
	B12			C				Not Reported	
	Magnesium			C				Not Reported	

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Calcium D3		C		C		Not Reported		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	14269135	EXPEDITED (15-DAY)		HO, OT	JP-OTSUKA-BJ201400556		< 1 DAY	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Neonatal Asphyxia; Tremor Neonatal	Abilify 3mg			S	Transplacental	3 Mg, Qd		Otsuka	
	Abilify 3mg			S	Transplacental	6 Mg, Qd		Otsuka	
	Abilify 3mg			S	Transplacental	9 Mg, Qd		Otsuka	
	Abilify 3mg			S	Transplacental	15 Mg, Qd		Otsuka	
	Abilify 3mg			S	Transplacental	12 Mg, Qd		Otsuka	
	Lexapro			S	Transplacental	10 Mg, Bid		Not Reported	
	Silece			S	Transplacental	2 Mg, Qd		Not Reported	
	Contomin			S	Transplacental	25 Mg, Bid		Not Reported	
	Seroquel			S	Transplacental	25 Mg, Qd		Not Reported	
	Cymbalta			S	Transplacental	30 Mg, Bid		Not Reported	
	Pyrethia			C	Transplacental	25 Mg, Qd		Not Reported	
	Tasmolin			C	Transplacental	1 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	14782095	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-882488		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Hallucination, Visual; Persecutory Delusion	Escitalopram			S	Oral	1 Cp		Ivax	
	Modopar 125 Dispersible			S	Oral	100 Mg/ 25 Mg		Not Reported	
	Modopar 125 Dispersible			S	Oral	4 Dosage Forms Daily;		Not Reported	
	Modopar			S	Oral			Not Reported	
	Modopar			S	Oral			Not Reported	
	Modopar			S	Oral	1 Cp 62,5 (50 Mg/12,5		Not Reported	

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Mg), Gelule

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	14816226	EXPEDITED (15-DAY)		HO, LT	DE-ALLERGAN-1822947US		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Esomeprazol			S	Unknown	40 Mg, Unk		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Baclofen			C	Unknown			Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Naloxone W/Tilidine			C	Unknown	10 Gtt, Unk		Not Reported
	Ivabradine			C	Unknown	15 Mg, Qd		Not Reported
	Prednisolon			C	Unknown			Not Reported
	Levetiracetam			C	Unknown	2 Df, Qd		Not Reported
	Scopolamin			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	L-Thyroxin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15253544	EXPEDITED (15-DAY)		HO	IN-CIPLA LTD.-2018IN20507			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Quetiapine			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15273908	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-939638		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Tardive Dyskinesia	Aripiprazole			S	Unknown			Teva	
	Aripiprazole			S	Oral			Teva	
	Seroplex			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15274348	EXPEDITED (15-DAY)		HO, OT	DE-BAUSCH-BL-2018-021733		58 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Dexamethason			S	Oral			Valeant	
	Sycrest			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Pantoprazol			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15274609	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR-APL-2018-041304		69 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Film-Coated Tablets 10mg			S	Unknown	10 Milligram, Once A Day, 1 X Per Dag 1 Stuk		Aurobindo	
	Hydrochlorothiazide 25 Mg			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15274661	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-041186		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Toxic Skin Eruption	Escitalopram	S	Oral	1 Dosage Form, Once A Day	Aurobindo
	Stresam	S	Oral	3 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15275564	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2018-GB-939270		70 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Tube Insertion; Laryngectomy	Escitalopram			S	Unknown			Ivax
	Salbutamol Inhaler			C	Unknown			Not Reported
	Prucalopride			C	Unknown			Not Reported
	Morphine Sulphate			C	Unknown			Not Reported
	Cald-3			C	Unknown			Not Reported
	Bendroflumethaide			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Calciferol [Ergocalciferol]			C	Unknown			Not Reported
	Tiotropium Inhaler			C	Unknown			Not Reported
	Alendronic Acid			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15275833	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009358			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Overdose; Seizure	Escitalopram			S		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15275844	EXPEDITED (15-DAY)		CA, OT	US-TORRENT-00006746			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Atrial Septal Defect; Congenital Abdominal Hernia; Congenital Diaphragmatic Eventration; Dextrocardia; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Rib Hypoplasia; Supernumerary Nipple	Topiramate Escitalopram Tramadol Hydrochloride Oxycodone And Acetaminophen	S S S S	Transplacental Transplacental Transplacental Transplacental	Unknown	Unknown Unknown Unknown Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15275852	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009350			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Overdose; Seizure	Escitalopram			S		Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15276454	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-939749		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Prednisolone			S	Oral	40 Milligram Daily;		Actavis	
	Bevacizumab			S				Not Reported	
	Lomustine			S	Oral			Not Reported	
	Seroplex Film-Coated Tablets			S	Oral	5 Milligram Daily;		Not Reported	
	Silodyx			C	Unknown			Not Reported	
	Xanax			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277122	EXPEDITED (15-DAY)		DE, HO, OT	DE-TEVA-2018-DE-939775		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hyperhidrosis;	Lorazepam			S	Oral	6 Milligram Daily;		Actavis	

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Restlessness; Schizoaffective Disorder	Quetiapine	S	Oral	200 Milligram Daily;	Teva
	Abilify 3mg	S	Oral	Unk	Not Reported
	Abilify 3mg	S	Oral		Not Reported
	Cipralex /01588502/	S	Oral	Unk	Not Reported
	Lexapro	S	Oral	10 Milligram Daily;	Not Reported
	Lexapro	S	Unknown		Not Reported
	Tavor (Lorazepam)	S	Oral	Unk	Not Reported
	Tavor (Lorazepam)	S	Oral	Unk	Not Reported
	Seroquel	S	Oral	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Simeticone	C	Unknown	Unk	Not Reported
	Eferox	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277706	EXPEDITED (15-DAY)		DE	AU-MYLANLABS-2018M1061179			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Toxicity To Various Agents	Escitalopram			S		Unk		Not Reported	
	Diazepam			S		Unk		Not Reported	
	Heroin			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277735	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-939251		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S	Unknown	Unk		Ivax	
	Xarelto 20 Mg			S	Unknown	20 Mg, Unk		Not Reported	
	Zofenil			C	Unknown	Unk		Not Reported	
	Carbidopa, Levodopa			C	Unknown	Unk		Not Reported	
	Androtardyl			C	Unknown	Unk		Not Reported	

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	Amoxicillin Sodium, Potassium Clavulanate Requip	C	Unknown	Unk				Not Reported
		C	Unknown	Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277793	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2018-09139			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Coma; Hypotension; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Oral			Pierre Fabre Medicament
	Paracetamol			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Ibuprofene			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15278023	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1839784US		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autonomic Nervous System Imbalance; Malaise; Off Label Use; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Risperdal			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15278381	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL204532		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathic Syndrome; Arrhythmia; Atrial Tachycardia; Drug Ineffective; Drug Interaction;	Metoprolol Tartrate Sandoz			S	Unknown	Unk		Novartis
	Zolpidem Tartrate			S	Oral	10 Mg,Hs		Not Reported
	Escitalopram			S	Unknown			Not Reported

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Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Venlafaxine	S	Oral	150 Mg,Qd	Not Reported
	Trazodone	S	Unknown		Not Reported
	Moclobemide	S	Unknown	150 Mg, Qhs	Not Reported
	Sertraline	S	Unknown	50 Mg, Qhs	Not Reported
	Ginkgo Biloba Extract	C	Unknown		Not Reported
	Warfarin	C	Unknown		Not Reported
	Sotalol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15311000	DIRECT					20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Blood Glucose Decreased; Impaired Driving Ability; Nausea; Vertigo	Escitalopram			S	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Tylenol			C				Not Reported
	Midol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15314517	DIRECT	Y	HO, RI			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depression; Insomnia; Post-Traumatic Stress Disorder	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15099981	EXPEDITED (15-DAY)		HO, OT	PL-ALLERGAN-1833018US		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trazodone			S	Unknown	Unk		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported

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Moklar	S	Unknown	150 Mg, Qd	Not Reported
Cyproheptadine	S	Oral	16 Mg, Unk	Not Reported
Zolpidem	S	Unknown	10 Mg, Qhs	Not Reported
Ivabradine	S	Unknown	Unk	Not Reported
Sertraline	S	Unknown	50 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15276506	EXPEDITED (15-DAY)		HO, LT	ES-JNJFOC-20180815523		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Haloperidol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Enalapril/Hydrochlorothiazide			S	Oral	1-0-0. EI 23/01		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15281563	EXPEDITED (15-DAY)		DS	FI-ALLERGAN-1840008US		73 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Cohemin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	14038961	EXPEDITED (15-DAY)		HO, OT	IT-JNJFOC-20170927217		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sopor	Haldol			S	Oral			Not Reported	
	Losartan			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

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Delorazepam

S

Oral

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	14573122	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA049203		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Alprazolam			S	Oral	0.25 Mg,Qd		Not Reported
	Alprazolam			S	Oral	.75 Mg,Tid		Not Reported
	Bisoprolol Hemifumarate			S	Oral	1.25 Mg,Qd		Not Reported
	Amlodipine Besilate			S	Oral	10 Mg,Qd		Not Reported
	Irbesartan			S	Oral	300 Mg,Qd		Sanofi
	Irbesartan			S	Oral	300 Mg,Qd		Sanofi
	Pantoprazole			S	Oral	20 Mg,Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg,Qd		Not Reported
	Tavanic			S	Oral	250 Mg,Qd		Not Reported
	Tavanic			S	Oral	500 Mg,Qd		Not Reported
	Furosemide			S	Oral	30 Mg,Qd		Sanofi
	Furosemide			S	Oral	2 Df,Qd		Sanofi
	Furosemide			S	Oral	30 Mg,Bid		Sanofi
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df,Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg,Qd		Not Reported
	Xarelto			S	Oral	20 Mg,Qd		Not Reported
	Metformin Hydrochloride			S	Oral	500 Mg,Qd		Not Reported
	Metformin Hydrochloride			S	Oral	1000 Mg,Qd		Not Reported
	Diffu K			S	Oral	3 Df,Qd		Not Reported
	Diffu K			S	Oral	6 Df,Qd		Not Reported
	Seroplex			S	Oral	1 Df,Qd		Not Reported
	Valium			S	Unknown	3 Df,Unk		Not Reported
	Valium			S	Oral	10 Mg,Tid		Not Reported

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Colchicine Opocalcium	S	Oral	1 Mg,Qd	Not Reported
Nefopam Hydrochloride	S	Oral	1 Df,Qd	Not Reported
Nefopam Hydrochloride	S	Oral	3 Df,Qd	Not Reported
Nefopam Hydrochloride	S	Oral	3 Df,Tid	Not Reported
Dafalgan	S	Oral	3000 Mg,Qd	Not Reported
Dafalgan	S	Oral	1000 Mg,Tid	Not Reported
Diazepam	S	Oral	30 Mg,Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	14592868	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-860742		53 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Somnolence; Sopor; Suicide Attempt	Venlafaxine			S	Oral			Teva
	Escitalopram			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	14836236	EXPEDITED (15-DAY)		HO, LT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-171472		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazol			S	Unknown	40 Mg, Unk		Sun
	Escitalopram			S	Unknown	Unk		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Daily		Not Reported
	Levetiracetam			C	Unknown	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Ivabradin			C	Unknown	Daily Dose: 15 Mg Milligram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown	10 Gtt, Unk		Not Reported

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Scopolamin	C	Unknown	Unk	Not Reported
Baclofen	C	Unknown		Not Reported
Prednisolon	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	Daily Dose: 1 Mg Milligram(S) Every Days	Not Reported
L-Thyroxin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15118969	EXPEDITED (15-DAY)	HO		DE-TEVA-2018-DE-922706		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	10 Milligram Daily; 10 Mg, Qd		Ivax
	Escitalopram			S	Oral	10 Milligram Daily; 10 Mg, Qd		Ivax
	Escitalopram			S	Oral	15 Milligram Daily; 15 Mg, Qd		Ivax
	Escitalopram			S	Oral	20 Milligram Daily; 20 Mg, Qd		Ivax
	Escitalopram			S	Oral	20 Milligram Daily; 20 Mg, Qd		Ivax
	Escitalopram			S	Oral	15 Milligram Daily; 15 Mg, Qd		Ivax
	Candesartan			S	Oral	16 Milligram Daily; 16 Mg, Od		Not Reported
	Aripiprazole			S	Oral	10 Milligram Daily; 10 Mg, Od		Teva
	Aripiprazole			S	Oral	5 Milligram Daily;		Teva
	L-Thyroxin			C	Oral	100 Microgram Daily; 100 Mg, Qd		Not Reported
	Risperdal			C	Unknown	2 Milligram Daily; 2 Mg, Od		Not Reported
	Risperdal			C	Unknown	2 Mg, Hs		Not Reported

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Risperdal	C	Unknown	1.5 Milligram Daily; 1.5 Mg, Od	Not Reported
Risperdal	C	Unknown	2 Milligram Daily; 2 Mg, Od	Not Reported
Metformin	C	Oral	1500 Milligram Daily; 1500 Mg, Od	Not Reported
Atorvastatin	C	Oral	20 Milligram Daily; 20 Mg, Od	Not Reported
Amisulpride	C	Unknown	200 Milligram Daily; 200 Mg, Qd	Not Reported
Acetylsalicylic Acid	C	Oral	100 Milligram Daily; 100 Mg, Od	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15160941	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1835497US		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lorazepam			S	Oral	2.5 Mg, Qd		Not Reported
	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Warfarin Sodium			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15204712	EXPEDITED (15-DAY)		HO	PHHY2018IT052890		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported	
	Escitalopram			S	Oral	140 Mg, Total		Not Reported	
	Alprazolam			S	Oral	15 MI, Total		Novartis	
	Zitromax			S	Oral	1500 Mg, Total		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15282728	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE- HET2018DE00796		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 [Mg/D]		Hetero	
	Sertraline			C	Transplacental	150 [Mg/D]		Not Reported	
	Quetiapine			C	Transplacental	25 [Mg/D]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15282869	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR- APL-2018-041258		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma-Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Tachycardia; Vomiting	Escitalopram			S	Oral	Unk		Aurobindo	
	Dafalgan Codeine			S	Oral	Unk		Not Reported	

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16-Aug-2018	15282876	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2018-FR-942895		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Propranolol			S	Oral			Actavis	
	Paracetamol			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Teva	
	Escitalopram			S	Oral			Not Reported	
	Alprazolam			S	Oral			Actavis	
	Ibuprofene			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15282942	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00009344		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Sertraline			C	Transplacental	150 [Mg/D]		Unknown	
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown	
	Quetiapine			C	Transplacental	25 [Mg/D]		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15283129	EXPEDITED (15-DAY)		HO	IN-ACCORD-070710		33 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Drug Intolerance; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation Complication	Escitalopram			S				Not Reported	
	Quetiapine			S				Not Reported	
	Lithium			C				Not Reported	
	Olanzapine			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15283314	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-041283		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Gastrointestinal Haemorrhage	Escitalopram			S	Oral	Unk		Aurobindo	
	Plavix			S	Oral	1 Dosage Form, Once A Day		Not Reported	
	Bisocce			C	Oral	Unk		Not Reported	
	Glibenclamide			C	Oral	Unk		Not Reported	
	Metformine /00082701/			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15284149	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001806		23 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; General Physical Health Deterioration; Psychotic Disorder	Escitalopram			S		At Adequate Dose		Unknown	
	Fluoxetine			S		At Adequate Dose And Duration		Unknown	
	Fluvoxamine			S		At Adequate Dose And Duration		Unknown	
	Clomipramine			S		At Adequate Dose And Duration		Unknown	
	Sertraline			S		At Adequate Dose And Duration		Unknown	
	Paroxetine			S		At Adequate Dose And Duration		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15286149	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-942706		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Abuse; Sopor	Escitalopram Oxalate	S	Oral	Ivax
	Tavor (Lorazepam)	S	Oral	Not Reported
	Olanzapine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15286404	EXPEDITED (15-DAY)		OT	DK-ALLERGAN-1840031US		38 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Behaviour Disorder; Sedation; Sensory Disturbance; Social Avoidant Behaviour; Social Problem; Type 2 Diabetes Mellitus; Weight Increased	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan
	Abilify			S	Oral	Unk, Unknown		Not Reported
	Orap			S	Oral	Unk, Unknown		Not Reported
	Ritalin			S	Oral	120 Mg, Unknown		Not Reported
	Cymbalta			S	Oral	Unk, Unknown		Not Reported
	Ritalin			S	Oral	Unk, Unknown		Not Reported
	Concerta			C	Unknown	54 Mg, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	13961665	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-JNJFOC-20170908648		50 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Suicide Attempt; Tinnitus	Tramadol			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported

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Perindopril	S	Oral	Not Reported
Sertraline	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Escitalopram Oxalate	S	Unknown	Not Reported
Escitalopram Oxalate	S	Unknown	Not Reported
Atoris	S	Oral	Not Reported
Polisen	S	Unknown	Not Reported
Concor	S	Oral	Not Reported
Trosicam	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	14356511	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20180100857			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Headache; Insomnia; Treatment Noncompliance	Tramadol Hydrochloride/Paracetamol			S	Unknown	Strength: 1 Df= 37.5/ 325 Mg		Not Reported
	Topiramate			S	Unknown			Not Reported
	Topiramate			S	Unknown	Strength= 50 Mg		Not Reported
	Amitriptyline			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Unknown	Strength= 10 Mg		Not Reported
	Omeprazole			S	Unknown	Strength 20 Mg		Not Reported
	Lormetazepam			S	Unknown			Not Reported
	Tepazepam			S	Unknown			Not Reported
	Enalapril Hct			S	Unknown	Strength: 1 Df= 20/ 12.5 Mg		Not Reported
	Diazepam			S	Unknown	Strength= 5 Mg		Not Reported
	Amlodipine			S	Unknown			Not Reported

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Glibenclamida	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Simvastatin	S	Unknown	Strength 40 Mg	Not Reported
Simvastatin	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Metoclopramide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	14985218	EXPEDITED (15-DAY)		HO, LT	DE-TEVA-2018-DE-902922		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S				Ivax
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Forms Daily;		Teva
	Esomeprazole			S	Unknown			Teva
	Levetiracetam			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Ivabradin			C		15 Milligram Daily;		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Dosage Forms Daily;		Not Reported
	Naloxone, Tilidine			C				Not Reported
	Scopolamin			C				Not Reported
	Baclofen			C				Not Reported
	Prednisolon			C				Not Reported
	Lorazepam			C		1 Milligram Daily;		Not Reported
	L-Thyroxin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15027029	NON-EXPEDITED			US-CELGENEUS-USA-20180604568		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depression; Diarrhoea	Otezla			S	Oral	30 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene

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Lexapro	S	Unknown	Not Reported
Xanax	S	Unknown	Not Reported
Humira	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15132983	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2017-45077		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Unknown	100 Mg, Once A Day		Aurobindo
	Lorazepam Tablets			S	Unknown	2.5 Mg, Once A Day, At Bed Time		Aurobindo
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Once A Day		Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Cipralex /01588501/			S	Oral	20 Milligram, Once A Day		Not Reported
	Cipralex /01588501/			S				Not Reported
	Cipralex /01588501/			S				Not Reported
	Brintellix			S	Unknown	15 Mg,Qd		Not Reported
	Brintellix			S	Unknown	10 Mg,Qd		Not Reported
	Brintellix			S	Unknown	5 Mg,Qd		Not Reported
	Coumadin			C	Unknown	Unk Unk,Unk		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg,Qd		Not Reported
	Alprazolam			C	Unknown	2 Milligram, Daily		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported
	Warfarin Sodium			C	Unknown	Unknown Dose		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15287181	EXPEDITED (15-DAY)		HO	IN-MACLEODS PHARMACEUTICALS US LTD- MAC2018016355			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Escitalopram Oxalate			S				Macleods	
	Escitalopram Oxalate			S				Macleods	
	Escitalopram Oxalate			S				Macleods	
	Escitalopram Oxalate			S				Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15287185	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018016345			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Electrocardiogram Qt Prolonged; Moaning	Escitalopram Tablet			S	Oral	Unk, Abuse/Misuse		Macleods	
	Alprazolam			S	Oral	Unk, Abuse/Misuse		Not Reported	
	Trilafon			S	Oral	Unk, Abuse/Miuse		Not Reported	
	Ramipril			C	Oral	2.5 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15287591	EXPEDITED (15-DAY)		OT	DE-TORRENT- 00009361		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Unknown	
	Impfstoff Grippe (Saisonale)			C	Transplacental	Unknown		Unknown	
	L-Thyroxin			C	Transplacental	100 [G/D]/ Initial 75g/D, Dosage Increase To 100g/D From Week 34+2		Unknown	
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15287813	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-041562		90 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Daily		Aurobindo	
	Eliquis			S	Unknown	Unk		Not Reported	
	Eliquis			S	Unknown	10 Milligram, Daily (5 Mg, Bid)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15288226	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-041358		59 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	()		Aurobindo	
	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo	
	Trilafon /00023401/			S	Oral	Unk		Not Reported	
	Ramipril			C	Oral	2.5 Milligram, Unk		Not Reported	
	Ramipril			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15288829	EXPEDITED (15-DAY)		HO, LT	ES-BAUSCH-BL-2018-022261		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Enalapril/Hidroclorotiazida Lareq Comprimidos Efg			S	Oral	1-0-0. On 23/01 Suspended Hydrochlorotiazide. Continued With Enalapril.		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Haloperidol			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15290002	EXPEDITED (15-DAY)		DS	FI-TEVA-2018-FI-943289		73 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Cohemin Depot			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15290080	NON-EXPEDITED			US-NEUROCRINE BIOSCIENCES INC.-2018NBI02336			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences	
	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15290488	EXPEDITED (15-DAY)		CA	PHHY2012DE144006			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Autism Spectrum Disorder; Camptodactyly Congenital; Clinodactyly; Congenital Arterial Malformation; Congenital Central Nervous System Anomaly; Congenital Renal Cyst; Dysplasia; External Auditory Canal	Lorazepam			S	Unknown	Unk		Novartis	
	Fosfomycin			S	Unknown	Unk		Not Reported	
	Valaciclovir			S	Unknown	Unk		Not Reported	
	Abatacept			S	Unknown	Unk		Not Reported	
	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	

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Atresia; Foetal Exposure During Pregnancy; Foetal Malformation; Hydronephrosis; Meningocele; Microtia; Oesophageal Atresia; Premature Baby	Acebutolol	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Colchicine	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Methyldopa	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15290549	NON-EXPEDITED			US-TEVA-2018-US-945809			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S				Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15290737	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-942189		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence	Paroxetine Base			S	Oral			Not Reported	
	Ibuprofene			S	Oral			Actavis	
	Escitalopram			S	Oral			Not Reported	
	Havlane			S	Oral			Not Reported	
	Dafalgan			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15291315	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-941735		21 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol Base			S	Oral	Inconnue		Teva	
	Seroplex 15 Mg, Comprimé			S	Oral	Inconnue		Not Reported	
	Pelliculé Sécable Paracetamol			C	Oral	Inconnue		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15291317	NON-EXPEDITED			US-MYLANLABS-2018M1061873		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Fatigue; Feeling Abnormal	Diazepam			S	Oral	5 Mg, Unk		Not Reported	
	Lexapro			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15318032	DIRECT	Y	LT			36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Suicidal Ideation	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292009	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00795		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Milligram, Qd		Hetero	
	Femibion Schwangerschaft 1 (Nem)			C	Transplacental	0.8 [Mg/D]		Not Reported	
	Impfstoff Grippe (Saisonale)			C	Transplacental	Unk		Not Reported	
	L-Thyroxin			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292208	EXPEDITED (15-DAY)		HO	IN-HETERO CORPORATE- HET2018IN00800		33 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity	Escitalopram			S	Unknown	Unk		Hetero	
	Escitalopram			S				Hetero	
	Escitalopram			S				Hetero	
	Escitalopram			S				Hetero	
	Escitalopram			S				Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292276	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018016396			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Qd		Macleods	
	Eliquis			S	Unknown	10 Milligram, Qd,5 Mg, Bid,Paused Approx. On 10-May-2018 And Re- Started On 01-Jun-2018		Not Reported	
	Eliquis			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292375	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR- APL-2018-042477		26 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome	Escitalopram Film-Coated Tablets 10mg			S	Other	1 Keer Per Dag 1 Tablet		Aurobindo	
	Sumatriptan Tablets 50 Mg			S	Other	Bij Migraine 1 Tablet, Herhaal Zo Nodig 2 Keer Per Dag, Wacht Meer Dan 2 Uur Na De Vorige Tablet.		Aurobindo	

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Loperamide	C	Zo Nodig 6 Keer Per Dag 1 Capsule	Not Reported
Imodium	C	1dd1	Not Reported
Imodium	C	1dd1	Not Reported
Colestyramine	C	2dd1	Not Reported
Oxazepam	C	Zo Nodig 1 Keer Per Dag 1 Tablet	Not Reported
Psylliumvezels	C	2 Keer Per Dag Zo Nodig 1 Zakje	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2018	15318844	DIRECT	Y	OT			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety;	Escitalopram			S	Oral		14 DAY	Cipla	
Headache; Malaise;	Levocetirizine			C				Not Reported	
Migraine; Nausea; Stress	Alprazolam			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	12493393	EXPEDITED (15-DAY)		HO, OT	FR-FRI-1000085530		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clonus; Confusional State;	Escitalopram Oxalate - Bp			S	Oral	840 Mg, Single		Allergan	
Electrocardiogram Qt	Venlafaxine			S	Oral	7875 Mg, Single		Not Reported	
Prolonged; Eye Movement	Bromazepam			S	Oral	180 Mg, Single		Not Reported	
Disorder; Hypoglycaemia;	Lormetazepam			S	Oral	14 Mg, Single		Not Reported	
Intentional Overdose;									
Nystagmus; Overdose;									
Psychomotor Retardation;									
Suicide Attempt; Toxicity									
To Various Agents;									
Toxicity To Various Agents									

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20-Aug-2018	13867289	NON-EXPEDITED			US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004671			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dysphagia; Hallucination; Tremor	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals	
	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals	
	Nuplazid			S	Oral	34 Mg, Qd		Acadia Pharmaceuticals	
	Escitalopram			S		20 Mg, Unk		Not Reported	
	Escitalopram			S		20 Mg		Not Reported	
	Escitalopram			S		20 Mg		Not Reported	
	Escitalopram			S		20 Mg		Not Reported	
	Escitalopram			S		20 Mg		Not Reported	
	Vitamin D3			C		2000 U		Not Reported	
	Probiotic			C		Unk		Not Reported	
	Aleve			C		220 Mg, Unk		Not Reported	
	Tylenol			C		325 Mg, Unk		Not Reported	
	Ocuvite			C		Unk		Not Reported	
	Alfuzosin			C		10 Mg, Unk		Not Reported	
	Rivastigmine			C		Unk		Not Reported	
	Rivastigmine			C		Unk		Not Reported	
	Rivastigmine			C		Unk		Not Reported	
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported	
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported	
	Carbidopa And Levodopa			C		50-200 Mg		Not Reported	
	Pilocarpine			C		1% Op		Not Reported	
	Pilocarpine			C		1% Op		Not Reported	
	Brimonidine			C		0.15 %, Unk		Not Reported	

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Brimonidine	C	0.15 %, Unk	Not Reported
Brimonidine	C	0.15 %, Unk	Not Reported
Latanoprost	C	0.005 %, Unk	Not Reported
Latanoprost	C	0.005 %, Unk	Not Reported
Cephalexin	C	500 Mg	Not Reported
Ciprofloxacin	C	250 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	14024381	EXPEDITED (15-DAY)		DE, OT	ZA-MYLANLABS-2017M1059414		65 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronary Artery Insufficiency	Mylacand Plus			S	Oral	1 Df, Unk		Mylan	
	Forvent			S	Oral	18 Mg, Unk		Mylan	
	Bilocor			S	Oral	5 Mg, Unk		Mylan	
	Glucophage Xr			S	Oral	1000 Mg, Unk		Mylan	
	Rivotril			S	Oral	0.3 Mg, Unk		Mylan	
	Lexamil			S	Oral	10 Mg, Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	14983140	EXPEDITED (15-DAY)		HO	FR-ACCORD-067832		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Amlodipine			S	Oral	10 Mg, Once Daily (Qd)		Accord	
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Accord	
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Not Reported	
	Irbesartan			S	Oral	300 Mg, Once Daily (Qd)		Accord	
	Terbutaline			S	Respiratory (inhalation)	1 Df, Once Daily (Qd)		Not Reported	
	Dafalgan			S	Oral	1000 Mg, 3x/Day (Tid)		Not Reported	

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Alprazolam	S	Oral	0.25 Mg, 3x/Day (Tid)	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Diazepam	S	Oral	10 Mg, 3x/Day (Tid)	Not Reported
Colchicine	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
Nefopam	S	Oral	1 Df, 3x/Day (Tid)	Not Reported
Diffu-K	S	Oral	3 Df Daily (2-1-0) 2x/Day (Bid)	Not Reported
Pantoprazole	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Metformin	S	Oral	500 Mg, 2x/Day (Bid)	Not Reported
Mirtazapine	S	Oral	15 Mg, Once Daily (Qd)	Not Reported
Valium	S	Oral	Strength: 10 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15145579	EXPEDITED (15-DAY)	HO		DE-ALLERGAN-1831225US		37 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haematoma; Haemorrhagic Diathesis; Menometrorrhagia; Respiratory Tract Infection; Sleep Disorder	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported	
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported	
	Risperidone			S				Not Reported	
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported	
	Pregabalin			C	Unknown	100 Mg, Qpm		Not Reported	
	Pregabalin			C				Not Reported	
	Pregabalin			C				Not Reported	
	Opipramol			C	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	

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	Atorvastatin		C	Unknown	Unk			Not Reported	
	Promethazine		C	Unknown	Unk			Not Reported	
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20-Aug-2018	15156892	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-926893		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral			Actavis	
	Paracetamol			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Tolep			S	Oral			Not Reported	
	Brintellix			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15260949	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1839200US		43 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Intentional Underdose	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qpm		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qpm		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qpm		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qpm		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15293471	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-944053		59 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral			Actavis	
	Escitalopram			S				Ivax	
	Trilafon			S	Oral			Not Reported	
	Ramipril			C	Oral			Not Reported	

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20-Aug-2018	15294914	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1840426US		25 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Interaction; Dissociation; Feeling Abnormal; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	
	Alcohol			S	Unknown	4 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15294917	NON-EXPEDITED			US-TEVA-2018-US-944230		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Twitching	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15294922	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1840394US		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Fallot'S Tetralogy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan	
	Amitriptyline-Form-Unknown			S	Transplacental	37.5 Mg, Qd		Not Reported	
	Metoprolol			S	Transplacental	71.25 Mg, Qd (47.5-0-23.75 Mg/D)		Not Reported	
	Paracetamol			C	Transplacental	200 Mg, Qd (1-2 G/D If Required)		Not Reported	
	Clexane			C	Transplacental	120 Mg, Qd (Dosage Increase To 2 X 60 Mg/D)		Not Reported	
	Clexane			C	Transplacental	40 Mg, Qd		Not Reported	
	Ibuprofen			C	Transplacental	600 Mg, Qd (If Required)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15296619	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2018328876		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension; Suicide Attempt	Alprazolam			S	Oral	Unk		Pfizer	
	Propranolol			S	Oral	Unk		Not Reported	
	Paracetamol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15297045	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2018-NL-944650		69 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Tablet, 10 Mg (Milligram)			S	Unknown	10 Milligram Daily; 1 X Per Dag 1 Stuk		Ivax	
	Hydrochlorothiazide 25mg			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298000	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1840381US		48 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastritis; Gastroesophageal Reflux Disease; Gastroesophageal Sphincter Insufficiency; Off Label Use	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Rivotril			C	Unknown	0.5 Mg, Unknown		Not Reported	
	Euthyrox			C	Oral	100-125 Mcg Per Day		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298004	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1840441US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Expired Product Administered; Poisoning; Product Storage Error	Escitalopram Oxalate - Bp			S	Unknown	10 Gtt, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298098	EXPEDITED (15-DAY)		DS	PT-ALLERGAN-1840579US		77 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Dry Mouth; Headache; Muscular Weakness; Nausea; Product Dosage Form Issue; Taste Disorder; Tinnitus; Vertigo	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan	
	Victan			C	Oral	Unk		Not Reported	
	Vastarel			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298108	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1840578US		59 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Electrocardiogram Qt Prolonged; Moaning	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Alprazolam			S	Oral			Not Reported	
	Trilafon			S	Oral			Not Reported	
	Ramipril			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298109	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1840390US		48 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Altered State Of Consciousness;	Escitalopram Oxalate - Bp	S	Oral	14 Df, Single	Allergan
Depressed Mood;	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
Intentional Overdose;	Stilnox	S	Oral	10 Df, Single	Not Reported
Suicide Attempt	Stilnox	S	Oral	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298253	EXPEDITED (15-DAY)		HO, LT	PHHY2018ES073955		18 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hypocoagulable State	Paracetamol			S	Oral	12 G, Total		Not Reported
	Ibuprofeno			S	Oral	2800 Mg, Total (400 Mg X 7 Cps)		Novartis
	Escitalopram			S	Oral	5 Df, Unk		Not Reported
	Exforge			S	Oral	5 Df, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298280	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1840632US		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Intentional Overdose; Miosis	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Unk		Allergan
	Plaquenil			S	Oral	3 G, Unk		Not Reported
	Doliprane			S	Oral	6 G, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298290	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1840583US		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Miosis; Off Label Use; Prothrombin Time Shortened;	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan
	Dafalgan Codeine			S	Oral	Unk, Unknown		Not Reported

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Tachycardia; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298291	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1840544US		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Laroxyl			S	Intramuscular	50 Mg/2 MI		Not Reported
	Theralene			S	Oral	Si Besoin		Not Reported
	Solian			S	Intramuscular	200mg/4ml		Not Reported
	Imovane			C	Oral	Si Besoin		Not Reported
	Dexeryl (Glycerol And White Soft Paraffin And Liquid Paraffin)			C	Cutaneous			Not Reported
	Plavix			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Losartan Potassique			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298356	EXPEDITED (15-DAY)		HO, LT	NL-ALLERGAN-1840566US		69 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Hydrochlorothiazide Unk			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298357	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1840587US		73 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Gait Disturbance	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd (0.5 Df, Qd)		Allergan
	Lorans			S	Oral	1 Mg, Qd (1 Df, Qd)		Not Reported

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Lorans	S	Oral	2.5 Mg, Qd (1df, Qd)	Not Reported
Quetiapine	S	Oral	150 Mg, Qd	Not Reported
Carbolithium	S	Oral	225 Mg, Qd (1.5 Df, Qd)	Not Reported
Motilium	C	Unknown		Not Reported
Metformina Teva	C	Unknown		Not Reported
Omeprazen	C	Unknown		Not Reported
Eskim	C	Unknown		Not Reported
Totalip	C	Unknown		Not Reported
Nicetile	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298407	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1840624US		< 1 DAY	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Heart Disease Congenital	Escitalopram Oxalate - Bp			S	Transplacental	1 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	1 Df, Qd		Allergan	
	Cymbalta			S	Transplacental	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298543	EXPEDITED (15-DAY)		DE, HO	FR-NAPPMUNDI-GBR-2013-0015606		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Oxynorm Solution Injectable			S	Intravenous (not otherwise specified)	Unk		Purdue	
	Fortum /00559701/			S	Intravenous (not otherwise specified)	4 G, Qid		Not Reported	
	Flagyl /00012501/			S	Oral	3 Df, Tid		Not Reported	
	Gentamicine Panpharma			S	Intravenous (not otherwise specified)	210 Mg, Daily		Not Reported	
	Noxafil			S	Oral	200 Mg, Tid		Not Reported	

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Cancidas	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ambisome	S	Intravenous (not otherwise specified)	180 Mg, Daily	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	2 Df, 3/Week	Not Reported
Folinic Acid	S	Intravenous (not otherwise specified)	50 Mg, 3/Week	Not Reported
Zelitrex	S	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
Cymevan	S	Intravenous (not otherwise specified)	700 Mg, Bid	Not Reported
Foscavir	S	Intravenous (not otherwise specified)	2 Df, Bid	Not Reported
Human Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Granocyte /03200101/	S	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin Sodium	S		7000 Iu, Daily	Not Reported
Inexium /01479302/	S	Intravenous (not otherwise specified)	1 Df, Daily	Not Reported
Spasfon /00765801/	S	Intravenous (not otherwise specified)	2 Df, Tid	Not Reported
Delursan	S	Oral	3 Df, Bid	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	25 Mg/Kg, Daily	Not Reported
Largactil /00011901/	S	Intravenous (not otherwise specified)	1 Df, Daily	Not Reported
Tranxene Sd	S	Oral	1 Df, Qid	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	1 Df, Tid	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	1 G, Tid	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	140 Mg, Daily	Not Reported

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			otherwise specified)		
Droleptan	S	Intravenous (not otherwise specified)	0.625 Mg, Qid		Not Reported
Ultiva	S	Intravenous (not otherwise specified)	100 Gbq, Qid		Not Reported
Atarax /00058401/	S	Oral	0.5 Df, Daily		Not Reported
Lasilix /00032601/	S	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
Seroplex	S	Oral	10 Mg, Daily		Not Reported
Ceris	S	Oral	2 Df, Bid		Not Reported
Noctamide	S	Oral	1 Df, Daily		Not Reported
Gentamicine	C		Unk		Not Reported
Vancomycine	C		Unk		Not Reported
Ciflox /00697201/	C		Unk		Not Reported
Targocid	C		Unk		Not Reported
Mycostatine	C		Unk		Not Reported
Zovirax /00587301/	C		Unk		Not Reported
Methotrexate	C		Unk		Not Reported
Elvorine	C		Unk		Not Reported
Sandimmun	C		Unk		Not Reported
Mopral /00661201/	C		20 Mg, Unk		Not Reported
Ogastoro	C		Unk		Not Reported
Gelox	C		Unk		Not Reported
Smecta /00837601/	C		Unk		Not Reported
Luteran	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15298564	EXPEDITED (15-DAY)		DE, HO	US-ALLERGAN-1840672US		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Overdose	Escitalopram Oxalate Unk	S	Unknown	Unk	Allergan
	Valproic Acid	S	Unknown	Unk	Not Reported
	Sertraline	S	Unknown	Unk	Not Reported
	Quetiapine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	10638234	EXPEDITED (15-DAY)		DS, HO, OT	US-SA-2014SA149672		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alopecia;	Teriflunomide			S	Oral	14 Mg, Qd		Sanofi
Asthenia; Blood	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Cholesterol Abnormal;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Blood Glucose Increased;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Brain Oedema; Cognitive	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Disorder; Cough; Fatigue;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Fatigue; Fatigue; Feeding	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Disorder; Headache;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Hypertension;	Lexapro			S	Unknown	20 Mg,Qd		Not Reported
Hypoaesthesia;	Lexapro			S				Not Reported
Hypoaesthesia; Mental	Lamictal			C		100 Mg,Bid		Not Reported
Disorder; Migraine;	Cyanocobalamin			C		1000 Df,Unk		Not Reported
Multiple Sclerosis	Cyanocobalamin			C		2500 Ug,Unk		Not Reported
Relapse; Muscular	Vitamin D3			C		5000 Df,Unk		Not Reported
Weakness; Nasal	Vitamin D3			C				Not Reported
Congestion;	Metformin			C		Unk		Not Reported
Nasopharyngitis;	Omeprazole			C				Not Reported
Nasopharyngitis; Nervous								
System Disorder;								
Paraesthesia; Respiratory								
Disorder; Seizure; Sinus								
Disorder; Sleep Disorder;								
Somnolence; Stress;								
Unevaluable Event;								
Urinary Incontinence;								
Vomiting; Weight								
Decreased								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	13882141	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1735577US		32 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Function Abnormal; Lymphocyte Morphology Abnormal; Rash	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Prodif			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Fluconazole			S	Oral	Unk, Unknown		Not Reported	
	Famotidine			C	Unknown	Unk, Unknown		Not Reported	
	Miya Bm			C	Oral	2 Df, Unk		Not Reported	
	Talion Od			C	Oral	10 Mg, Q12h		Not Reported	
	Albumin Tannate			C	Oral	1 G, Unk		Not Reported	
	Loperamide Hydrochloride			C	Oral	1 Mg, Q12h		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15160991	NON-EXPEDITED		OT	US-JAZZ-2018-US-007044		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Narcolepsy; Nausea; Vomiting	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Xyrem			S	Oral	1.125 G, Qd		Jazz	
	Xyrem			S	Oral	Dose Adjustment		Jazz	
	Xyrem			S	Oral	3.5 G, Bid		Jazz	
	Xyrem			S	Oral	Decreased Dose		Jazz	
	Xyrem			S	Oral	3.5 G, Bid		Jazz	
	Lexapro			S				Not Reported	
	Amoxicillin			C		Unk		Not Reported	
	Ritalin			C		Unk		Not Reported	
	Allegra Allergy			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15298919	EXPEDITED (15-DAY)		HO, OT	IN-LUPIN PHARMACEUTICALS INC.-2018-05873		33 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Drug Intolerance; Inappropriate Affect; Insomnia; Psychomotor Hyperactivity; Sedation	Escitalopram			S	Unknown	Unk		Lupin	
	Escitalopram			S				Lupin	
	Escitalopram			S				Lupin	
	Escitalopram			S				Lupin	
	Escitalopram			S				Lupin	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Lithium			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15299516	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE- 945309		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Fallot'S Tetralogy	Metoprolol			S	Transplacental	71.25 [Mg/D]/ 47.5-0- 23.75 Mg/D		Not Reported	
	Amitriptylin			S	Transplacental	37.5 Milligram Daily; 37.5 [Mg/D]		Not Reported	
	Cipralext			S	Transplacental	5 Milligram Daily; 5 [Mg/D]		Not Reported	
	Paracetamol			C	Transplacental	2000 [Mg/D]/ 1-2 G/D If Required		Not Reported	
	Clexane 40			C	Transplacental	120 [Mg/D (-40)]/ Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D		Not Reported	
	Ibuprofen			C	Transplacental	6 Milligram Daily; 600 [Mg/D]/ If Required		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15299559	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2018-DE- 945262		58 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Dexamethasone			S	Oral	8 Milligram Daily;		Actavis	
	Sycrest			S	Oral	5 Milligram Daily;		Not Reported	
	Cipralext			S	Oral	5 Milligram Daily;		Not Reported	
	Pantoprazol			C	Oral	20 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15301220	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018327013		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Overdose; Somnolence	Ibuprofen			S	Oral	20 Df, Unk		Pfizer	
	Havlane			S	Oral	20 Df, Unk		Not Reported	
	Paroxetine			S	Oral	12 Df, Unk		Not Reported	
	Dafalgan Codein			S	Oral	8 G, Unk		Not Reported	
	Escitalopram			S	Oral	28 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15301629	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP019299		81 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15301722	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-944775		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma-Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Tachycardia;	Escitalopram			S	Oral			Ivax	
	Dafalgan Codeine, Comprimé Pelliculé			S	Oral			Not Reported	

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Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15301978	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-944908		17 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; No Adverse Event; Suicide Attempt	Q Pin			S	Oral	50 Milligram Daily;		Teva	
	Aripiprazol			S	Oral	20 Milligram Daily;		Teva	
	Citram			S	Oral	90 Milligram Daily;		Not Reported	
	Ketonal			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15302862	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2018M1061882			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Suicidal Ideation	Loxalate			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15303112	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1840787US		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15170639	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-036628		24 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	Overdose: 30 Milligram Daily		Aurobindo	

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Escitalopram	S	Oral	20 Milligram, Daily	Aurobindo
Escitalopram	S	Oral	30 Milligram, Daily	Aurobindo
Prothipendyl	C	Oral	80 Milligram, Daily	Not Reported
Diazepam	C	Oral	10 Milligram, Daily	Not Reported
Diazepam	C	Oral	5 Milligram, Daily	Not Reported
Pantozol /01263204/	C	Oral	20 Milligram, Daily	Not Reported
Pantozol /01263204/	C	Oral	40 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15266964	EXPEDITED (15-DAY)		OT	IT-TAKEDA-2018TUS024416		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia;	Brintellix			S	Unknown	15 Mg, Qd		Takeda
Anxiety; Apathy;	Brintellix			S	Unknown	10 Mg, Qd		Takeda
Decreased Appetite; Drug	Brintellix			S	Unknown	5 Mg, Qd		Takeda
Ineffective; Major	Cipralext /01588501/			S	Unknown	20 Mg, Qd		Not Reported
Depression; Self Esteem	Cipralext /01588501/			S				Not Reported
Decreased; Sexual	Lorazepam			S	Oral	2.5 Mg, Qd		Not Reported
Dysfunction; Social	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
Avoidant Behaviour;	Duloxetine Hydrochloride			S	Unknown	60 Mg, Qd		Not Reported
Weight Increased	Duloxetine Hydrochloride			S				Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Coumadin /00014802/			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Warfarin Sodium			C	Unknown	Unk		Not Reported

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22-Aug-2018	15297995	EXPEDITED (15-DAY)		OT	SA-ALLERGAN-1840447US		26 YR	Female	SAU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure; Partial Seizures	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Levetiracetam			S	Unknown	500 Mg, Bid		Not Reported	
	Lamotrigine			S	Unknown	50 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15297997	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1840453US		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15304888	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-181877		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported	
	Ibuprofene		Y	S	Oral	Unk		Ranbaxy	
	Paroxetine			S	Oral	Unk		Sun	
	Havlane			S	Oral	Unk		Not Reported	
	Dafalgan			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15305409	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2017005849			Unknown	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine 60 Mg			S	Unknown	60 Mg, Qd		Macleods
	Duloxetine 60 Mg			S	Unknown	Unk		Macleods
	Ciprallex			S	Unknown	20 Mg, Qd		Not Reported
	Ciprallex			S	Unknown	Unk		Not Reported
	Sertraline Hydrochloride			S	Oral	100 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Qd, At Bed Time		Not Reported
	Lorazepam			S				Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Ezetimab			C	Unknown	Unk		Not Reported
	Ezetimab			C	Oral	10 Milligram, Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	30 Milligram, Qd		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	20 Milligram, Qd		Not Reported
	Amidarone			C	Unknown	Unk		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Cordarone			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15306661	EXPEDITED (15-DAY)		HO	FR- GLAXOSMITHKLINE- FR2018148847		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphadenitis; Rash Maculo-Papular	Lamictal			S	Oral	75 Mg, Qd		Glaxosmithkline
	Seroplex			S	Oral	5 Mg, Qd		Glaxosmithkline

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22-Aug-2018	15306680	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018016399			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	20 Milligram, Qd		Macleods	
	Escitalopram			S	Oral	30 Milligram, Qd		Macleods	
	Escitalopram			S	Oral	10 Milligram, Qd,Overdose: 30 Milligram Daily		Macleods	
	Diazepam			C	Oral	10 Milligram, Qd		Not Reported	
	Diazepam			C	Oral	5 Milligram, Qd		Not Reported	
	Pantozol			C	Oral	20 Milligram, Qd		Not Reported	
	Pantozol			C	Oral	40 Milligram, Qd		Not Reported	
	Prothipendyl			C	Oral	80 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15307061	EXPEDITED (15-DAY)		OT	FR-SA-2018SA219386		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous	Escitalopram Oxalate			S	Oral	20 Mg Le Matin		Not Reported	
	Doxylamine Succinate			S	Oral	Non Renseign��e		Sanofi	
	Alprazolam			S	Oral	0.5 Mg Puis 0.25 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15307128	NON-EXPEDITED		OT	US-APOTEX- 2018AP019587		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Exposure During Pregnancy; Therapeutic	Paroxetine			S	Unknown	Unk		Apotex	
	Bupropion			S	Unknown	Unk		Apotex	

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Product Effect Incomplete; Treatment Failure	Escitalopram	S	Unknown	Unk	Apotex
	Lamotrigine	S	Unknown	400 Mg Per Day	Apotex
	Aripiprazole	S	Unknown	15 Mg Per Day	Apotex
	Venlafaxine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15307694	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-944635		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Skin Eruption	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax	
	Stresam			S	Oral	3 Dosage Forms Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	15308533	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1841015US		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Malaise; Off Label Use; Rash	Escitalopram Oxalate Unk			S	Oral	20 Mg, Tid		Allergan	
	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan	
	Diazepam			C	Oral	10 Mg, Qid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	14613081	EXPEDITED (15-DAY)		DE, HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-01610		1 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Lupin	
	Sildenafil Citrate			S	Unknown	Unk		Not Reported	
	Spirolactone			S	Unknown	Unk		Not Reported	
	Phenobarbital			S	Unknown	Unk		Not Reported	
	Varivax /06643105/			S	Intramuscular	1 Df		Not Reported	

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Synagis	S	Intramuscular		Not Reported
Exodus /01588502/	S	Unknown	Unk	Not Reported
Carbohydrates Nos W/Carnitine/Fats Nos/Minera	C	Other	4 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15145722	EXPEDITED (15-DAY)	HO		FR-TEVA-2018-FR-925080		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral	40 Milligram Daily;		Teva
	Esidrex 25 Mg, Comprimé			S	Oral	.5 Dosage Forms Daily;		Not Reported
	Seroplex 15 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported
	Pelliculé Sécable							
	Procoralan 5 Mg, Comprimé			C	Unknown			Not Reported
	Pelliculé							
	Aspirine Protect 100 Mg, Comprimé			C	Unknown			Not Reported
	Gastro-Résistant							
	Seresta 50 Mg, Comprimé			C	Unknown			Not Reported
	Sécable							
	Dafalgan 1 G, Comprimé			C	Unknown			Not Reported
	Pelliculé							
	Pravastatine Sodique			C	Unknown			Not Reported
	Mediatensyl 30 Mg, Gélule			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Acebutolol (Chlorhydrate D')			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15266914	EXPEDITED (15-DAY)	HO, OT		PHHY2018IT069494		45 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Tolep			S	Oral	38 Df, Total		Novartis
	Oxcarbazepina			S	Oral	Unk		Novartis
	Lorazepam			S	Oral	20 Mg, Total		Not Reported

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Paracetamol	S	Oral	2 G, Unk	Not Reported
Tachipirina	S	Oral	2 G, Total	Not Reported
Cipralelex	S	Oral	15 MI, Total	Not Reported
Brintellix	S	Oral	15 MI, Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15280401	EXPEDITED (15-DAY)		OT	FR- GLAXOSMITHKLINE- FR2018143794		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Lichen Planus	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Esomeprazole			S	Oral	Unk		Glaxosmithkline
	Seroplex			S	Oral	Unk		Glaxosmithkline
	Atorvastatine			S	Oral	20 Mg, Unk		Glaxosmithkline
	Macrogol			S	Oral	Unk		Glaxosmithkline
	Hydrochlorothiazide			S	Oral	25 Mg, Unk		Not Reported
	Xeroquel			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	2 Mg, Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	240 Mg, Unk		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Aldactone (Spirolactone)			S	Unknown	Unk Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15310565	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2018NO076406		40 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Fibrillation; Dizziness; Eye Disorder; Myalgia; Palpitations; Tooth Injury	Quetiapine Sandoz			S	Unknown	25 Mg, Q12h		Novartis
	Calcigran Forte			S	Unknown	4 lu, Q12h		Not Reported
	Cipralelex			S	Unknown	20 Mg, Q12h		Not Reported

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Ciprallex	S	Unknown	20 Mg, Q12h	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Etalpha	C	Oral	Unk	Not Reported
Etalpha	C	Oral	Unk	Not Reported
Zopiklon Mylan	C	Unknown	Unk	Not Reported
Zopiklon Mylan	C	Unknown	Unk	Not Reported
Multi Mineral	C	Unknown	Unk	Not Reported
Vitaman	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15311935	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-947059		60 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Generalised	Escitalopram			S		5 Milligram Daily;		Ivax
	Atarax			S		75 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	12951890	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1676191US		7 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Intellectual Disability	Escitalopram Oxalate - Bp			S	Transplacental			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	14737680	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1812889US		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depression	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
Suicidal; Dizziness	Bupropion Sr			S	Oral	300 Mg, Qd		Not Reported
	Bupropion Sr			S	Oral	150 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15251481	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018312592		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	20 Mg, Total		Pfizer	
	Tachipirina			S	Oral	2 G, Total		Not Reported	
	Brintellix			S	Oral	15 Ml, Total		Not Reported	
	Tolep			S	Oral	38 Df, Total		Not Reported	
	Ciprallex /01588501/			S	Oral	15 Ml, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15288798	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1840041US		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Transient Ischaemic Attack	Escitalopram Oxalate 5mg Tab			S	Unknown	10 Mg, Unknown		Allergan	
	Escitalopram Oxalate 5mg Tab			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15313968	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-182428		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Paracetamol		Y	S	Oral	()		Ohm Lab	
	Escitalopram			S	Oral	()		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	()		Not Reported	
	Alprazolam			S	Oral	()		Not Reported	
	Ibuprofene			C	Unknown	()		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15313971	NON-EXPEDITED			US-DRREDDYS- USA/USA/17/0094635			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Injection Site Pain; Product Complaint; Tinnitus	Fondaparinux Sodium			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Lisinopril			C	Unknown			Not Reported	
	Temazepam			C	Unknown			Not Reported	
	Iron			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15313977	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE- 946135		24 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Headache; Malaise; Product Substitution Issue; Tremor; Tunnel Vision	Escitalopram Teva			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15314107	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 948269		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose;	Escitalopram			S	Unknown			Ivax	
Acute Kidney Injury;	Lercanidipine			S	Unknown			Not Reported	
Anxiety; Dehydration;	Cyamemazine			S	Unknown			Not Reported	
Depression; Drug	Cyamemazine			S	Unknown	50 Milligram Daily;		Not Reported	
Interaction; Hepatocellular	Cyamemazine			S	Unknown	25 Mg To 75 Mg Daily		Not Reported	
Injury; Hypernatraemia;	Cyamemazine			S	Unknown	Continued At A Low Dose,		Not Reported	
Hypotension; Mucosal	Cyamemazine			S	Unknown	50 Mg To 100 Mg		Not Reported	
Disorder; Neuroleptic	Zuclopenthixol Decanoate			S	Unknown	Long-Acting Injectable		Not Reported	
Malignant Syndrome;									
Psychomotor									
Hyperactivity; Skin									

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Atrophy; Suicide Attempt; Vasoplegia Syndrome; Wrong Product Administered	Zuclopenthixol Acetate	S	Intramuscular	The Short-Acting Form Of The Drug	Not Reported
	Zuclopenthixol Dihydrochloride	S	Unknown	Dose Was Titrated From 5 To 40 Mg Daily Over 2 Weeks	Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15314529	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2018-042878		24 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	30 Milligram, Once A Day		Aurobindo
	Diazepam			C	Oral	5 Milligram, Once A Day		Not Reported
	Diazepam			C	Oral	10 Milligram		Not Reported
	Pantozol /01263204/			C	Unknown	20 Milligram, Once A Day		Not Reported
	Pantozol /01263204/			C	Unknown	40 Milligram, Once A Day		Not Reported
	Prothipendyl			C	Oral	80 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15314684	EXPEDITED (15-DAY)		DS, HO, LT	PT-MACLEODS PHARMACEUTICALS US LTD- MAC2018016426			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor	Escitalopram Tablet			S	Oral	1 Dosage Form, Qd, Ram Appeared A Few Days After The Start Of Administration Of The Suspected Drug		Macleods

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Hyperactivity; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15314866	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-042978		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Melaena; Rectal Haemorrhage	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported	
	Crestor			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15315443	EXPEDITED (15-DAY)			US-ASPEN- GLO2018US007643		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia	Benzotropine Mesylate			S				Nuvo Research	
	Escitalopram			S	Unknown			Not Reported	
	Bupropion			S				Not Reported	
	Aripiprazole			S	Unknown			Not Reported	
	Lithium			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15316857	EXPEDITED (15-DAY)		HO	CA-ALLERGAN- 1841136US		29 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Rash; Swelling	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Imovane			C	Unknown	Unk, Unknown		Not Reported	
	Gravol			C	Unknown	Unk, Unknown		Not Reported	
	Ativan			C	Unknown	Unk, Unknown		Not Reported	
	Pregvit			C	Unknown	Unk, Unknown		Not Reported	

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24-Aug-2018	15317558	EXPEDITED (15-DAY)		HO	PHHY2016FR187181		34 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Interstitial Lung Disease	Atorvastatin Calcium			S	Oral	10 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Oral	2 Df, Qd		Not Reported
	Inexium			S	Oral	20 Mg, Qd		Not Reported
	Seroplex			S	Oral	10 Mg, Bid		Not Reported
	Stilnox			S	Oral	10 Mg, Qd		Not Reported
	Theralene			S	Oral	5 Mg, Bid		Not Reported
	Triatec (Ramipril)			S	Oral	5 Mg, Qd		Not Reported
	Ixprim			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	5 Mg, Bid		Not Reported
	Lasilix			C	Unknown	Unk		Not Reported
	Seresta			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15333399	DIRECT					52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Sodium Decreased	Escitalopram 20 Mg			S	Oral	Quantity:30 Tablets		Aurobindo
	Oxcarbazepine			S	Oral	Quantity:3 Tablets		Breckenridge
	Levothyroxine			C				Not Reported
	Depo Inj.			C				Not Reported
	Eye Ddrop			C				Not Reported
	Iron			C				Not Reported
	Metformin			C				Not Reported
	Aspirin			C				Not Reported
	Omeprazole			C				Not Reported
	Pioglitizone			C				Not Reported
	Clonasepam			C				Not Reported
	Dicyclomine			C				Not Reported

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Divalproex Ec	C	Not Reported
Aimovig Inj	C	Not Reported
Lisinopril	C	Not Reported
Pravastatin	C	Not Reported
Lexapro	C	Not Reported
Mirtazapine	C	Not Reported
Trazadone	C	Not Reported
Vraylar	C	Not Reported
Vitamin B-12	C	Not Reported
Vitamin D-3	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2018	15333879	DIRECT		HO			40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombosis; Uterine Haemorrhage	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2018	15334594	DIRECT		DS, HO			22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour;	Latuda, 60 Mg			S	Oral	Quantity:2 Tablet(S);		Not Reported
Anhedonia; Burning	Lexapro			S				Not Reported
Sensation; Chromaturia;	Abilify			S				Not Reported
Depression; Dyscalculia;	Risperidone			S				Not Reported
Flatulence; Frustration	Multi-Vitamin			C				Not Reported
Tolerance Decreased;	Fish Oil			C				Not Reported
Galactorrhoea; Heart Rate	Zyprexa			C				Not Reported
Decreased; Nausea; Salt	Vitamin D Nos			C				Not Reported
Craving; Somnolence;								
Somnolence; Weight								
Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	12934226	EXPEDITED (15-DAY)		LT, OT	JP-ALLERGAN-1675344US		47 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Feeling Abnormal; Pyrexia; Syncope	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Dogmatyl			C	Oral	0.05 G, Q12h		Not Reported
	Sepazon			C	Oral	0.05 G, Q12h		Not Reported
	Lactose			C	Oral	0.75 G, Q12h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15154548	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT047244		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Quetiapine			S	Oral	200 Mg, Qd		Novartis
	Valproic Acid Sandoz			S	Oral	300 Mg, Qd		Not Reported
	Venlafaxine			S	Oral	300 Mg, Qd		Not Reported
	Alprazolam			S	Oral	1.5 Mg, Qd		Not Reported
	Alprazolam			S		1 Mg		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Qd		Not Reported
	Trazodone			S	Oral	75 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15260542	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2012FR143999		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Olanzapine			S	Unknown	15 Mg, Unk		Novartis
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Anafranil			S	Oral	Daily Dose Increased		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported

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	Depamide	S	Oral	Unk	Not Reported
	Seroplex	S	Unknown	Unk	Not Reported
	Seroplex	S			Not Reported
	Dopamide	S	Oral	Unk	Not Reported
	Abilify	S	Unknown	10 Mg, Unk	Not Reported
	Seresta	S	Oral	Unk Unk, Bid (Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening)	Not Reported
	Lexapro	S	Unknown	10 Mg, Qd (Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy)	Not Reported
	Zyprexa	S	Unknown	Unk	Not Reported
	Imovane	S	Oral	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15298300	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1840588US		32 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Headache;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
Hepatitis Infectious	Doliprane			C	Oral	Unk, Unknown		Not Reported
Mononucleosis;	Fluoxetine Zentiva			C	Unknown	Unk Unk, Unknown		Not Reported
Hepatocellular Injury;								
Myalgia; Pyrexia; Vertigo								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15319512	EXPEDITED (15-DAY)		HO, OT	FR-ZYDUS-024691		57 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose;	Escitalopram			S	Unknown			Zydu Pharm
Acute Kidney Injury;	Lercanidipine			S	Unknown			Not Reported
Antipsychotic Drug Level	Cyamemazine			S	Unknown	50 Mg To 100 Mg Daily		Not Reported
Increased; Anxiety;	Zuclopenthixol			S	Unknown	Titratd From 5 To 40 Mg		Not Reported
Confusional State;								
Dehydration; Depression;								

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Drug Interaction;				Daily Over 2 Weeks	
Hepatocellular Injury;	Zuclopenthixol	S	Unknown		Not Reported
Hypernatraemia;	Zuclopenthixol	S	Intramuscular		Not Reported
Hypertension;	Bisoprolol	C	Unknown		Not Reported
Hyperthermia;	Atorvastatin	C	Unknown		Not Reported
Hypotension; Intentional	Metformin	C	Unknown		Not Reported
Overdose; Mucosal	Cyamemazine	S	Unknown	25 Mg To 75 Mg	Not Reported
Disorder; Muscle Rigidity;	Cyamemazine	S	Unknown		Not Reported
Neuroleptic Malignant	Cyamemazine	S	Unknown		Not Reported
Syndrome; Product					
Administration Error;					
Psychomotor					
Hyperactivity; Skin					
Atrophy; Stupor; Suicide					
Attempt; Vasoplegia					
Syndrome					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15319850	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-944505		32 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Headache;	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
Hepatitis Infectious	Doliprane			C	Oral			Not Reported
Mononucleosis;	Fluoxetine Zentiva 20 Mg,			C	Oral			Not Reported
Hepatocellular Injury;	Comprimé Dispersible Sécable							
Myalgia; Pyrexia; Vertigo								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15322254	EXPEDITED (15-DAY)		OT	PHHY2018IT076818		43 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, 813 (Total)		Novartis
	Escitalopram			S	Oral	50 Mg, (Total)		Not Reported
	Tavor (Lorazepam)			S	Oral	Unk		Not Reported

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27-Aug-2018	15323229	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1841348US		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Donormyl (Doxylamine Succinate)			S	Oral	Unk		Not Reported	
	Xanax			S	Oral	0.5 Mg Puis 0.25 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15336247	DIRECT		DS			22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Odour; Dry Mouth; Intentional Overdose; Unhealthy Diet	Vyvanse			S	Oral	Quantity:1 Capsule(S);		Shire	
	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Phenibut			C				Not Reported	
	Astaxanthin			C				Not Reported	
	Spirulina			C				Not Reported	
	Fish Oil			C				Not Reported	
	Aged Garlic Extract			C				Not Reported	
	Nac			C				Not Reported	
	Zinc			C				Not Reported	
	Copper			C				Not Reported	
	Magnesium			C				Not Reported	
	Vitamin C			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Vitamin K2 Mk07			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	12683839	NON-EXPEDITED			US-FRI-1000084257			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Lexapro			S	Unknown	Unk		Allergan	

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Hyperhidrosis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	12771179	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016434898		35 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Interstitial Lung Disease	Tahor			S	Oral	10 Mg, Daily		Pfizer
	Triatec (Ramipril)			S	Oral	5 Mg, Daily		Pfizer
	Inexium			S	Oral	20 Mg, Daily		Unknown
	Cellcept			S	Oral	1 G, 2x/Day		Not Reported
	Cortancyl			S	Oral	5 Mg, 2x/Day		Not Reported
	Theralene			S	Oral	5 Mg, 2x/Day		Not Reported
	Stilnox			S	Oral	10 Mg, Daily		Not Reported
	Seroplex			S	Oral	10 Mg, 2x/Day		Not Reported
	Ixprim			S	Oral	Unk		Not Reported
	Seresta			C		50 Mg, Unk		Not Reported
	Lasilix			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960390	NON-EXPEDITED			US-ALLERGAN-1713790US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Hyperhidrosis; Nightmare	Lexapro			S	Oral	5 Mg, Qod		Allergan
	Lexapro			S	Oral	10 Mg, Qam		Allergan
	Carvedilol			C	Oral	(Half Tablet) 3.125 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960420	NON-EXPEDITED			US-ALLERGAN-1725967US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Fatigue	Lexapro	S	Oral	10 Mg, Qd	Allergan
	Insulin	C		Unk	Not Reported
	Insulin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960437	NON-EXPEDITED			US-ALLERGAN-1727899US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Nausea	Lexapro			S	Oral	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960440	NON-EXPEDITED			US-ALLERGAN-1728597US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lexapro			S		Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960441	NON-EXPEDITED			US-ALLERGAN-1728083US		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Influenza Like Illness; Night Sweats; Product Dose Omission; Sleep Disorder	Lexapro			S	Unknown	Unk		Allergan
	Synthroid			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960456	NON-EXPEDITED			US-ALLERGAN-1731048US		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Retching; Sneezing; Wrong Technique In Product Usage Process; Yawning	Lexapro			S	Oral	10 Mg, Unk		Allergan
	Clonazepam			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960457	NON-EXPEDITED			US-ALLERGAN-1731442US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960459	NON-EXPEDITED			US-ALLERGAN-1731045US		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	0.125 Df, Qd		Allergan	
	Lexapro			S	Oral	0.25 Df, Qd		Allergan	
	Clonazepam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960467	NON-EXPEDITED			US-ALLERGAN-1735803US		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Feeling Hot; Hiatus Hernia; Vertigo; Wrong Technique In Product Usage Process	Lexapro			S	Oral	1 Df, Unknown		Allergan	
	Lexapro			S	Oral	0.5 Df, Unknown		Allergan	
	Lexapro			S	Oral	1 Df, Unknown		Allergan	
	Lexapro			S	Oral	0.5 Df, Unknown		Allergan	
	Aspirin			S	Unknown	Low Dose		Not Reported	
	Synthroid			C	Unknown	25 Mg, Unk		Not Reported	
	Premarin			C	Unknown	Lowest Dose		Not Reported	
	Benicar			C	Unknown	Unk		Not Reported	
	Vitamin E			C	Unknown	Unk		Not Reported	
	Vitamin C			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960479	NON-EXPEDITED			US-ALLERGAN-1735884US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Anxiety	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate Unk			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960480	NON-EXPEDITED			US-ALLERGAN-1734826US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Malaise; Nausea	Lexapro			S	Oral	20 Mg, Unknown		Allergan	
	Lexapro			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960488	NON-EXPEDITED			US-ALLERGAN-1746963US		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Malaise; Palpitations	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	13960657	NON-EXPEDITED			US-ALLERGAN-1708963US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Anxiety; Depression; Drug Ineffective; Labile Blood Pressure; Mental Status Changes	Lexapro			S	Oral	20 Mg, Qd		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	14630095	NON-EXPEDITED			US-PFIZER INC-2018098356		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown	
	Flagyl			S		Unk		Pfizer	
	Doxy			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15093247	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1832855US		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Aggression; Cardiac Failure; Compulsive Shopping; Derealisation; Disinhibition; Grandiosity; Insomnia; Irritability; Mania; Myocardial Infarction; Obsessive-Compulsive Disorder; Oedema; Persecutory Delusion; Stent Placement; Suicidal Ideation; Thinking Abnormal; Verbal Abuse; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan	
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported	
	Brintellix			S	Unknown	10 Mg, Unk		Not Reported	
	Brintellix			S	Unknown	15 Mg, Unk		Not Reported	
	Brintellix			S	Unknown	20 Mg, Unk		Not Reported	
	Lasilix			C	Unknown			Not Reported	
	Aldactone			C	Unknown			Not Reported	
	Kardegic			C	Unknown			Not Reported	
	Depakote			C	Unknown			Not Reported	
	Xanax			C	Unknown			Not Reported	
	Inexium			C	Unknown			Not Reported	
	Noctamide			C	Unknown	2 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15225734	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL		45 YR	Female	ITA

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INDUSTRIES LTD-
2018RR-178389

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	In Total		Sun
	Brintellix			S	Oral	In Total		Not Reported
	Cipralex			S	Oral	In Total		Not Reported
	Tachipirina 500 Mg Compresse			S	Oral	In Total		Not Reported
	Tolep			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15249943	EXPEDITED (15-DAY)		OT	CH- GLAXOSMITHKLINE- CH2018136572		41 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety; Aphasia; Aphasia; Hyperhidrosis	Wellbutrin			S	Oral	150 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	300 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	450 Mg, Unk		Glaxosmithkline
	Wellbutrin			S	Oral	300 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline
	Trittico			S	Oral	50 Mg, Qd		Not Reported
	Benocten			C	Unknown	25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15256156	EXPEDITED (15-DAY)		CA, HO, OT	IT-ALLERGAN- 1839033US		273 DAY	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hypoplastic Left Heart Syndrome	Escitalopram Oxalate Unk			S	Transplacental	Unk Unk, Unknown		Allergan
	Carbolithium			S	Transplacental	750 Mg, Daily		Not Reported
	Lorazepam			C	Transplacental	Unk Unk, Unknown		Not Reported

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28-Aug-2018	15323774	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-947903		24 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Diazepam			C	Oral	5 Milligram Daily;		Not Reported
	Diazepam			C	Oral			Not Reported
	Pantozol			C	Unknown	40 Milligram Daily;		Not Reported
	Pantozol			C				Not Reported
	Prothipendyl			C	Oral	80 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15325755	EXPEDITED (15-DAY)		HO	CH-JNJFOC-20180828437		82 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Lower Gastrointestinal Haemorrhage; Prescribed Overdose	Xarelto			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Risperidone			C	Unknown			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Benserazide Hydrochloride W/Levodopa Concor			C	Unknown			Not Reported
	Calcium Carbonate W/Colecalciferol			C	Oral			Not Reported
	Vitamin D3 Streuli			C	Unknown			Not Reported
	Solmucol			C	Oral			Not Reported
	Tiotropium Bromide			C	Respiratory (inhalation)			Not Reported

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Temesta (Lorazepam)	C	Unknown	Not Reported
Metoclopramide	C	Unknown	Not Reported
Imodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15326040	EXPEDITED (15-DAY)		HO	PHHY2018IT082571		73 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Mg, Qd		Novartis
	Ciprallex			S	Oral	0.5 Df, Qd		Not Reported
	Lorans			S	Oral	1 Df, Qd		Not Reported
	Carbolithium			S	Oral	1.5 Df, Qd		Not Reported
	Motilium			C	Unknown			Not Reported
	Metformina Teva			C	Unknown			Not Reported
	Nicetile			C	Unknown			Not Reported
	Totalip			C	Unknown			Not Reported
	Eskim			C	Unknown			Not Reported
	Omeprazen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15326464	EXPEDITED (15-DAY)		HO, OT	ES-COVIS PHARMA B.V.-2018COV03741			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Dizziness; Electrocardiogram Qt Prolonged; Erythema; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia; Vomiting	Omeprazole Magnesium			S	Oral			Covis
	Escitalopram			S		Unk		Not Reported
	Incb050465			S	Oral	20 Mg		Not Reported
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.3999939 Mg		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

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Co-Trimoxazol
Atorvastatin
Valsartan

S
C
C

Not Reported
Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15326903	EXPEDITED (15-DAY)		HO, LT	PHHY2018NL082340		69 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S	Unknown	10 Mg, Qd (1 Per Dag 1 Stuk)		Not Reported
	Hydrochlorothiazide Sandoz			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327344	NON-EXPEDITED			US-ALLERGAN-1837870US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression	Lexapro			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327345	NON-EXPEDITED			US-ALLERGAN-1838690US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327354	NON-EXPEDITED			US-ALLERGAN-1736000US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Nausea; Panic Attack; Sleep Disorder; Vomiting	Lexapro			S		10 Mg, Unk		Allergan
	Lexapro			S		20 Mg, Unk		Allergan

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28-Aug-2018	15327356	NON-EXPEDITED			IE-ALLERGAN-1839935US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Lexapro			S	Unknown	Unk		Allergan	
	Vortioxetine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327357	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1748353US		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Suicidal Ideation	Lexapro			S	Oral	2.5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327358	NON-EXPEDITED			US-ALLERGAN-1747875US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Off Label Use; Product Dose Omission	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Toprol			C	Oral	50 Mg, Qd		Not Reported	
	Hytrol			C	Oral	10 Mg, Qd		Not Reported	
	Nitroglycerin			C	Sublingual	3 Df, Prn		Not Reported	
	Amoxicilina /00249603/			C		100 Mg, After Dentist Appointment		Not Reported	
	Amoxicilina /00249603/			C				Not Reported	
	Levothyroxine			C	Oral	50 Mg, Qd		Not Reported	
	Ectrin /00086101/			C	Oral	81 Mg, Qd		Not Reported	
	Isosorbide			C	Oral	60 Mg, Qd		Not Reported	
	Icaps			C	Oral	2 Df, Bid		Not Reported	

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	Nexium		C	Unknown	1 Df, Bid			Not Reported	
	Nexium		C	Unknown	2 Df, Bid			Not Reported	
	Nexium		C	Unknown	1 Df, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327359	NON-EXPEDITED			US-ALLERGAN-1746756US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Asthenia; Fatigue; Hyperhidrosis; Malaise; Somnolence; Yawning	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327360	NON-EXPEDITED			US-ALLERGAN-1735996US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327361	NON-EXPEDITED			US-ALLERGAN-1747490US		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Off Label Use; Overdose; Vision Blurred	Lexapro			S	Oral	25 Mg, Unk		Allergan	
	Lexapro			S	Oral	5 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327363	NON-EXPEDITED			US-ALLERGAN-1747111US		20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Lexapro			S	Unknown	2 Mg, Qd		Allergan	

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28-Aug-2018	15327364	NON-EXPEDITED			US-ALLERGAN-1746780US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Metoprolol			C		Unk		Not Reported	
	Losartan			C		Unk		Not Reported	
	Amlodipine			C		Unk		Not Reported	
	Atorvastatin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327367	NON-EXPEDITED			US-ALLERGAN-1735799US		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Lexapro			S	Oral	10 Mg, Unk		Allergan	
Abdominal Pain Upper;	Lexapro			S	Oral	5 Mg, Unk		Allergan	
Anxiety; Gastritis;	Lexapro			S	Oral	8 Mg, Unk		Allergan	
Headache; Hyperhidrosis;	Lexapro			S	Oral	20 Mg Cuts In Half For		Allergan	
Inflammation; Lethargy;						Daily Dose Of 10 Mg			
Metrorrhagia; Nausea;									
Nervousness; Photopsia;									
Product Dose Omission;									
Therapeutic Response									
Decreased; Vulvovaginal									
Dryness; Wrong									
Technique In Product									
Usage Process									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327368	NON-EXPEDITED			US-ALLERGAN-1747109US		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Lexapro			S	Unknown	2 Mg, Qd		Allergan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327369	NON-EXPEDITED			US-ALLERGAN-1736026US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Jittery; Paraesthesia	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327370	NON-EXPEDITED			US-ALLERGAN-1733941US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Incorrect Dose Administered	Lexapro			S	Oral	10 Mg, Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327371	NON-EXPEDITED			US-ALLERGAN-1746696US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Functional Gastrointestinal Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Wrong Technique In Product Usage Process	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Baclofen			C	Unknown			Not Reported	
	Copaxone			C	Unknown	40mg Mon/Wed/Fri		Not Reported	
	Alprazolam			C	Oral	0.5 Mg, Unk		Not Reported	
	Centrum /02217401/			C	Unknown			Not Reported	
	Vitamin D /00107901/			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327372	NON-EXPEDITED			US-ALLERGAN-1756707US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327373	NON-EXPEDITED			US-ALLERGAN-1769283US		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Losartan			C	Oral	100 Mg, Qd		Not Reported	
	Amlodipine			C	Oral	10 Mg, Qd		Not Reported	
	Ambien			C	Oral	Unk Unk, Qd		Not Reported	
	Xanax			C	Oral	Unk Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327374	NON-EXPEDITED			US-ALLERGAN-1755733US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Breast Tenderness;	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
Dysmenorrhoea;	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
Menorrhagia;	Lexapro			S	Unknown	2.5 Mg, Unk		Allergan	
Premenstrual Syndrome									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327378	NON-EXPEDITED			US-ALLERGAN-1769539US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Unk		Allergan	
	Escitalopram Oxalate Unk			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327379	NON-EXPEDITED			US-ALLERGAN-1752109US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dyspnoea; Intentional Product Use Issue	Lexapro	S	Oral	20 Mg, Qd	Allergan
	Lexapro	S	Oral	10 Mg, Qd	Allergan
	Oxygen	C			Not Reported
	Xanax	C	Unknown	.5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327380	NON-EXPEDITED			US-ALLERGAN-1756709US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327381	NON-EXPEDITED			US-ALLERGAN-1749920US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Mental Disorder; Product Prescribing Error	Lexapro			S	Unknown	Unk, Unknown		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327382	NON-EXPEDITED			US-ALLERGAN-1753279US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Paraesthesia	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Oral	Unk		Allergan
	Omega 3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327383	NON-EXPEDITED			US-ALLERGAN-1749302US		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Drug Ineffective	Lexapro	S	Oral	20 Mg, Unk	Allergan
	Lexapro	S	Oral	10 Mg, Unk	Allergan
	Latanoprost	C	Ophthalmic	Unk	Not Reported
	Tamsulosin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327384	NON-EXPEDITED			US-ALLERGAN-1751308US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Inappropriate Schedule Of Product Administration	Lexapro			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327385	NON-EXPEDITED			US-ALLERGAN-1759292US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Depression	Lexapro			S		Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327386	NON-EXPEDITED			US-ALLERGAN-1748372US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Depression; Drug Ineffective; Feeling Abnormal; Hypersomnia; Joint Swelling; Pain In Extremity	Lexapro			S	Unknown	5 Unk, Unk		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Calcium			C	Oral	Unk		Not Reported	
	Xanax			C	Oral	Unk Unk, Prn		Not Reported	
	Pantoprazole			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327387	NON-EXPEDITED			US-ALLERGAN-1763064US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327388	NON-EXPEDITED			US-ALLERGAN-1772383US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327389	NON-EXPEDITED			US-ALLERGAN-1769710US		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Head Discomfort; Nervous System Disorder; Prescription Drug Used Without A Prescription	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327391	NON-EXPEDITED			US-ALLERGAN-1763097US		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia	Lexapro			S	Unknown	Unk Unk, Qam		Allergan	
	Ampyra			S	Oral	10 Mg, Qam		Not Reported	
	Gilenya			C		Unk, Qpm		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327392	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1755113US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Aggression; Asthenia;	Lexapro	S	Oral	10 Mg, Qd	Allergan
Cardiac Disorder; Chest	Oxazepam	C	Unknown	Unk, Unknown	Not Reported
Pain; Contusion;	Oxazepam	C			Not Reported
Decreased Appetite; Fall;					
Mobility Decreased;					
Nausea; Speech Disorder;					
Suicidal Ideation; Tremor;					
Vision Blurred					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327393	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1753276US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Lexapro			S	Oral	10 Mg, Qd		Allergan	
Exposure During Pregnancy	Omega 3			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327394	NON-EXPEDITED			US-ALLERGAN-1748675US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Insomnia	Lexapro			S	Unknown	10 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327395	NON-EXPEDITED			US-ALLERGAN-1759035US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	30 Mg, Qd		Allergan	
	Lexapro			S	Unknown	20 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327396	NON-EXPEDITED			US-ALLERGAN-1749266US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dizziness; Eye Pain; Feeling Abnormal; Headache; Photophobia; Visual Impairment		Lexapro	S	Unknown					Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327397	NON-EXPEDITED			US-ALLERGAN-1754169US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness; Product Dose Omission	Lexapro			S	Oral	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327398	NON-EXPEDITED			US-ALLERGAN-1771840US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Fatigue; Menstrual Disorder; Paranoia	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Lexapro			S	Unknown	5 Unk, Unk		Allergan	
	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Lexapro			S	Unknown	12.5 Mg, Unk		Allergan	
	Lexapro			S	Unknown	15 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327399	NON-EXPEDITED			US-ALLERGAN-1771879US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Medication Error; Off Label Use; Product Dose Omission	Lexapro			S	Unknown	25 Mg, Unk		Allergan	
	Diphenoxylate/ Atropine			C	Oral	1 Df, Prn		Not Reported	
	Plavix			C	Oral	75 Mg, Qd		Not Reported	
	Benazepril			C	Oral	40 Mg, Qd		Not Reported	
	Amlodipin			C		5 Mg, Qd		Not Reported	
	Ativan			C	Unknown	0.5 Mg, Bid		Not Reported	

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Zocor	C	Oral	2.5 Mg, Qd	Not Reported
Metoprolol	C	Unknown	25 Mg, Qd	Not Reported
Folic Acid	C		400 Mg, Qd	Not Reported
Vitamin D2	C		1 Df, Q Week	Not Reported
Aspirin	C	Oral	81 Mg, Qd	Not Reported
Gabapentin	C		100 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327400	NON-EXPEDITED			US-ALLERGAN-1769084US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Muscular Weakness	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327401	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1755141US		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Disturbance In Attention	Lexapro			S	Unknown	Unk, Qd		Allergan	
	Zoloft			S	Unknown	125 Mg, Qd		Not Reported	
	Wellbutrin			S	Unknown	Unk, Qd		Not Reported	
	Cymbalta			S	Unknown	30 Mg, Unk		Not Reported	
	Concerta			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327402	NON-EXPEDITED			US-ALLERGAN-1755787US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration	Lexapro			S	Unknown	Unk, Bid		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327403	NON-EXPEDITED			US-ALLERGAN-1750058US		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations; Product Dose Omission; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Unknown		Allergan	
	Lexapro			S	Unknown	5 Mg, Unknown		Allergan	
	Adderall			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327404	NON-EXPEDITED			US-ALLERGAN-1764052US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown			Allergan	
	Topamax			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327405	NON-EXPEDITED			US-ALLERGAN-1756400US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327406	NON-EXPEDITED			US-ALLERGAN-1752446US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Body Height Decreased; Disturbance In Attention; Dizziness; Drug Ineffective; Weight Increased	Lexapro			S	Unknown			Allergan	
	Effexor			S	Oral	Unk, Qd		Not Reported	
	Effexor			S				Not Reported	
	Effexor			S				Not Reported	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327407	NON-EXPEDITED			US-ALLERGAN-1749085US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327410	NON-EXPEDITED			US-ALLERGAN-1815793US		51 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Panic Attack; Suicidal Behaviour	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327411	NON-EXPEDITED			US-ALLERGAN-1803583US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Agitation; Vision Blurred	Lexapro			S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327412	NON-EXPEDITED			US-ALLERGAN-1802009US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acne; Anorgasmia;	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
Anxiety; Head Discomfort;	Lexapro			S	Unknown	7.5 Mg, Unk		Allergan	
Panic Attack; Withdrawal Syndrome	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Lexapro			S	Unknown	2.5 Mg, Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327413	NON-EXPEDITED			US-ALLERGAN-1817150US			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Disorder; Product Dose Omission; Somnolence	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327414	NON-EXPEDITED			US-ALLERGAN-1773204US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327415	NON-EXPEDITED			US-ALLERGAN-1772819US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hypersensitivity; Off Label Use; Pruritus; Swelling Face; Urticaria	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qod		Allergan	
	Imitrex			C	Oral	Unk Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327416	NON-EXPEDITED			US-ALLERGAN-1805533US		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Paraesthesia	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327417	NON-EXPEDITED			US-ALLERGAN-1812317US			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Night Sweats	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327418	NON-EXPEDITED			US-ALLERGAN-1804416US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Dry Throat; Productive Cough	Lexapro			S	Oral	10 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327423	NON-EXPEDITED			US-ALLERGAN-1803684US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Gastrooesophageal Reflux Disease	Lexapro			S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327424	NON-EXPEDITED			US-ALLERGAN-1803341US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypertension; Off Label Use	Escitalopram Oxalate - Bp Use			S	Unknown	7.5 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327425	NON-EXPEDITED			US-ALLERGAN-1815255US		57 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tremor	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327426	NON-EXPEDITED			US-ALLERGAN-1811680US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Dry Mouth	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327427	NON-EXPEDITED				US-ALLERGAN-1804597US		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Eyelid Disorder; Headache	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Detrol La			C	Oral	Unk		Not Reported	
	Lisinopril			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327428	NON-EXPEDITED				US-ALLERGAN-1812387US		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Off Label Use	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qam		Allergan	
	Multivitamins			C	Oral	Unk		Not Reported	
	Ergocalciferol			C	Oral	2000 Units, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327429	NON-EXPEDITED				US-ALLERGAN-1816156US	55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Lexapro			S	Unknown	80 Mg, Unk		Allergan	
	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Ativan			C	Oral	Unk, 1-2 Times A Day		Not Reported	
	Lipitor			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327430	NON-EXPEDITED			US-ALLERGAN-1812450US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenopia; Eye Allergy; Off Label Use; Product Dispensing Error	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan	
	Procardia			C	Unknown			Not Reported	
	Lisinopril			C	Unknown			Not Reported	
	Omeprazole			C	Unknown			Not Reported	
	Aspirin			C	Unknown	81 Mg, Unk		Not Reported	
	Lorazepam			C	Unknown	4 Mg, Qhs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327431	NON-EXPEDITED			US-ALLERGAN-1815337US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327432	NON-EXPEDITED			US-ALLERGAN-1814011US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraesthesia	Lexapro			S	Oral	Unk		Allergan	
	Xanax			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327433	NON-EXPEDITED			US-ALLERGAN-1819467US		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Off Label Use	Lexapro	S	Oral	5 Mg, Qd	Allergan
	Atenolol	C	Oral	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327434	NON-EXPEDITED			US-ALLERGAN-1816251US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Chills; Decreased Appetite; Depression; Disturbance In Attention; Drug Ineffective; Hot Flush; Weight Decreased	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
	Prempro			S		Unk		Not Reported
	Xanax			S	Oral	0.5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327435	NON-EXPEDITED			US-ALLERGAN-1816762US		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327436	NON-EXPEDITED			US-ALLERGAN-1809390US		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327437	NON-EXPEDITED			US-ALLERGAN-1812427US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Eye Pain; Fatigue; Headache; Insomnia	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan

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		Lorazepam	C	Unknown	Unk			Not Reported	
		Fosamax	C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327438	NON-EXPEDITED			US-ALLERGAN-1813935US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Erectile Dysfunction; Eye Pain; Sexual Dysfunction	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported	
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327439	NON-EXPEDITED			US-ALLERGAN-1817309US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Drug Hypersensitivity; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327440	NON-EXPEDITED			US-ALLERGAN-1773401US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sedation	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327441	NON-EXPEDITED			US-ALLERGAN-1816287US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	

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28-Aug-2018	15327442	NON-EXPEDITED			US-ALLERGAN-1820022US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Decreased Appetite; Dermatitis; Disturbance In Sexual Arousal; Dry Skin; Erectile Dysfunction; Fatigue; Gingival Atrophy; Gingivitis; Pain Of Skin; Palpitations; Pruritus; Rash Macular; Rash Macular; Self-Injurious Ideation; Squamous Cell Carcinoma; Toothache; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported	
	Salicylic Acid			S	Topical	Unk		Not Reported	
	Lisinopril			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Valium			C		Unk		Not Reported	
	Budesonide			C	Oral			Not Reported	
	Carvedilol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327443	NON-EXPEDITED			US-ALLERGAN-1803085US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	15 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327444	NON-EXPEDITED			US-ALLERGAN-1827796US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Off Label Use	Lexapro			S	Unknown	60 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	

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28-Aug-2018	15327445	NON-EXPEDITED			US-ALLERGAN-1831662US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Panic Attack; Therapeutic Response Decreased	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Unknown	15 Mg, Unk		Allergan	
	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Prozac			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327449	NON-EXPEDITED			US-ALLERGAN-1827749US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327450	NON-EXPEDITED			US-ALLERGAN-1823919US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Discharge	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327451	NON-EXPEDITED			US-ALLERGAN-1832673US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Muscle Spasms; Nausea	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Metoprolol			C	Oral	Unk, Qd		Not Reported	
	Omeprazole			C	Oral	Unk, Qd		Not Reported	

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	Hydrocodone	C	Oral	Unk	Not Reported
	Dicyclomine	C	Oral	Unk, Qd	Not Reported
	Potassium	C	Oral	Unk, Qd	Not Reported
	Claritin	C	Oral	Unk	Not Reported
	Magnesium	C	Oral	Unk Unk, Qd	Not Reported
	Cozaar	C	Oral	Unk Unk, Qd	Not Reported
	Albuterol Sulfate	C	Respiratory (inhalation)	Unk Unk, Qd	Not Reported
	Ondansetron	C	Oral	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327452	NON-EXPEDITED			US-ALLERGAN-1831985US		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sleep Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Protonix			C	Oral	Unk		Not Reported
	Coreg			C	Oral	Unk		Not Reported
	Iron			C	Oral	Unk		Not Reported
	Prenatal Vitamins			C	Oral	Unk		Not Reported
	Lipitor			C	Oral	Unk		Not Reported
	Plavix			C	Oral	Unk		Not Reported
	Flomax			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327453	NON-EXPEDITED			US-ALLERGAN-1830866US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Dose Omission	Lexapro			S	Oral	Unk, Qd		Allergan

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327454	NON-EXPEDITED			US-ALLERGAN-1832570US		49 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327455	NON-EXPEDITED			US-ALLERGAN-1827993US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use; Off Label Use	Lexapro			S	Unknown	100 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327456	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1829555US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression; Suicide Attempt	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327457	NON-EXPEDITED			US-ALLERGAN-1825194US		< 1 DAY	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Muscle Spasticity	Lexapro			S	Transplacental	20 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327458	NON-EXPEDITED			US-ALLERGAN-1803800US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Drug Intolerance; Nausea; Off Label Use	Lexapro	S	Unknown	400 Mg, Unk	Allergan
	Lexapro	S	Unknown	300 Mg, Unk	Allergan
	Clonazepam	C	Unknown	0.5 Mg, Unk	Not Reported
	Bupropion Hcl Er	C	Unknown	150 Mg, Unk	Not Reported
	Wellbutrin	C	Unknown	350 Mg, Qd	Not Reported
	Wellbutrin	C	Unknown	150 Mg, Qd	Not Reported
	Gabapentin	C	Unknown	750 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327459	NON-EXPEDITED			US-ALLERGAN-1816843US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Increased Tendency To Bruise; Swelling; Swelling Face	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327460	NON-EXPEDITED			US-ALLERGAN-1826477US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Off Label Use	Lexapro			S	Unknown	20 Mg, Qd		Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan
	Lexapro			S				Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327461	NON-EXPEDITED			US-ALLERGAN-1823001US		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dry Mouth; Off Label Use; Wrong Technique In Product Usage Process	Lexapro			S	Oral	5 Mg, Unk		Allergan
	Temazepam			C	Oral	30 Mg, Qd		Not Reported

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28-Aug-2018	15327462	NON-EXPEDITED			US-ALLERGAN-1823092US		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Personality Change; Rapid Eye Movements Sleep Abnormal	Lexapro			S	Oral	15 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Lorazepam			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327463	NON-EXPEDITED			US-ALLERGAN-1831327US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	25 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327464	NON-EXPEDITED			US-ALLERGAN-1823979US		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Remeron			S		15 Mg, Unk		Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Methotrexate			S	Oral	9 Df, Q Week		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Cymbalta			S				Not Reported	
	Atorvastatin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Cardiazem			C		240 Mg, Qd		Not Reported	
	Carvedilol			C	Oral	12.5 Mg, Qd		Not Reported	
	Cozaar			C	Oral	25 Mg, Qd		Not Reported	

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Potassium	C	Oral	10 Meq, Qd	Not Reported
Pantoprazole	C			Not Reported
Folic Acid	C	Oral	1 Mg, Unk	Not Reported
Aldactone	C	Oral	2 Df, Qd	Not Reported
Hydrocodone	C	Oral	1 Df, Unk	Not Reported
Tramadol	C		Unk Unk, Prn	Not Reported
Bumex	C	Oral	2 Mg, Qd	Not Reported
Gabapentin	C		400 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327465	NON-EXPEDITED			US-ALLERGAN-1827021US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Drug Ineffective	Lexapro			S	Unknown			Allergan	
	Cipro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327466	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1833835US		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Confusional State; Dizziness; Drug Ineffective; Dry Eye; Insomnia; Vision Blurred; Wrong Technique In Product Usage Process	Lexapro			S	Oral	7.5 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Lexapro			S	Oral	2.5 Mg, Qd		Allergan	
	Vitamin B-12			C	Unknown	Unk		Not Reported	
	Vitamin C			C	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	Unk		Not Reported	
	Statin			C	Unknown	Unk		Not Reported	
	Propafenone			C	Unknown	Unk		Not Reported	
	Eliquis			C	Oral	25 Mg, Qd		Not Reported	
	Fish Oil			C	Oral	Unk Unk, Qd		Not Reported	

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		B Vitamin Comp	C	Oral		Unk Unk, Qd		Not Reported	
		Melatonin	C	Oral		Unk Unk, Prn		Not Reported	
		Mirtazapine	C	Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327468	NON-EXPEDITED			US-ALLERGAN-1827797US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Off Label Use	Lexapro			S	Unknown	60 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327470	NON-EXPEDITED			US-ALLERGAN-1830230US		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Dose Omission	Lexapro			S	Unknown	5 Mg, Qhs		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327471	NON-EXPEDITED			US-ALLERGAN-1833309US		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Vision Blurred	Lexapro			S	Unknown	Unk		Allergan	
	Humira			S	Subcutaneous	Unk Unk, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327472	NON-EXPEDITED			US-ALLERGAN-1825187US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety	Lexapro			S	Unknown			Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327473	NON-EXPEDITED			US-ALLERGAN-1829418US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Lexapro			S	Intramuscular	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327474	NON-EXPEDITED			US-ALLERGAN-1832125US		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Cough;	Lexapro			S	Oral	15 Mg, Unk		Allergan	
Insomnia; Laryngitis;	Lexapro			S	Oral	20 Mg, Qd		Allergan	
Nasal Dryness; Off Label	Faslodex			C	Intramuscular	Unk Unk, Q Month		Not Reported	
Use; Weight Decreased;									
Weight Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327475	NON-EXPEDITED			US-ALLERGAN-1824629US		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Hypoaesthesia;	Lexapro			S	Unknown	Unk		Allergan	
Influenza Like Illness;									
Nausea; Night Sweats;									
Panic Attack;									
Paraesthesia; Tremor;									
Withdrawal Syndrome									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327476	NON-EXPEDITED			US-ALLERGAN-1827995US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	80 Mg, Unk		Allergan	

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28-Aug-2018	15327477	NON-EXPEDITED			US-ALLERGAN-1832205US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gait Disturbance	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327478	NON-EXPEDITED			US-ALLERGAN-1825193US		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pregnancy	Lexapro			S	Unknown	20 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327479	NON-EXPEDITED			US-ALLERGAN-1827994US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	100 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327480	NON-EXPEDITED			US-ALLERGAN-1836678US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327481	NON-EXPEDITED			US-ALLERGAN-1835526US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression;	Lexapro			S	Unknown	Unk		Allergan	

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Dizziness; Lacrimation	Lexapro	S	Unknown	40 Mg, Unk	Allergan
Increased; Nausea; Oedema	Viibryd	S	Unknown	Unk	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327482	NON-EXPEDITED			US-ALLERGAN-1837226US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Unk		Allergan
	Advil			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Baby Aspirin			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Omega 3			C		Unk		Not Reported
	D3			C		2000 Mg, Unk		Not Reported
	B12			C		Unk		Not Reported
	Osteo Bi-Flex			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327483	NON-EXPEDITED			US-ALLERGAN-1833861US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327484	NON-EXPEDITED			US-ALLERGAN-1834685US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Increased Appetite; Weight Increased	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Acetaminophen			C				Not Reported

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		Bupropion Hydrochloride		C					Not Reported
		Buspirone Hydrochloride		C					Not Reported
		Clonazepam		C					Not Reported
		Docusate Sodium		C					Not Reported
		Gabapentin		C					Not Reported
		Letrozole		C					Not Reported
		Ondansetron		C					Not Reported
		Oxycodone Hydrochloride		C					Not Reported
		Pantoprazole Sodium		C					Not Reported
		Preservision Areds		C					Not Reported
		Promethazine Hydrochloride		C					Not Reported
		Sertraline Hydrochloride		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327485	NON-EXPEDITED			US-ALLERGAN-1834785US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327489	NON-EXPEDITED			US-ALLERGAN-1825972US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Cymbalta			C	Oral	Unk		Not Reported	
	Prozac			C	Oral	Unk		Not Reported	
	Trazodone			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327493	NON-EXPEDITED			US-ALLERGAN-1834457US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Unknown	20 Mg, Unk		Allergan	

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28-Aug-2018	15327494	NON-EXPEDITED			US-ALLERGAN-1837325US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327495	NON-EXPEDITED			US-ALLERGAN-1835958US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Pruritic	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate Unk			S				Allergan	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Flonase			C	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Loratadine			C	Unknown	Unk		Not Reported	
	Baby Aspirin			C	Unknown	Unk		Not Reported	
	B Complex			C	Unknown	Unk		Not Reported	
	Vitamin D2			C				Not Reported	
	Fish Oil			C	Unknown	Unk		Not Reported	
	Multivitamins			C	Unknown	Unk		Not Reported	
	Calcium Citrate			C	Unknown	Unk		Not Reported	
	Miralax			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327496	NON-EXPEDITED			US-ALLERGAN-1837791US		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Feeling Abnormal; Libido Decreased; Sexual	Lexapro			S	Oral	Unk, Bid		Allergan	
	Lexapro			S				Allergan	

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Dysfunction

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327497	NON-EXPEDITED			US-ALLERGAN-1834906US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327751	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1000028164		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Presyncope	Escitalopram Oxalate Unk			S	Oral	1 Df, Qd		Allergan	
	Microser			S	Oral	2 Df, Qd		Not Reported	
	Lyrica			S	Oral	2 Df, Qd		Not Reported	
	Lansoprazole			C	Unknown	Unk		Not Reported	
	Simvastatin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15341984	DIRECT					22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enuresis; Intentional Product Misuse; Intentional Product Use Issue	Vyvanse			S	Oral	Quantity:1 Capsule(S);		Not Reported	
	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Phenibut			C				Not Reported	
	Magnesium			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Vitamin C			C				Not Reported	
	Vitamin K2 Mk-7			C				Not Reported	
	N-Acetul Cystine			C				Not Reported	
	Zinc And Cooper			C				Not Reported	
	Calcium			C				Not Reported	

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Aged Garlic Powder Pills	C	Not Reported
Astaxanthin	C	Not Reported
Spirulina	C	Not Reported

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29-Aug-2018	15111680	EXPEDITED (15-DAY)		HO, LT	PHHY2018DE036016		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Qd		Novartis
	Esomeprazole			S	Unknown	40 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	2 Df, Qd		Not Reported
	Ivabradine			C	Unknown	15 Mg, Qd		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported
	Naloxone			C	Unknown	10 Gtt, Unk		Not Reported
	Scopolamine			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Prednisolon			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	L-Thyroxine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15211689	EXPEDITED (15-DAY)		OT	PHHY2018IT056779		85 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sopor	Delorazepam			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Novartis
	Venlafaxine			S	Oral	1 Mg/L, Qd		Not Reported
	Cipralext			S	Oral	Unk		Not Reported

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Donepezil	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Madopar	C	Unknown	Unk	Not Reported
Terazosin Hydrochloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15298011	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1840548US		90 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Per Day		Allergan
	Eliquis			S	Unknown	5 Mg, Bid		Not Reported
	Eliquis			S	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15328964	EXPEDITED (15-DAY)		DE	FR-ACCORD-071082		69 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Escitalopram			S	Oral			Not Reported
	Furosemide			S	Oral			Accord
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Intravenous drip			Accord
	Bisoprolol			S				Not Reported
	Methotrexate			S	Intravenous drip			Accord
	Doxorubicin			S	Intravenous drip			Accord
	Pantoprazole			S	Intravenous drip			Not Reported
	Fungizone			S	Buccal			Not Reported
	Exacyl			S	Intravenous drip			Not Reported
	Vincristine			S	Intravenous drip			Not Reported
	Eprex			S	Subcutaneous			Not Reported
	Zarzio			S	Subcutaneous			Not Reported

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Meropenem/Meropenem Trihydrate	S	Intravenous drip	Not Reported
Hextril	S	Buccal	Not Reported
Lidocaine	S	Buccal	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Calciparine	S	Subcutaneous	Not Reported
Voraxaze	S	Intravenous drip	Not Reported
Valaciclovir	S	Oral	Not Reported
Cyclophosphamide/Cyclophosphamide Monohydrate	S	Intravenous drip	Not Reported
Prednisone	S	Intravenous drip	Not Reported
Ondansetron	S	Oral	Not Reported
Sulfamethoxazole/Trimethoprim	S	Oral	Not Reported
Bromazepam	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15328992	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-182759		59 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	()		Sun
	Escitalopram			S	Unknown	()		Not Reported
	Trilafon			S	Oral	()		Not Reported
	Ramipril			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15330451	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2018341292		23 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous	Xanax			S	Oral	0.5 Mg, 1x/Day		Pfizer
	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer

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Donormyl [Doxylamine Succinate]	S	Oral	Unk	Not Reported
Seroplex	S	Oral	20 Mg, 1x/Day (In The Morning)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15331775	EXPEDITED (15-DAY)		LT, OT	NO-OTSUKA-2018_029547		56 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite;	Abilify			S	Oral	Unk		Otsuka
Dehydration;	Trilafon			S	Oral	Unk		Not Reported
Haemorrhage;	Cymbalta			S	Oral	Unk		Not Reported
Hyperhidrosis; Muscle	Remeron			S	Oral	Unk		Not Reported
Rigidity; Nausea;	Fluoxetine			S	Oral	Unk		Not Reported
Neuroleptic Malignant	Efexor Depot			S	Oral	Unk		Not Reported
Syndrome; Product Use In	Stemetil			S	Oral	Unk		Not Reported
Unapproved Indication;	Ibux			S	Oral	Unk		Not Reported
Pyrexia; Tremor; Vomiting	Fluanxol			S	Oral	Unk		Not Reported
	Vallergan			S	Oral	Unk		Not Reported
	Nozinan			S	Oral	Unk		Not Reported
	Zyprexa			S	Oral	Unk		Not Reported
	Sobril			S	Oral	Unk		Not Reported
	Truxal			S	Oral	Unk		Not Reported
	Cipralext			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15331926	EXPEDITED (15-DAY)		LT	NO-ELI_LILLY_AND_COMP ANY-NO201808012564		56 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Dehydration;	Cymbalta			S	Oral	Unk Unk, Unknown		Eli Lilly And Co

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Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Trilafon /00023401/	S	Oral	Unk Unk, Unknown	Not Reported
	Remeron	S	Oral	Unk Unk, Unknown	Not Reported
	Fluoxetine	S	Oral	Unk Unk, Unknown	Not Reported
	Efexor	S	Oral	Unk Unk, Unknown	Not Reported
	Stemetil /00013301/	S	Oral	Unk Unk, Unknown	Not Reported
	Ibux	S	Oral	Unk Unk, Unknown	Not Reported
	Fluanxol /00109702/	S	Oral	Unk Unk, Unknown	Not Reported
	Vallergan	S	Oral	Unk Unk, Unknown	Not Reported
	Nozinan /00038601/	S	Oral	Unk Unk, Unknown	Not Reported
	Zyprexa	S	Oral	Unk Unk, Unknown	Not Reported
	Sobril	S	Oral	Unk Unk, Unknown	Not Reported
	Truxal /00012101/	S	Oral	Unk Unk, Unknown	Not Reported
	Cipralext /01588501/	S	Oral	Unk Unk, Unknown	Not Reported
	Abilify	S	Oral	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332143	EXPEDITED (15-DAY)		HO	PHHY2018IT082370		59 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Trilafon			S	Oral	Unk		Not Reported
	Ramipril			C	Oral	2.5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332176	EXPEDITED (15-DAY)		OT	NL-ALLERGAN-1841691US		26 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Sumatriptan			S	Unknown	50 Mg, Unk		Not Reported

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Muscle Tightness;	Loperamide	C	Unknown	2 Mg, Unk	Not Reported
Musculoskeletal Stiffness;	Imodium	C	Unknown	2 Mg, Qd	Not Reported
Myalgia; Serotonin	Colestyramine	C	Unknown	4 G, Q12h	Not Reported
Syndrome	Oxazepam	C		10 Mg, Unk	Not Reported
	Psylliumvezels	C		3 G, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	9660486	NON-EXPEDITED			US-PFIZER INC- 2013308886		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Metformin Hcl			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Tramadol Hcl			S		Unk		Pfizer
	Zofran			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	14180649	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1764684US		14 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Intentional Overdose; Intentional Self- Injury; Off Label Use;	Escitalopram Oxalate - Bp			S	Oral	10 Df, Unk		Allergan
Poisoning Deliberate;	Haldol			S	Oral	15 MI, Unk		Not Reported
Sluggishness; Sopor	Xanax			S	Oral	12 Df, Unk		Not Reported

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30-Aug-2018	14941504	EXPEDITED (15-DAY)		DE	FR-BIOCOMPATIBLES UK LTD-2018BTG01674			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Voraxaze			S	Intravenous drip	Unk		Unknown	
	Furosemide			S	Oral	Unk		Not Reported	
	Lidocaine			S	Buccal	Unk		Not Reported	
	Zarzio			S	Subcutaneous	Unk		Not Reported	
	Prednisone			S	Intravenous drip	Unk		Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Amphotericin B			S	Buccal	Unk		Not Reported	
	Meropenem Anhydrous			S	Intravenous drip	Unk		Not Reported	
	Valaciclovir			S	Oral	Unk		Not Reported	
	Tranexamic Acid			S	Intravenous drip	Unk		Not Reported	
	Bromazepam			S	Oral	Unk		Not Reported	
	Rituximab			S	Intravenous drip	Unk		Not Reported	
	Ciprofloxacin, Ciprofloxacin Hydrochloride			S	Intravenous drip	Unk		Not Reported	
	Pantoprazole			S	Intravenous drip	Unk		Not Reported	
	Doxorubicin Hydrochloride			S	Intravenous drip	Unk		Not Reported	
	Ondansetron			S	Oral	Unk		Not Reported	
	Sulfamethoxazole, Trimethoprim			S	Oral	Unk		Not Reported	
	Hexetidine			S	Buccal	Unk		Not Reported	
	Methotrexate			S	Intravenous drip	Unk		Not Reported	
	Epoetin Alfa			S	Subcutaneous	Unk		Not Reported	
	Heparin Calcium			S	Subcutaneous	Unk		Not Reported	
	Vincristine			S	Intravenous drip	Unk		Not Reported	
	Cyclophosphamide			S	Intravenous drip	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15312888	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2018SUN003296			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Depression; Suicide Attempt	Latuda			S	Oral	Unk		Sunovion	
	Lexapro			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15332889	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN00398			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash Pruritic	Escitalopram			S		Unk		Prinston Pharmaceutical	
	Escitalopram			S		Increased Dose		Prinston Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15332890	NON-EXPEDITED			US-PRINSTON PHARMACEUTICAL INC.-2018PRN01129			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nervousness; Therapeutic Product Effect Incomplete	Escitalopram			S		10 Mg		Prinston Pharmaceutical	
	Escitalopram			S				Prinston Pharmaceutical	
	Gabapentin			C		Unk		Not Reported	
	Gabapentin			C		100 Mg, 1x/Day At Bedtime		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15333472	EXPEDITED (15-DAY)		DE, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-07049		33 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Lamotrigine			S	Unknown	Unk		Alkem	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Propranolol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15333543	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00009656		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Unknown	
	Folio (Nahrungserganzungsmittel)			C	Transplacental	0.4 [Mg/D]		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334837	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-949742		24 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Product Substitution Issue; Tremor; Tunnel Vision	Escitalopram Teva 15 Mg Filmdragerad Tablett			S	Oral			Ivax	
	Escitalopram Teva 15 Mg Filmdragerad Tablett			S				Ivax	
	Liothyronine			C				Not Reported	
	Euthyrox			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15335304	EXPEDITED (15-DAY)		HO	PHHY2018FR080602		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence	Escitalopram			S	Oral	28 Df, Unk		Not Reported	
	Ibuprofen			S	Oral	20 Df, Unk		Novartis	
	Dafalgan			S	Oral	8 G, Unk		Not Reported	

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Paroxetine	S	Oral	12 Df, Unk	Not Reported
Havlane	S	Oral	20 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15335314	EXPEDITED (15-DAY)	OT		PHHY2017IT121515		60 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Sertraline			S	Oral	100 Mg,Qd		Not Reported
	Lorazepam			S	Unknown	2.5 Mg, Qd		Novartis
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Ciprallex			S	Unknown	20 Mg, Qd		Not Reported
	Brintellix			S	Unknown	15 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Qd		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15335645	EXPEDITED (15-DAY)	OT		US-MYLANLABS- 2018M1063383		19 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation	Xulane® (Norelgestromin And Ethinyl Estradiol Transdermal			S	Transdermal	Unk		Mylan

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System) Escitalopram			S		Topical		Unk		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
30-Aug-2018	15336349	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1842131US		83 YR	Female	FRA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Anaemia; Melaena; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan		
	Kardegic			S	Oral	1 Df, Qd		Not Reported		
	Crestor			C	Unknown			Not Reported		
	Ramipril			C	Unknown			Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
30-Aug-2018	15354991	DIRECT		OT			26 YR	Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Condition Aggravated; Self-Injurious Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported		
	Cetirizine			C				Not Reported		
	Fluticasone Peopionate Nasal Spray			C				Not Reported		
	Propionate Nasal Spray Multi-Vitamin			C				Not Reported		
	Docosahexaenoic Acid			C				Not Reported		
	Vitamin D3			C				Not Reported		
	Kavalactones			C				Not Reported		
	Melatonin			C				Not Reported		
	Naproxen			C				Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
31-Aug-2018	14170339	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017476660		14 YR	Female	ITA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Bradyphrenia; Intentional Overdose; Intentional Self-	Xanax			S	Oral	12 Df, Total		Pfizer		

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Injury; Poisoning	Haldol	S	Oral	15 MI, Total	Not Reported
Deliberate; Sluggishness; Sopor	Cipralex /01588501/	S	Oral	10 Df, Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	14170997	EXPEDITED (15-DAY)		OT	JP-SA-2017SA217862			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Off Label Use; Premature Delivery	Zolpidem Tartrate			S	Oral	Unk		Sanofi
	Escitalopram Oxalate			S	Oral	Unk Unk,Unk		Not Reported
	Yokukansan			S	Oral	Unk Unk,Unk		Not Reported
	Hirnamin (Levomepromazine)			S	Oral	40 To 225 Mg,Qd		Not Reported
	Horizon			S	Oral	2 To 5 Mg,Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	14648505	EXPEDITED (15-DAY)		DE, HO, OT	DE-PFIZER INC- 2018103600		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil Citrate			S		Unk		Pfizer
	Spironolactone			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported
	Varivax			S	Intramuscular	1 Df, Single		Not Reported
	Topiramate			S		Unk		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Exodus (Escitalopram Oxalate)			S		Unk		Not Reported
	Nutrition With Nutrini Mixed With Water			C	Other	Unk, 4x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15136760	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA- 2018_009663		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Condition Aggravated;	Aripiprazole	S	Unknown	5 Mg, Qd	Otsuka
Delirium; Drug Ineffective;	Aripiprazole	S			Otsuka
Drug Interaction;	Escitalopram Oxalate	S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)	Not Reported
Haematoma;	Escitalopram Oxalate	S	Oral	20 Mg, Qd	Not Reported
Haemorrhage; Insomnia;	Escitalopram Oxalate	S	Unknown	20 Mg, Qd (In A Morning Target Dose Of 20 Mg)	Not Reported
Menorrhagia; Product Use In Unapproved Indication;	Escitalopram Oxalate	S			Not Reported
Respiratory Tract Infection; Restlessness;	Escitalopram Oxalate	S			Not Reported
Sleep Disorder; Thinking Abnormal	Pregabalin	S	Oral	100 Mg, Qd (Evening Dose Of 100 Mg)	Not Reported
	Pregabalin	S			Not Reported
	Pregabalin	S			Not Reported
	Risperidone	S	Oral	0.5 Mg, Unk (For 10 Days)	Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Risperidone	S			Not Reported
	Opipramol	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Unk (In Crisis Situations With Temporary Effect)	Not Reported
	Promethazine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15338608	NON-EXPEDITED			US-INTERCEPT-PMOCA2018000967			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Fatigue; Pruritus	Ocaliva			S	Oral	5 Mg, Qd		Not Reported
	Ocaliva			S	Oral	10 Mg, Qd		Not Reported
	Ocaliva			S	Oral	5 Mg, Qd		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Aczone			C	Topical	5 %, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium Carbonate And Vitamin D	C	Oral		Not Reported
Estrace	C	Vaginal	2 G, Qd	Not Reported
Estrace	C		1 G, Qd	Not Reported
Estrace	C		1 G, Unk	Not Reported
Lofibra	C	Oral	54 Mg, Qd	Not Reported
Bactroban	C	Nasal	Unk Unk, Bid	Not Reported
Percocet	C		Unk Mg, Prn	Not Reported
Deltasone	C	Unknown	40 Mg, Qd	Not Reported
Ultracet	C		Unk Mg, Prn	Not Reported
Actigall	C		500 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15339088	NON-EXPEDITED			US-TEVA-2018-US-948780		90 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Dizziness; Gait Disturbance; Nausea	Venlafaxine			S	Unknown			Teva
	Zoloft			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15340389	EXPEDITED (15-DAY)		OT	HK-LANNETT COMPANY, INC.-HK-2018LAN001003		43 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Somnolence	Escitalopram Oxalate			S	Unknown	5 Mg, Unk (Nocte)		Lannett
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk (Nocte; On Day 8)		Lannett
	Escitalopram Oxalate			S	Unknown	5 Mg, Unk (Nocte)		Lannett

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15340608	EXPEDITED (15-DAY)		HO	IE-LANNETT COMPANY, INC.-IE- 2018LAN001004			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Syndrome; Drug Interaction; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Lannett	
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett	
	Lamotrigine			S	Unknown	Unk		Not Reported	
	Clobazam			C		10 Mg, Bid		Not Reported	
	Clobazam			C		10 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2018	15341635	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE- HET2018DE00844			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertensive Crisis; Hypokalaemia; Myocardial Infarction; Tachycardia	Escitalopram			S	Oral	10 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2018	15341636	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE- HET2018DE00845		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 Mg, Qd (Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D)		Hetero	
	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero	
	Folio (Nahrungsergänzungsmittel)			C	Transplacental	0.4 [Mg/D]		Not Reported	

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02-Sep-2018	15366793	DIRECT		DS			18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Dizziness; Feeling Abnormal; Insomnia; Malaise; Migraine; Panic Reaction; Product Quality Issue; Product Substitution Issue	Escitalopram 10mg Tablet		Y	S	Oral	Quantity:1 Df Dosage Form;		Aurobindo	
	Escitalopram			C				Not Reported	
	Equate Adult Multivitamins			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	8386402	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2012025457		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Presyncope	Lyrica			S	Oral	2 Df, 1x/Day		Pfizer	
	Microser			S	Oral	2 Df, 1x/Day		Not Reported	
	Entact			S	Oral	1 Df, 1x/Day		Not Reported	
	Lansoprazole			C				Not Reported	
	Simvastatin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15271574	EXPEDITED (15-DAY)		OT	PHHY2018FR070172		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Lichen Planus	Esidrex			S	Oral	25 Mg, Unk		Novartis	
	Atorvastatine			S	Oral	20 Mg, Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Esomeprazole			S	Oral	Unk		Not Reported	
	Aldactone			S	Oral	Unk		Not Reported	
	Perindopril			S	Oral	2 Mg, Unk		Not Reported	

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Kardegic	S	Oral	Unk	Not Reported
Verapamil	S	Oral	240 Mg, Unk	Not Reported
Teralithe	S	Oral	Unk	Not Reported
Seroplex	S	Oral	Unk	Not Reported
Macrogol	S	Oral	Unk	Not Reported
Xeroquel	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15297845	EXPEDITED (15-DAY)		OT	PHHY2018AT075991		21 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Olanzapine			S	Unknown	2.5 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	25 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	50 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	100 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown	80 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Unknown	40 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Unknown	80 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Unknown	75 Mg, Qd		Not Reported
	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Not Reported
	Lorazepam			S	Oral	1 Ot, Qd (2-5 Mg)		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Unknown	80 Mg, Unk		Not Reported
	Dominal (Prothipendyl Hydrochloride)			S	Unknown	40 Mg, Unk		Not Reported
	Trazodone			S	Unknown	50 Mg, Qd		Not Reported
	Trazodone			S	Unknown	100 Mg, Qd		Not Reported
	Trazodone			S	Unknown	150 Mg, Qd		Not Reported
	Diazepam			S	Unknown	5 Mg, Qd		Not Reported

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	Diazepam	S	Unknown	10 Mg, Qd	Not Reported
	Diazepam	S	Unknown	15 Mg, Qd	Not Reported
	Cipralelex	S	Unknown	5 Mg, Qd	Not Reported
	Cipralelex	S	Unknown	10 Mg, Qd	Not Reported
	Halcion	C	Unknown	0.25 Mg, Qd	Not Reported
	Zoldem	C	Unknown	10 Mg, Qd	Not Reported
	Quilonorm	C	Unknown	225 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15343257	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-043885		61 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthyroidism	Escitalopram Film-Coated Tablets 10mg Ptui			S	Unknown	10 Milligram, Daily		Aurobindo	
				C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15344186	EXPEDITED (15-DAY)		HO, LT	PHHY2018FR081755		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension	Paracetamol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Novartis	
	Escitalopram			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Ibuprofene			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15344296	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1842164US		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Lymphadenitis; Rash	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
Maculo-Papular	Lamictal	S	Oral	75 Mg, Qd	Not Reported

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03-Sep-2018	15344402	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018349120		59 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Abuse; Electrocardiogram Qt Prolonged; Moaning	Alprazolam			S	Oral			Pfizer	
	Trilafon (Perphenazine)			S	Oral	18 Df, Single		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Delorazepam			S		Unk		Not Reported	
	Ramipril			C	Oral	2.5 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15344738	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-950951		61 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthyroidism	Escitalopram Tablet, 10 Mg (Milligram)			S	Unknown	10 Milligram Daily; 1dd		Ivax	
	Ptu			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15345093	EXPEDITED (15-DAY)		HO, LT	PHHY2018ES084674		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	Unk		Not Reported	
	Enalapril+Hydrochlorothiazide			S	Oral	Unk Unk, Qd (1-0-0)		Not Reported	
	Haloperidol			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	12878030	EXPEDITED (15-DAY)		HO, LT, OT	FR-OTSUKA-DJ20128687		45 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Product Use In Unapproved Indication; Suicide Attempt	Abilify			S	Oral	10 Mg, Unk		Otsuka
	Seroplex			S	Unknown	10 Mg, Qd (Dose Increased To 10 Mg/Day)		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Seresta			S	Oral	50 Mg (Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening)		Not Reported
	Imovane			S	Oral	7.5 Mg, Qd (1 Tablet/Dy)		Not Reported
	Imovane			S	Oral	Unk, Qd		Not Reported
	Depamide			S	Oral	300 Mg, Qd		Not Reported
	Depamide			S	Oral	Unk		Not Reported
	Anafranil			S	Oral	75 Mg, Unk (Daily Dose Increased)		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	Unk		Not Reported
	Methyldopa			S	Oral	300 Mg, Unk		Not Reported
	Methyldopa			S	Oral	Unk		Not Reported
	Lexapro			S	Unknown	5 Mg, Qd		Not Reported
	Lexapro			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S		Unk		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd (1tab/Dy)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	12982206	NON-EXPEDITED			US-PFIZER INC- 2016545929		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity	Metronidazole	S	Unk	Pfizer
	Elavil	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Mycelex	S	Unk	Not Reported
	Claritin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15323984	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-182760		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral	40 Mg, Qd		Sun
	Esidrex			S	Oral	0.5 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Pravastatine			C	Unknown	()		Not Reported
	Seresta			C	Unknown	Breckable ()		Not Reported
	Dafalgan			C	Unknown	()		Not Reported
	Mediatensyl			C	Unknown	()		Not Reported
	Ramipril			C	Unknown	()		Not Reported
	Procoralan			C	Unknown	()		Not Reported
	Acebutolol			C	Unknown	()		Not Reported
	Aspirin			C	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15345603	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-183253		10 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol		Y	S	Oral	2 G In Total		Ohm Lab
	Seroplex			S	Oral	40 Mg In Total		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seresta			S		Oral		10 Mg In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
04-Sep-2018	15346144	EXPEDITED (15-DAY)		CA, DE, OT	DE-DRREDDYS-GER/GER/18/0103613		< 1 DAY	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 (Mg/D)		Not Reported		
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported		
	Paroxetine			S	Transplacental	30 [Mg/D]		Not Reported		
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 (Mg/D)		Not Reported		
	Candesartan			S	Transplacental	16 [Mg/D]		Not Reported		
	Levothyroxine Sodium			C	Transplacental			Not Reported		
	Cytotec			C	Transplacental			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
04-Sep-2018	15347829	EXPEDITED (15-DAY)		HO, OT	TW-MYLANLABS-2018M1064326		87 YR	Female	TWN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Atrioventricular Block First Degree; Bradycardia; Electrocardiogram Qt Prolonged; Hypotension	Escitalopram			S	Unknown			Not Reported		
	Escitalopram			S				Not Reported		
	Imipramine			S	Unknown	25 Mg Hs (At The Bed Time)		Not Reported		
	Imipramine			S				Not Reported		
	Alprazolam			C	Unknown			Mylan		
	Estazolam			C	Unknown			Mylan		
	Seroquel			C	Unknown	50 Mg Hs (At The Bed Time)		Mylan		
	Propranolol			C	Unknown			Mylan		
	Fentanyl			C	Intravenous (not otherwise specified)			Mylan		
Lidocaine			C	Intravenous (not			Mylan			

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Propofol	C	otherwise specified)	Mylan
Cisatracurium	C	Intravenous (not otherwise specified)	Mylan
Desflurane	C	Unknown 6% Desflurane With Oxygen	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15348097	NON-EXPEDITED			US-TEVA-2018-US-950074			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Lip Disorder; Oral Disorder	Escitalopram			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15348358	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1842492US		34 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan
	Quetiapin			S	Unknown	12.5 Mg, Unknown		Not Reported
	Pantoprazol			C	Unknown	Unk, Unknown		Not Reported
	Novaminsulfon			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15349867	EXPEDITED (15-DAY)		DE, HO	PHHY2018FR089172		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder; Pulmonary Fibrosis	Atorvastatin			S	Oral	10 Mg, Qd		Novartis
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Paracetamol			S	Oral	1500 Mg, Qd		Not Reported

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Amiodarone	S	Oral	200 Mg, Qd	Not Reported
Escitalopram	S	Oral	10 Mg, Qd	Not Reported
Ramipril	S	Oral	5 Mg, Qd	Not Reported
Levothyrox	S	Oral	1 Ot, Qd	Not Reported
Kardegic	S	Oral	1 Df, Qd	Not Reported
Caltrate Vitamine D3	S	Oral	Unk (600 Mg / 400 lu)	Not Reported
Lorazepam	S	Oral	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15068896	EXPEDITED (15-DAY)		HO, LT, OT	FR- ELI_LILLY_AND_COMP ANY-FR201806010763		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Suicide Attempt	Zyprexa			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Olanzapine			S	Unknown	15 Mg, Unknown		Eli Lilly And Co
	Lepticur			S	Unknown	Unk Unk, Unknown		Not Reported
	Depamide			S	Oral	Unk Unk, Unknown		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Daily		Not Reported
	Seroplex			S	Unknown	5 Mg, Daily		Not Reported
	Seroplex			S	Unknown	10 Mg, Unknown		Not Reported
	Dopamide			S	Oral	Unk Unk, Unknown		Not Reported
	Abilify			S	Oral	10 Mg, Unknown		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening		Not Reported
	Anafranil			S	Oral	75 Mg, Daily		Not Reported
	Lexapro			S	Unknown	10 Mg, Daily		Not Reported
	Imovane			S	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15249690	EXPEDITED (15-DAY)		CA, OT	JP-SA-2017SA217880			Unknown	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Infantile Apnoea; Premature Baby; Speech Disorder Developmental	Zolpidem Tartrate			S	Transplacental			Sanofi	
	Lexapro			S	Transplacental	Unk Unk,Unk		Not Reported	
	Yokukansan			S	Transplacental	Unk Unk,Unk		Not Reported	
	Hirnamin [Levomepromazine]			S	Transplacental	40-225 Mg/Day		Not Reported	
	Horizon			S	Transplacental	2-5 Mg/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15350471	EXPEDITED (15-DAY)		CA, DE	DE-TEVA-2018-DE-951327		< 1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Milligram Daily;		Teva	
	Escitalopram			S	Transplacental	220 Milligram Daily; 20 [Mg/D]		Ivax	
	Candesartan			S	Transplacental	16 Milligram Daily;		Not Reported	
	Paroxetine			S	Transplacental	30 Milligram Daily;		Teva	
	Nepresol (Dihydralazine Sulfate)			S	Transplacental	25 Milligram Daily;		Not Reported	
	L-Thyroxin 50			C	Transplacental			Not Reported	
	Cytotec			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15350546	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-071277		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Neuroleptic Malignant Syndrome; Product Administration Error	Escitalopram			S	Intramuscular			Not Reported	
	Zuclopenthixol			S				Not Reported	
	Zuclopenthixol			S				Not Reported	
	Cyamemazine/Cyamemazine Tartrate			S		25 Mg To 75 Mg Daily		Not Reported	
	Zuclopenthixol			S		Titrated From 5 To 40mg Daily Over 2 Weeks		Not Reported	

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	Bisoprolol	C		Not Reported
	Atorvastatin	C		Not Reported
	Metformin	C		Not Reported
	Cyamemazine	S	50 Mg To 100 Mg Daily	Not Reported
	Cyamemazine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15350573	EXPEDITED (15-DAY)		DE, HO	FR-MERCK KGAA-2054619		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder; Pulmonary Fibrosis	Novothyrox			S	Oral			Merck Kgaa
	Atorvastatine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Caltrate Vitamine D3 (Lekovit Ca)			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15351541	EXPEDITED (15-DAY)		OT	FR-ACCORD-071330			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Amnesia; Arthralgia; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus;	Simvastatin			S				Accord
	Atenolol/Atenolol Hydrochloride			S				Accord
	Zyloric			S				Not Reported
	Levothyroxine			S	Oral			Not Reported
	Cotareg			S				Not Reported
	Amlor			S				Not Reported
	Oxazepam			S				Not Reported
	Uvedose			S				Not Reported

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Urticaria; Vertigo; Vision Blurred	Imovane	S					Not Reported
	Seroplex	S					Not Reported
	Herbal Extract Nos/Vitis Vinifera	S		2 To 3 Cp / D			Not Reported
	Diclofenac	S		2x / Week			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15352555	EXPEDITED (15-DAY)		LT, OT	PHHY2018FR088385		47 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Unk (Inconnue)		Novartis
	Mirtazapine			S	Oral	Unk (Inconnue)		Not Reported
	Escitalopram			S	Oral	Unk (Inconnue)		Not Reported
	Methadone			S	Oral	Unk (Inconnue)		Not Reported
	Havlane			S	Oral	Unk (Inconnue)		Not Reported
	Theralene			S	Oral	Unk (Inconnue)		Not Reported
	Tercian			S	Oral	Unk (Inconnue)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15352560	EXPEDITED (15-DAY)		LT	PHHY2018NO089260		56 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral	Unk		Novartis
	Trilafon			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported
	Efexor			S	Oral	Unk		Not Reported
	Stemetil			S	Oral	Unk		Not Reported
	Ibux			S	Oral	Unk		Not Reported
	Fluanxol			S	Oral	Unk		Not Reported
	Vallergan			S	Oral	Unk		Not Reported

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Nozinan	S	Oral	Unk	Not Reported
Zyprexa	S	Oral	Unk	Not Reported
Sobril	S	Oral	Unk	Not Reported
Truxal	S	Oral	Unk	Not Reported
Cipralex	S	Oral	Unk	Not Reported
Abilify	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15353619	EXPEDITED (15-DAY)		CA, DE	DE-ANIPHARMA-2018-DE-000151			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Foetal Exposure During Pregnancy	Candesartan Cilexetil			S	Other	16 Mg Daily		Ani
	Escitalopram			S	Other	Daily		Not Reported
	Levetiracetam			S	Other	1500 Mg Daily		Not Reported
	Nepresol (Dihydralazine Mesilate)			S	Other	25 Mg Daily		Not Reported
	Cytotec			S	Other	Unk		Not Reported
	Paroxetine			S	Other	30 Mg Daily		Not Reported
	Thyroxin			C	Other	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	10754169	EXPEDITED (15-DAY)		HO	FR-ROCHE-1529544		36 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyramidal Tract Syndrome; Tremor	Valium			S	Oral			Not Reported
	Teralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tablets		Not Reported
	Seroplex			S	Oral	10 Mg 60 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	12784788	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160924928			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Interstitial Lung Disease	Ixprim			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Triatec (Ramipril)			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Seresta			C	Oral			Not Reported
	Lasilix			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	14823712	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-022851		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Delirium; Drug Ineffective; Drug Interaction; Haematoma; Haemorrhage; Insomnia; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder; Thinking Abnormal	Escitalopram			S	Unknown	15 Milligram, Daily (Reduced)		Aurobindo
	Escitalopram			S	Oral	20 Milligram, Daily (Increased To 20 Mg In Morning)		Aurobindo
	Escitalopram			S	Oral	(Evening Dose)100 Milligram		Aurobindo
	Pregabalin			S				Not Reported
	Pregabalin			S	Unknown	0.5 Mg, Unk (For 10 Days)		Not Reported
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo

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	Aripiprazole	S	Unknown	5 Milligram, Once A Day	Aurobindo
	Promethazine	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Opipramol	C	Unknown	In Crisis Situations With Temporary Effect ()	Not Reported
	Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
	Pregabalin	C	Intracardiac	In The Evening	Not Reported
	Pregabalin	C	Unknown	100 Milligram, Once A Day	Not Reported
	Pregabalin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15135199	EXPEDITED (15-DAY)	HO		DE- GLAXOSMITHKLINE- DE2018119799		28 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Risperidone			S	Unknown	Unk		Glaxosmithkline
	Risperidone			S				Glaxosmithkline
	Risperidone			S				Glaxosmithkline
	Quetiapine			S	Unknown	Unk		Glaxosmithkline
	Quetiapine			S				Glaxosmithkline
	Duloxetine			S	Unknown	Unk		Glaxosmithkline
	Bupropion			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Zopiclone			S	Unknown	Unk		Glaxosmithkline
	Oxazepam			S	Unknown	Unk		Glaxosmithkline
	Oxazepam			S				Glaxosmithkline
	Olanzapine			S	Unknown	Unk		Glaxosmithkline
	Venlafaxine			S	Unknown	Unk		Glaxosmithkline
	Promethazine			S	Unknown	Unk		Glaxosmithkline
	Biperiden			S	Unknown	Unk		Not Reported
	Biperiden			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clozapine	S	Unknown	75 Mg, Unk	Not Reported
Clozapine	S			Not Reported
Fluoxetine	S	Unknown	Unk	Not Reported
Fluoxetine	S			Not Reported
Aripiprazole	S	Unknown	Unk	Not Reported
Aripiprazole	S			Not Reported
Mirtazapine	S	Unknown	Unk	Not Reported
Amisulpride	S	Unknown	Unk	Not Reported
Amisulpride	S			Not Reported
Zonisamide	C	Unknown	Up To 100mg	Glaxosmithkline
Brivaracetam	C	Unknown	Unk	Not Reported
Oxcarbazepine	C	Unknown	Unk	Not Reported
Carbamazepine	C	Unknown	Unk	Not Reported
Clobazam	C	Unknown	Up To 20mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15289901	EXPEDITED (15-DAY)	DE		US-PFIZER INC-2018331615		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anion Gap;	Propanolol Hcl			S		Unk		Unknown
Arrhythmia;	Escitalopram			S		Unk		Not Reported
Atrioventricular Block;	Lamotrigine			S		Unk		Not Reported
Bradycardia; Coma;								
Delirium; Depressed Level Of Consciousness;								
Dystonia;								
Electrocardiogram Qrs Complex Prolonged;								
Electrocardiogram Qt Prolonged; Hyperreflexia;								
Hyperthermia;								
Hypoglycaemia;								
Hypotension; Metabolic Acidosis; Muscle Rigidity;								
Myocardial Infarction;								
Myocardial Ischaemia;								

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Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Toxicity To Various
Agents; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15320718	EXPEDITED (15-DAY)		OT	PHHY2017IT193539		60 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Sertraline			S	Oral	100 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Lorazepam			S	Unknown	2.5 Mg, Qd		Novartis
	Brintellix			S	Unknown	15 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Qd		Not Reported
	Warfarin			C	Unknown			Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Alprazolam			C	Unknown			Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Amiodarone			C	Unknown			Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Triatec Hct			C	Unknown	15 Mg,Qd		Not Reported
	Cordarone			C	Unknown	200 Mg,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15354658	EXPEDITED (15-DAY)		CA, DE, OT	DE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	DEU

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MAC2018016490

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Foetal Exposure During Pregnancy	Candesartan			S	Transplacental	16 Milligram, Qd, (0. - 4.4. Gestational Week)		Macleods
	Escitalopram			S	Transplacental	220 Milligram, Qd, 1 {Trimester} , 4.4. - 11.5. Gestational Week, (20mg/D)		Macleods
	Levetiracetam			S	Transplacental	1500 Milligram, Qd, 1 {Trimester}, (0. - 11.5. Gestational Week)		Not Reported
	Nepresol (Dihydralazine Sulfate)			S	Transplacental	25 Milligram, Qd, 1 {Trimester}, (4.4. - 11.5. Gestational Week)		Not Reported
	L-Thyroxine Sodium			C	Transplacental	Unk (0. - 11.5. Gestational Week)		Not Reported
	Cytotec			C	Transplacental	Unk (11. - 11.5. Gestational Week)		Not Reported
	Paroxetine			S	Transplacental	30 Milligram, Qd, 1 {Trimester}, (0. - 4.4. Gestational Week)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15354815	EXPEDITED (15-DAY)		CA, DE, OT	DE-AUROBINDO-AUR-APL-2018-044247			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Foetal Exposure During Pregnancy	Candesartan			S	Transplacental	16 Milligram, Daily		Not Reported
	Escitalopram			S	Transplacental	220 Milligram, Daily		Aurobindo
	Levetiracetam			S	Transplacental	1500 Milligram, Daily		Aurobindo
	Paroxetine			S	Transplacental	30 Milligram, Daily		Aurobindo

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	Nepresol /00007602/	S	Transplacental	25 Milligram, Daily	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Thyroxin	C	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15355454	EXPEDITED (15-DAY)		CA, DE, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-06221			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Mg, Qd		Lupin	
	Escitalopram			S	Transplacental	220 Mg, Qd		Not Reported	
	Paroxetine			S	Transplacental	30 Mg, Qd		Not Reported	
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported	
	Nepresol /00007602/			S	Transplacental	25 Mg, Qd		Not Reported	
	L-Thyroxin /00068001/			C	Transplacental	Unk		Not Reported	
	Cytotec			C	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15355530	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2018DE00883			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	1x Täglich Morgens		Hetero	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15355651	EXPEDITED (15-DAY)		HO, LT, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2018016505			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Intentional Overdose; Neuroleptic Malignant Syndrome; Product Administration Error; Vasoplegia Syndrome	Escitalopram Oxalate	S	Unknown	10 Milligram, Qd	Macleods
	Cyamemazine	S	Unknown	Unk, 25 Mg To 75 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	Unk, 50 Mg To 100 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	50 Milligram, Qd	Not Reported
	Cyamemazine	S	Oral	750 Milligram, 1 Total, Tablet	Not Reported
	Lercanidipine	S	Oral	300 Milligram, 1 Total, Tablet	Not Reported
	Lercanidipine	S	Unknown	Unk	Not Reported
	Zuclopenthixol Acetate	S	Intramuscular	100 Milligram	Not Reported
	Zuclopenthixol Decanoate	S	Unknown	300 Milligram, 1 Month, Injection	Not Reported
	Zuclopenthixol Hydrochloride	S	Oral	Unk, Titrated From 5 To 40mg Daily Over 2 Weeks	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Metformin Hydrochloride	C	Unknown	Unk	Macleods
	Bisoprolol	C	Unknown	Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	4 Mg/Hour	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15356556	EXPEDITED (15-DAY)		OT	BR-ALLERGAN- 1842949US		34 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Diabetes Mellitus; Fatigue; Hypersomnia; Off Label Use; Somnolence	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15356558	EXPEDITED (15-DAY)		OT	DE-ALLERGAN- 1842966US		31 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion; Dizziness; Headache; Heart Rate Irregular; Mania	Escitalopram Oxalate - Bp			S	Unknown	20mg/ML; One Drop		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20mg/ML; One Drop		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15357767	EXPEDITED (15-DAY)		CA, DE	DE-ALLERGAN-1842819US		< 1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan	
	Levetiracetam			S	Transplacental	1500 Mg, Qd		Not Reported	
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 Mg, Qd		Not Reported	
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported	
	Paroxetine			S	Transplacental	30 Mg, Qd		Not Reported	
	L-Thyroxin 50			C	Transplacental	Unk Unk, Qd		Not Reported	
	Cytotec			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15357874	EXPEDITED (15-DAY)		CA	PHHY2018DE085657		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Fallot'S Tetralogy	Metoprolol			S	Transplacental	Maternal Dose: 71.25 Mg, Qd (47.5-0-23.75 Mg, Qd)		Novartis	
	Amitriptyline			S	Transplacental	Maternal Dose: 37.5 Mg, Qd		Not Reported	
	Amitriptyline			S	Transplacental	Maternal Dose: 37.5 Mg, Qd		Not Reported	
	CipraleX			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported	
	CipraleX			S	Transplacental	Maternal Dose: 5 Mg, Qd		Not Reported	
	Paracetamol			C	Transplacental	Maternal Dose: 2000 Mg, Qd (1 To 2 G Per Day If		Not Reported	

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Clexane	C	Transplacental	Required)	Not Reported
Clexane	C	Transplacental	Maternal Dose: 40 Mg, Qd	Not Reported
Ibuprofen	C	Transplacental	Maternal Dose: 120 Mg, Qd (2x60 Mg, Qd)	Not Reported
			Maternal Dose: 600 Mg, Qd (If Required)	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	10792546	EXPEDITED (15-DAY)		HO	FR-FRI-1000074388		36 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Pyramidal Tract Syndrome; Tremor	Escitalopram Oxalate Unk			S	Oral	Seroplex 10 Mg 60 Tablets		Allergan
	Theralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tablets		Not Reported
	Valium			S	Oral	30 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15066346	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SE79504		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hemianopia; Hyponatraemia; Language Disorder	Esomeprazole			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Esidrex			S	Oral			Not Reported
	Procoralan			C				Not Reported
	Aspirine Protect			C				Not Reported
	Seresta			C				Not Reported
	Dafalgan			C	Unknown			Not Reported
	Pravastatin Sodium			C				Not Reported
	Mediatusyl			C				Not Reported
	Ramipril			C				Not Reported
	Acebutolol			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15066665	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-032615		28 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Juvenile Myoclonic Epilepsy; Myoclonus; Schizophreniform Disorder	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S				Aurobindo	
	Aripiprazole			S	Unknown	Unk		Aurobindo	
	Aripiprazole			S				Aurobindo	
	Aripiprazole			S				Aurobindo	
	Duloxetine			S	Unknown	Unk		Aurobindo	
	Duloxetine			S				Aurobindo	
	Olanzapine			S	Unknown	Unk		Aurobindo	
	Olanzapine			S				Aurobindo	
	Olanzapine			S				Aurobindo	
	Olanzapine			S				Aurobindo	
	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo	
	Escitalopram 20 Mg			S				Aurobindo	
	Mirtazapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Mirtazapine Film-Coated Tablet			S				Aurobindo	
	Venlafaxine Prolonged-Release Capsule, Hard			S	Oral	Unk		Aurobindo	
	Venlafaxine Prolonged-Release Capsule, Hard			S				Aurobindo	
	Amisulpride			S	Unknown	Unk		Not Reported	
	Amisulpride			S				Not Reported	
	Amisulpride			S				Not Reported	
	Amisulpride			S				Not Reported	
	Risperidone			S	Unknown	Unk		Aurobindo	
	Risperidone			S				Aurobindo	
	Zopiclone			S	Unknown	Unk		Not Reported	
	Zopiclone			S				Not Reported	
	Oxazepam			S	Unknown	At Different Doses		Not Reported	
	Biperiden			S	Unknown	Unk		Not Reported	
	Biperiden			S				Not Reported	

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Bupropion	S	Unknown	Unk	Not Reported
Bupropion	S			Not Reported
Clozapine	S	Unknown	75 Milligram	Not Reported
Fluoxetine	S	Unknown	Unk	Not Reported
Fluoxetine	S			Not Reported
Fluoxetine	S			Not Reported
Promethazine	S	Unknown	Unk	Not Reported
Promethazine	S			Not Reported
Promethazine	S			Not Reported
Zonisamide	C	Unknown	Up To 100mg	Not Reported
Clobazam	C	Unknown	Up To 20mg	Not Reported
Brivaracetam	C	Unknown	200-250mg; Received Over One Year ()	Not Reported
Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year ()	Not Reported
Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15135051	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR- APL-2018-035103		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Haemorrhage; Menorrhagia; Respiratory Tract Infection; Restlessness; Sleep Disorder	Aripiprazole			S	Unknown	5 Milligram Daily		Aurobindo
	Risperidone			S	Unknown	0.5 Milligram, Once A Day		Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Risperidone			S				Aurobindo
	Escitalopram			S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily (In A Morning Target Dose Of 20 Mg)		Aurobindo
	Escitalopram			S	Unknown	15 Milligram Daily; Reduced To 15 Mg/Day		Aurobindo

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Escitalopram	S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg	Aurobindo
Escitalopram Pregabalin	S C	Unknown	100 Milligram Daily; Evening Dose Of 100 Mg ()	Aurobindo Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect ()	Not Reported
Promethazine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15214868	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2018297087		21 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Temesta (Lorazepam)			S		2-5 Mg		Pfizer
	Seroquel			S		75 Mg, Unk		Not Reported
	Seroquel			S		100 Mg, Unk		Not Reported
	Trittico			S		50 Mg, Unk		Not Reported
	Trittico			S		100 Mg, Unk		Not Reported
	Trittico			S		150 Mg, Unk		Not Reported
	Dominal /00018902/			S		80 Mg, Unk		Not Reported
	Dominal /00018902/			S		40 Mg, Unk		Not Reported
	Dominal /00018902/			S		80 Mg, Unk		Not Reported
	Cipralelex /01588501/			S		5 Mg, Unk		Not Reported
	Cipralelex /01588501/			S		10 Mg, Unk		Not Reported

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Lamictal	S		25 Mg, Unk	Not Reported
Lamictal	S		50 Mg, Unk	Not Reported
Lamictal	S		100 Mg, Unk	Not Reported
Gewacalm	S		5 Mg, Unk	Not Reported
Gewacalm	S		10 Mg, Unk	Not Reported
Gewacalm	S		15 Mg, Unk	Not Reported
Zyprexa	S		2.5 Mg, Unk	Not Reported
Zyprexa	S		5 Mg, Unk	Not Reported
Acetylic Acid	S	Unknown	80 Mg, 1x/Day	Not Reported
Acetylic Acid	S		40 Mg, 1x/Day	Not Reported
Acetylic Acid	S		80 Mg, 1x/Day	Not Reported
Quilonorm /00033702/	C		225 Mg, Unk	Not Reported
Halcion	C		0.25 Mg, Unk	Not Reported
Zoldem	C		10 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15260530	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE040450		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Risperidone			S	Unknown	0.5 Mg, Qd		Novartis
Delirium; Drug Ineffective;	Risperidone			S				Novartis
Drug Interaction;	Risperidone			S				Novartis
Haematoma;	Escitalopram			S	Oral	20 Mg, Qd (Increased To The Dose Of 20 Mg Daily)		Not Reported
Haemorrhage; Insomnia;								
Menometrorrhagia;	Escitalopram			S	Unknown	15 Mg, Qd (Reduced To 15 Mg/Day)		Not Reported
Menorrhagia; Respiratory								
Tract Infection;	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported
Restlessness; Sleep	Aripiprazole			S				Not Reported
Disorder; Thinking	Pregabalin			C	Oral	100 Mg, Qd In The Evening		Not Reported
Abnormal								
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported

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Promethazine	C	Unknown	Unk	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Opipramol	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359154	EXPEDITED (15-DAY)	HO		DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018016276			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Olanzapine			S	Unknown	Unk		Macleods
	Olanzapine			S				Macleods
	Olanzapine			S				Macleods
	Aripiprazole			S	Unknown	Unk		Macleods
	Aripiprazole			S				Macleods
	Aripiprazole			S				Macleods
	Duloxetine			S	Unknown	Unk		Macleods
	Escitalopram			S	Unknown	20 Milligram		Macleods
	Quetiapine Tablet			S	Oral	Unk, Film Coated Tablet		Macleods
	Quetiapine Tablet			S				Macleods
	Venlafaxine Capsules			S	Oral	Unk, Hard		Macleods
	Fluoxetine			S	Unknown	Unk		Not Reported
	Amisulpride			S	Unknown	Unk		Not Reported
	Amisulpride			S				Not Reported
	Amisulpride			S				Not Reported
	Biperiden			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Clozapine			S	Unknown	75 Milligram		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

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Risperidone	S			Not Reported
Risperidone	S			Not Reported
Promethazine	S	Unknown	Unk	Not Reported
Promethazine	S			Not Reported
Promethazine	S			Not Reported
Zopiclone	S	Unknown	Unk	Not Reported
Oxazepam	S	Unknown	Unk (At Different Doses)	Not Reported
Carbamazepine	C	Unknown	Unk (Up To 900 Mg)	Not Reported
Brivaracetam	C	Unknown	Unk (200-250mg; Received Over One Year)	Not Reported
Oxcarbazepine	C	Unknown	Unk (Up To 2400mg; Received Over One Year)	Not Reported
Clobazam	C	Unknown	Unk (Up To 20mg)	Not Reported
Zonisamide	C	Unknown	Unk (Up To 100mg)	Not Reported
Benzodiazepine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359847	EXPEDITED (15-DAY)		DS, HO	CA-VIVIMED- 2017SP015463			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Blindness; Colour Blindness; Cytotoxic Oedema; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Infarction; Intentional Overdose; Mydriasis; Optic Atrophy; Optic Nerve Injury; Shock; Tachycardia; Vasodilatation; Visual Impairment	Amlodipine			S	Unknown	150 Mg		Strides
	Escitalopram			S	Unknown	60 Mg		Not Reported
	Risperidone			S	Unknown	6 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15360789	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-06218		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor	Escitalopram			S	Unknown	Unk		Lupin	
	Lamotrigine			S	Unknown	Unk		Not Reported	
	Propranolol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15361289	EXPEDITED (15-DAY)		DE	IT-MYLANLABS- 2018M1065754		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported	
	Alprazolam			S	Oral	0.75 Mg, Qd		Not Reported	
	Clonazepam			S	Oral	7 Gtt, Qd		Mylan	
	Venlafaxine Hydrochloride			S	Oral	75 Mg, Qd		Mylan	

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Venlafaxine Hydrochloride	S	Oral	150 Mg, Qd	Mylan
Venlafaxine Hydrochloride	S	Oral	37.5 Mg, Qd	Mylan
Cipralex /01588501/	S	Oral	2 Gtt, Qd	Mylan
Zolpidem Tartrate	S	Oral	15 Gtt, Qd	Mylan
Zolpidem Tartrate	S	Oral	10 Gtt, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15362423	EXPEDITED (15-DAY)	LT		FR-009507513-1809FRA000963		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Mirtazapine			S	Oral	Unknown		Merck	
	Alprazolam			S	Oral	Unknown		Not Reported	
	Methadone Hydrochloride			S	Oral	Unknown		Not Reported	
	Havlane			S	Oral	Unknown		Not Reported	
	Escitalopram			S	Oral	Unknown		Not Reported	
	Theralene			S	Oral	Unknown		Not Reported	
	Tercian			S	Oral	Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15362475	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2018161921		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia;	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Lamotrigine			S	Unknown	Unk		Glaxosmithkline	
	Propranolol			S	Unknown	Unk		Glaxosmithkline	

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Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Toxicity To Various
Agents; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15363066	EXPEDITED (15-DAY)		LT	NO-009507513-1809NOR000979		56 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite;	Remeron			S	Oral			Merck
Dehydration;	Trilafon (Perphenazine)			S	Oral			Not Reported
Haemorrhage;	Cymbalta			S	Oral			Not Reported
Hyperhidrosis; Muscle	Fluoxetine			S	Oral			Not Reported
Rigidity; Nausea;	Efexor Depot			S	Oral			Not Reported
Neuroleptic Malignant	Stemetil (Prochlorperazine)			S	Oral			Not Reported
Syndrome; Pyrexia;	Ibux			S	Oral			Not Reported
Tremor; Vomiting	Fluanxol			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Sobril			S	Oral			Not Reported
	Truxal (Chlorprothixene)			S	Oral			Not Reported
	Ciprallex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

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07-Sep-2018	15363278	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1842973US		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Rexulti			S	Oral	2 Mg, Qd		Not Reported	
	Rexulti			S	Oral	1 Mg, Qd		Not Reported	
	Lonasen			S	Oral			Not Reported	
	Rivotril			C	Oral			Not Reported	
	Flunitrazepam			C	Oral			Not Reported	
	Belsomra			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15363295	EXPEDITED (15-DAY)		OT	US-SUNOVION-2018SUN003450		67 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Indacaterol And Glycopyrrolate			S	Respiratory (inhalation)	1 Df, Qd (Glycopyrronium Bromide: 50 Ug And Indacaterol Maleate: 110 Ug)		Sunovion	
	Cipralext			S	Oral	20 Mg, Qd		Not Reported	
	Cipralext			S	Oral	10 Mg, Qd		Not Reported	
	Seroquel			S	Oral	25 Mg, Qd		Not Reported	
	Steri Neb Ipramol			S	Unknown	4 X 1 Dose, As Necessary		Not Reported	
	Beloc Zok			C	Unknown	Unk		Not Reported	
	Anxiolit			C	Unknown	Unk		Not Reported	
	Zoldorm			C	Unknown	Unk		Not Reported	
	Calcimagon D3			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15385120	DIRECT		DS			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral; Oedema Peripheral; Oedema Peripheral	Escitalopram Oxalate Waterpill Doterra Essential Oils Magnesium Calcium	Y		S C C C C	Oral	Quantity:30 Tablet(S);		Aurobindo Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2018	15364253	EXPEDITED (15-DAY)		OT	GB-TORRENT-00017362		25 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram Oxalate			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	14416444	EXPEDITED (15-DAY)		OT	US-ACCORD-062823		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Bedridden; Injury; Lyme Disease; Product Quality Issue; Psychotic Disorder; Withdrawal Syndrome	Escitalopram Accord Xanax			S C	Oral Oral	Strength: 20 Mg Dose: 100		Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15365481	EXPEDITED (15-DAY)		OT	US-ACCORD-071520		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthenia; Blood Urine	Escitalopram			S	Oral	Strength: 10 Mg		Not Reported	

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Present; Diarrhoea; Dry
Mouth; Haematemesis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15366261	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1065808		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Depressive Symptom; Disturbance In Attention; Drug Ineffective; Gamma-Glutamyltransferase Increased; Listless; Normocytic Anaemia; Off Label Use	Escitalopram			S	Unknown	(20mg-0mg-0mg-0mg) In The Morning		Not Reported
	Lamotrigine			S	Unknown	(1-1-1-0)		Not Reported
	Mirtazapine			S	Unknown	At Night		Not Reported
	Mirtazapine			S	Unknown	(0-0-1) At Night		Not Reported
	Milnacipran			S	Oral	200 Mg, Qd		Mylan
	Milnacipran			S	Oral	50 Mg, Q2d		Mylan
	Levothyroxine			C	Unknown	(1-0-0-0) In The Morning		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15367456	EXPEDITED (15-DAY)		OT	US-UCBSA-2018037167			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Status Epilepticus	Levetiracetam			S				Ucb
	Vimpat			S				Ucb
	Trileptal			S				Not Reported
	Lexapro			S				Not Reported
	Ativan			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15367735	EXPEDITED (15-DAY)		OT	PHEH2018US036987			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mood Altered; Seizure; Vision Blurred	Risperidone			S	Unknown	Unk		Novartis
	Mirtazapine			S	Unknown	Unk		Not Reported

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	Oxypro	S	Unknown	Unk				Not Reported	
	Lexapro	S	Unknown	Unk				Not Reported	
	Vitamin D3	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	14046947	NON-EXPEDITED			US-PFIZER INC-2017427872			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Retching; Vomiting	Metronidazole			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Chloraprep			S		Unk		Not Reported	
	Janumet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	14371399	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001341		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine Prolonged-Release Tablet			S	Oral	400 Mg, Qd		Aurobindo	
	Quetiapine Prolonged-Release Tablet			S				Aurobindo	
	Quetiapine Prolonged-Release Tablet			S				Aurobindo	
	Laroxyl			S	Unknown	Unk ()		Not Reported	
	Laroxyl			S				Not Reported	
	Laroxyl			S				Not Reported	
	Methylphenidate			S	Oral	110 Mg, Qd		Not Reported	
	Methylphenidate			S	Oral	100 Mg, Unk		Not Reported	
	Methylphenidate			S				Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported	

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	Xeroquel	S						Not Reported
	Xeroquel	S						Not Reported
	Seroplex	S	Oral		10 Mg, Qd			Not Reported
	Seroplex	S						Not Reported
	Seroplex	S						Not Reported
	Ritaline	S	Oral		100 Mg, Unk			Not Reported
	Ritaline	S	Oral		110 Mg, Qd			Not Reported
	Ritaline	S						Not Reported
	Lepticur	S	Unknown		15 Mg, Unk			Not Reported
	Lepticur	S						Not Reported
	Lepticur	S						Not Reported
	Abilify	S	Oral		15 Mg, Qd			Not Reported
	Abilify	S						Not Reported
	Abilify	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	14650225	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1814371US		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Cardiac Fibrillation; Crying; Drug Ineffective; Epilepsy; Libido Disorder; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Depakine			C				Not Reported	
	Zoloft			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	14901152	EXPEDITED (15-DAY)		HO, OT	ES-ASTRAZENECA-2018SE63409			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy;	Omeprazole			S	Oral			Not Reported	
Hypokalaemia;	Escitalopram			S	Unknown			Not Reported	
Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4mg Unknown		Not Reported	
	Obinutuzumab			S	Intravenous (not	1000.0mg Unknown		Not Reported	

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Cotrimoxamol	S	otherwise specified)	Not Reported
Atorvastatin	C	Unknown	Not Reported
Valsartan	C		Not Reported

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11-Sep-2018	15368703	EXPEDITED (15-DAY)	HO		FR-MERCK KGAA-2054809		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Lymphopenia; Neutropenia	Novothyrox			S	Oral			Merck Kgaa
	Loxapac			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Lorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15368853	EXPEDITED (15-DAY)	LT		FR-ACCORD-071472		47 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Methadone			S	Oral			Not Reported
	Havlane			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported

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Tercian			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15368958	EXPEDITED (15-DAY)		HO	FR-ACCORD-071562		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Allopurinol			S	Oral			Accord	
	Seroplex			S	Oral	Strength: Mg		Not Reported	
	Amiodarone			S	Oral			Not Reported	
	Topalgic (Tramadol Hydrochloride)			S	Oral	Strength:50 Mg		Not Reported	
	Oxynormoro			S	Oral	Strength:5 Mg		Not Reported	
	Tazocilline			S	Intravenous (not otherwise specified)	Strength: 4 G/500 Mg		Not Reported	
	Xanax			S	Oral	Strength : 0,25 Mg		Not Reported	
	Kardegic			S	Oral	Strength: 75 Mg		Not Reported	
	Mycophenolic Acid			C	Oral			Not Reported	
	Ciclosporin			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369168	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-044883		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poisoning Deliberate; Somnolence	Prazepam			S	Oral	Unk, Np		Not Reported	
	Escitalopram			S	Oral	Unk, Np		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369299	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2018-045039		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Pneumonia	Alprazolam			S	Oral	Unk		Aurobindo	

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Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Escitalopram	S	Oral	Inconnue	Aurobindo
	Mirtazapine	S	Oral	Inconnue	Aurobindo
	Methadone	S	Oral	Inconnue	Not Reported
	Havlane	S	Oral	Inconnue	Not Reported
	Theralene	S	Oral	Inconnue	Not Reported
	Tercian /00759301/	S	Oral	Inconnue	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369339	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-045033		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence	Diazepam			S	Oral	Non Renseign�e		Not Reported	
	Escitalopram			S	Oral	Non Renseign�e		Aurobindo	
	Imovane			S	Oral	7.5 Milligram, Daily		Not Reported	
	Theralene			S	Oral	20 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369373	NON-EXPEDITED			US-GLENMARK PHARMACEUTICALS- 2018GMK036521			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Product Use In Unapproved Indication	Fluconazole			S	Unknown	Unk		Glenmark	
	Lexapro			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369754	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP020260			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Impaired Healing	Apo-Escitalopram			S	Unknown	Unk		Apotex	

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11-Sep-2018	15370018	EXPEDITED (15-DAY)		OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-06335			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin	
	Lestavor			S	Oral	10 Mg, Unk		Not Reported	
	Adco Mirteron			S	Oral	15 Mg, Unk		Not Reported	
	Pharmapress Co			S	Oral	20/12.5mg		Not Reported	
	Asthavent /00139501/			S	Respiratory (inhalation)	100 Mcg, Unk		Not Reported	
	Adco-Zolpidem			S	Oral	10 Mg, Unk		Not Reported	
	Disprin Cardiocare			S	Oral	100 Mg, Unk		Not Reported	
	Aspavor			S	Oral	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15370500	EXPEDITED (15-DAY)		CA, DE, OT	DE-APOTEX- 2018AP020441			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Paroxetine			S	Transplacental	30 Mg, Qd		Apotex	
	Levetiracetam			S	Transplacental	1500 Mg, Qd		Not Reported	
	Escitalopram			S	Transplacental	220 Mg, Qd		Not Reported	
	Candesartan			S	Transplacental	16 Mg, Qd		Not Reported	
	Nepresol /00007602/			S	Transplacental	25 Mg, Qd		Not Reported	
	L-Thyroxin /00068001/			C	Transplacental	Unk		Not Reported	
	Cytotec			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15370722	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR- 953511		73 YR	Male	FRA

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Drug Interaction; International Normalised Ratio Increased	Paracetamol			S	Oral	4 Gram Daily; If Necessary		Not Reported
	Tramadol (Chlorhydrate De)			S	Oral	200 Milligram Daily; Form Lp, Morning And Evening If Necessary		Teva
	Coumadine 2 Mg, Comprimé Sécable			S	Oral	3 Milligram Daily;		Not Reported
	Ogastoro 15 Mg, Comprimé Orodispersible			S	Oral	15 Milligram Daily;		Not Reported
	Tahor 40 Mg, Comprimé Pelliculé			S	Oral	40 Milligram Daily;		Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	10 Milligram Daily;		Not Reported
	Coumadine 2 Mg, Comprimé Sécable			S	Oral			Not Reported
	Creon 25 000 U, Granulés			C				Not Reported
	Gastro-Résistants En Gélule			C				Not Reported
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet			C				Not Reported
	Nebivolol			C				Not Reported
	Eupressyl 60 Mg, Gélule			C				Not Reported
	Metformine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15370730	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR- 953646		47 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Inconnue		Actavis
	Mirtazapine			S	Oral	Inconnue		Teva
	Escitalopram			S	Oral	Inconnue		Ivax
	Methadone			S	Oral	Inconnue		Not Reported
	Havlane			S	Oral	Inconnue		Not Reported
	Theralene			S	Oral	Inconnue		Not Reported
	Tercian			S	Oral	Inconnue		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15371569	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-953553		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Partial Seizures	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	
	Alprazolam			C	Oral	.25 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15371624	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL090342		62 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Electrocardiogram Qt Prolonged; Fatigue; Palpitations; Syncope	Cyproheptadine			S	Oral	16 Mg, Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	10 Mg, Qhs		Novartis	
	Ivabradine			S	Unknown	Unk		Not Reported	
	Moclobemide			S	Unknown	150 Mg, Qd		Not Reported	
	Trazodone			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	150 Mg, Qd		Not Reported	
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15371715	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-953509		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poisoning Deliberate; Somnolence	Escitalopram			S	Oral	Np		Not Reported	
	Prazepam			S	Oral	Np		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15371816	EXPEDITED (15-DAY)		LT	NO-TEVA-2018-NO-953598		56 YR	Female	NOR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral			Barr
	Trilafon			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Remeron			S	Oral			Not Reported
	Efexor Depot			S	Oral			Not Reported
	Stemetil			S	Oral			Not Reported
	Ibux			S	Oral			Not Reported
	Fluanxol			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Sobril			S	Oral			Not Reported
	Truxal			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Abilify			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15371946	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-953645		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder; Pulmonary Fibrosis	Atorvastatine			S	Oral	10 Milligram Daily;		Teva
	Paracetamol			S	Oral	1500 Milligram Daily;		Not Reported
	Ramipril			S	Oral			Actavis
	Amiodarone			S	Oral	200 Milligram Daily;		Teva
	Pantoprazole			S	Oral	20 Milligram Daily;		Teva
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Levothyrox			S	Oral			Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-			S	Oral	1 Dosage Forms Daily;		Not Reported

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Dose									
Caltrate Vitamine D3 600		S	Oral						Not Reported
Mg/400 Ui, Comprimé Pelliculé									
Sécable									
Lorazepam		S	Oral		1 Milligram Daily;				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15372113	EXPEDITED (15-DAY)		DS, OT	GB-MYLANLABS-2018M1066298		33 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pain In Jaw	Escitalopram			S	Oral	5 Mg, Unk		Not Reported
	Lansoprazole			C		30 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15372144	EXPEDITED (15-DAY)		LT	NO-ALLERGAN-1844326US		56 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite;	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
Dehydration;	Truxal			S	Oral			Not Reported
Haemorrhage;	Fluanxol Tabletter (Flupentixol			S	Oral			Not Reported
Hyperhidrosis; Muscle	Dihydrochloride)							
Rigidity; Nausea;	Abilify			S	Oral			Not Reported
Neuroleptic Malignant	Trilafon			S	Oral			Not Reported
Syndrome; Pyrexia;	Cymbalta			S	Oral			Not Reported
Tremor; Vomiting	Remeron			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Efexor			S	Oral	Efexor Depot		Not Reported
	Stemetil			S	Oral			Not Reported
	Ibux			S	Oral			Not Reported
	Vallergan			S	Oral			Not Reported
	Nozinan			S	Oral			Not Reported

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Zyprexa	S	Oral		Not Reported
Sobril	S	Oral	Unk	Not Reported

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11-Sep-2018	15372467	EXPEDITED (15-DAY)		HO	PHHY2018FR092469		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Novartis
	Bendamustine			S	Intravenous (not otherwise specified)	346 Mg, Qmo		Not Reported
	Valaciclovir			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Loxapac			S	Oral			Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Fenofibrate			S	Oral	Unk		Not Reported
	Lorazepam			S	Oral	Long Cours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	12623826	NON-EXPEDITED			US-JAZZ-2016-US-003869			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Unknown Dose		Jazz
	Lexapro			S				Not Reported
	Colecalciferol			C		Unk		Not Reported
	Bystolic			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Nuvigil			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	13122629	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1701647US		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Lepticur			S	Unknown	Unk		Not Reported
	Methylidopa			S	Oral	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Depamide			S	Oral	300 Mg, Unk		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening		Not Reported
	Anafranil			S	Oral	75 Mg, Unkdaily Dose Increased. Oral Drug Unspecified Form		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zopiclone			S	Oral	7.5 Mg, Qd		Not Reported
	Imovane			S	Oral	7.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	14272549	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_016320			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Prolactin-Producing Pituitary Tumour	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	1 Mg, Unk		Otsuka
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	14412552	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1802859US		43 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Escitalopram Oxalate - Bp Antidepressants			S C	Oral	1 Df, Qpm (Before Sleep)		Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	14699165	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-016526		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram Film Tablets 10 Mg			S	Oral	Currently		Aurobindo	
	Escitalopram Film Tablets 10 Mg			S	Oral	15 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15372728	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184117		87 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Drug Interaction; Electrocardiogram Qt Prolonged; Hypotension; Hypotension	Escitalopram			S	Unknown	Unk		Not Reported	
	Imipramine			S	Unknown	25 Mg, Hs		Mutual	
	Alprazolam			S	Unknown	0.5 Mg, Bid		Sun	
	Fentanyl			S	Intravenous (not otherwise specified)	100 Ug		Not Reported	
	Propofol			S	Intravenous (not otherwise specified)	100 Mg		Not Reported	
	Sevoflurane			S	Unknown	Unk		Not Reported	
	Estazolam			S	Unknown	2 Mg		Not Reported	
	Seroquel			S	Unknown	5 Mg, Hs		Not Reported	
	Lidocaine			S	Intravenous (not	50 Mg, Unk		Not Reported	

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		otherwise specified)			
Desflurane	S	Unknown	6 %		Not Reported
Propranolol	C	Unknown	10 Mg		Not Reported
Cistracurium	C	Intravenous (not otherwise specified)	10 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15372806	EXPEDITED (15-DAY)	CA, DE		DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-184120			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 [Mg/D]		Sun
	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported
	Candesartan			S	Transplacental	16 [Mg/D]		Not Reported
	Nepresol (Dihydralazine Mesilate)			S	Transplacental	25 [Mg/D]		Not Reported
	Paroxetine			S	Transplacental	30 [Mg/D]		Not Reported
	L-Thyroxin 50			C	Transplacental	()		Not Reported
	Cytotec			C	Transplacental	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15374482	EXPEDITED (15-DAY)	HO, OT		FR-MYLANLABS- 2018M1066330		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Poisoning Deliberate	Venlafaxine			S	Oral	Non Précisée		Not Reported
	Zopiclone			S	Oral	Non Précisée		Not Reported
	Atarax /00058401/			S	Oral	Non Précisée		Mylan
	Previscan /00261401/			S	Oral	Non Précisée		Mylan
	Seroplex			S	Oral	Non Précisée		Mylan

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12-Sep-2018	15375131	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1844308US		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Poisoning Deliberate; Product Use In Unapproved Indication; Somnolence	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan	
	Prazepam			S	Oral	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15375810	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018365959		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk		Pfizer	
	Valaciclovir			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Unk		Pfizer	
	Loxapac [Loxapine]			S	Oral	Unk		Not Reported	
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Monthly		Not Reported	
	Levothyrox			S	Oral	Unk		Not Reported	
	Fenofibrate			S	Oral	Unk		Not Reported	
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Monthly		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15376406	EXPEDITED (15-DAY)		HO	PHHY2018DE094496		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown	Unk		Novartis	
	Melperone Hydrochloride			S	Unknown	Unk		Not Reported	

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Ciprallex	S	Unknown	10 Mg, Qd	Not Reported
Escitalopram	C	Unknown	Unk (From Beta Pharm)	Not Reported
L-Tyrosine	C	Unknown	Unk	Not Reported
Candesartan	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Mcp	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Amlodipin	C	Unknown	Unk	Not Reported
Kalinor (Potassium Chloride)	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15376674	EXPEDITED (15-DAY)		HO, LT, OT	JP-PRINSTON PHARMACEUTICAL INC.-2018PRN01275		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Escitalopram			S	Unknown			Prinston Pharmaceutical	
	Lorazepam			S	Unknown			Not Reported	
	Adrenaline			S	Unknown	Unk, Once		Not Reported	
	Adrenaline			S	Unknown	Three Injection		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15395759	DIRECT		DS, LT, OT			45 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome; Toxicity To Various Agents	Lexapro			S	Oral	Quantity:10 Df Dosage Form;		Astrazeneca	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	14906718	EXPEDITED (15-DAY)		DE, OT	FR-BAXTER- 2018BAX014039		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Endoxan 1000 Mg, Poudre Pour Solutioninjectable	S	Intravenous drip		Baxter
	Endoxan 1000 Mg, Poudre Pour Solutioninjectable	S	Intravenous drip		Baxter
	Rituximab (Mammal/Hamster/Cho Cells)	S	Intravenous drip		Not Reported
	Rituximab (Mammal/Hamster/Cho Cells)	S	Intravenous drip		Not Reported
	Calciparine	S	Subcutaneous		Not Reported
	Calciparine	S	Subcutaneous		Not Reported
	Bisoprolol (Fumarate Acid)	S	Oral		Not Reported
	Ciprofloxacin, Ciprofloxacin Hydrochloride	S	Intravenous drip		Not Reported
	Ciprofloxacin, Ciprofloxacin Hydrochloride	S	Intravenous drip		Not Reported
	Methotrexate	S	Intravenous drip	Unk	Not Reported
	Methotrexate	S	Intravenous drip		Not Reported
	Doxorubicin Hydrochloride	S	Intravenous drip		Not Reported
	Doxorubicin Hydrochloride	S	Intravenous drip		Not Reported
	Lidocaine	S	Buccal	Unk	Not Reported
	Lidocaine	S	Unknown		Not Reported
	Lidocaine	S	Buccal		Not Reported
	Fungizone	S	Buccal		Not Reported
	Fungizone	S	Buccal		Not Reported
	Voraxaze	S	Intravenous drip		Not Reported
	Voraxaze	S	Intravenous drip		Not Reported
	Zarzio	S	Subcutaneous		Not Reported
	Zarzio	S	Subcutaneous		Not Reported
	Valaciclovir	S	Oral		Not Reported
	Valaciclovir	S	Oral		Not Reported
	Valaciclovir	S	Unknown		Not Reported
	Furosemide	S	Oral		Not Reported
	Furosemide	S	Oral		Not Reported

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Exacyl	S	Intravenous drip	Unk	Not Reported
Exacyl	S	Unknown	Unk	Not Reported
Exacyl	S	Intravenous drip		Not Reported
Prednisone	S	Intravenous drip		Not Reported
Prednisone	S	Intravenous drip		Not Reported
Eprex	S	Subcutaneous		Not Reported
Eprex	S	Subcutaneous		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Vincristine Sulfate	S	Intravenous drip		Not Reported
Vincristine Sulfate	S	Intravenous drip		Not Reported
Bactrim	S	Oral		Not Reported
Bactrim	S	Oral		Not Reported
Hextril	S	Buccal	Unk	Not Reported
Hextril	S	Unknown	Unk	Not Reported
Hextril	S	Buccal		Not Reported
Pantoprazole	S	Intravenous drip		Not Reported
Pantoprazole	S	Intravenous drip		Not Reported
Bromazepam	S	Oral		Not Reported
Bromazepam	S	Oral		Not Reported
Bromazepam	S	Unknown		Not Reported
Escitalopram	S	Oral		Not Reported
Escitalopram	S	Oral		Not Reported
Meropenem Anhydrous	S	Intravenous drip		Not Reported
Meropenem Anhydrous	S	Intravenous drip		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15306299	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2018SF05639		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Oral Lichen Planus	Esomeprazole	S	Oral		Astrazeneca
	Xeroquel	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Esidrex	S	Oral	25 Mg Unknown Non Az Product	Not Reported
	Kardegic	S	Oral	Unk	Not Reported
	Atorvastatin	S	Oral	20.0mg Unknown	Not Reported
	Lamotrigine	S	Oral	Unk	Not Reported
	Teralithe	S	Oral	Unk	Not Reported
	Macrogol	S	Oral	Unk	Not Reported
	Perindopril	S	Oral	2.0mg Unknown	Not Reported
	Aldactone	S	Oral	Unk	Not Reported
	Verapamil	S	Oral	240.0mg Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15368257	EXPEDITED (15-DAY)		HO, OT	PHHY2018BR094226			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation; Anxiety; Asthenia; Choking; Disorientation; Disturbance In Attention; Dry Mouth; Emotional Distress; Hallucination; Impatience; Psychiatric Symptom; Screaming; Speech Disorder; Tremor; Weight Decreased	Quetiapine Fumarate			S	Unknown	1 Df, Qn		Not Reported
	Cloxazolam			S	Oral	1 Df, Qn		Not Reported
	Escitalopram			S	Oral	1 Df, Qd		Not Reported
	Escitalopram			S	Oral	2 Df, Qd (At Lunch 11 Am)		Not Reported
	Alprazolam			S	Unknown	1 Mg, Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15377039	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SF12283		74 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased	Seroplex			S	Oral	10.0mg Unknown		Not Reported	
	Inexium			S	Oral			Astrazeneca	
	Tardyferon			C				Not Reported	
	Tahor			C				Not Reported	
	Uvedose			C				Not Reported	
	Seresta			C				Not Reported	
	Doliprane			C				Not Reported	
	Zopiclone			C				Not Reported	
	Kardegic			C				Not Reported	
	Sinemet			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15377430	NON-EXPEDITED			US-TEVA-2018-US-953454		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Gluten Sensitivity	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15377451	EXPEDITED (15-DAY)		HO	FR-ZYDUS-026837		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Valaciclovir			S	Oral	Long Course		Zydus Pharm	
	Escitalopram			S	Oral			Zydus Pharm	
	Pantoprazole			S	Oral			Not Reported	
	Fenofibrate			S	Oral			Not Reported	
	Bendamustine Accord			S	Intravenous (not otherwise specified)			Not Reported	
	Loxapac			S	Oral			Not Reported	
	Levothyrox			S	Oral			Not Reported	
	Truxima			S	Intravenous (not otherwise specified)			Not Reported	

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Lorazepam			S	Oral	Long Course			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15378082	EXPEDITED (15-DAY)		LT	NO-PFIZER INC-2018369245		56 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Efexor Depot			S	Oral	Unk		Pfizer	
	Sobril			S	Oral	Unk		Pfizer	
	Trilafon Dekanoat			S	Oral	Unk		Not Reported	
	Cymbalta			S	Oral	Unk		Not Reported	
	Remeron			S	Oral	Unk		Not Reported	
	Fluoxetine			S	Oral	Unk		Not Reported	
	Stemetil			S	Oral	Unk		Not Reported	
	Ibux			S	Oral	Unk		Not Reported	
	Fluanxol			S	Oral	Unk		Not Reported	
	Vallergan			S	Oral	Unk		Not Reported	
	Nozinan			S	Oral	Unk		Not Reported	
	Zyprexa			S	Oral	Unk		Not Reported	
	Truxal			S	Oral	Unk		Not Reported	
	Ciprallex			S	Oral	Unk		Not Reported	
	Abilify			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15378497	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018368080		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Unk		Pfizer	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Methadone			S	Oral	Unk		Not Reported	
	Havlane			S	Oral	Unk		Not Reported	

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	Escitalopram	S	Oral	Unk		Not Reported			
	Theralene	S	Oral	Unk		Not Reported			
	Tercian [Cyamemazine Tartrate]	S	Oral	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	14273290	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2015_018135			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Abilify			S	Oral	15 Mg, Qd		Otsuka	
	Abilify			S				Otsuka	
	Abilify			S				Otsuka	
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported	
	Lepticur			S				Not Reported	
	Lepticur			S				Not Reported	
	Ritaline			S	Oral	100 Mg, Qd (80 In The Morning And 20 Mg At 4 Pm)		Not Reported	
	Ritaline			S	Oral	110 Mg, Qd (80 Mg In The Morning And 20 Mg At 4pm)		Not Reported	
	Ritaline			S				Not Reported	
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported	
	Xeroquel			S				Not Reported	
	Xeroquel			S				Not Reported	
	Seroplex			S	Oral	10 Mg, Qd		Not Reported	
	Seroplex			S				Not Reported	
	Seroplex			S				Not Reported	
	Laroxyl			S	Unknown	Unk		Not Reported	
	Laroxyl			S				Not Reported	
	Laroxyl			S				Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Lexapro			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	14305604	EXPEDITED (15-DAY)		HO, OT	DE-OTSUKA-2017_021775			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour;	Abilify			S	Unknown	Unk		Otsuka	
Accidental Overdose;	Cipraxel			S	Oral	20 Gtt, Qd		Not Reported	
Disinhibition; Drug	Cipraxel			S	Oral	5 Gtt, Qd		Not Reported	
Interaction;	Cipraxel			S	Oral	10 Gtt, Qd		Not Reported	
Hospitalisation; Mental	Cipraxel			S	Oral	10 Gtt, Qd		Not Reported	
Disorder; Product Use	Vitamin D + Calcium			C	Unknown	Unk		Not Reported	
Issue; Therapy Change									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15024042	EXPEDITED (15-DAY)		HO, LT, OT	CZ-MYLANLABS-2018M1040714			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea;	Olanzapine			S	Oral	Unk		Not Reported	
Electrocardiogram Qt	Ibuprofen			S	Unknown	Unk		Not Reported	
Prolonged;	Escitalopram			S	Oral	Unk		Not Reported	
Electrocardiogram Qt	Clonazepam			S	Oral	Unk		Not Reported	
Shortened; Epilepsy;	Venlafaxine			S	Oral	Unk		Not Reported	
Gastrointestinal	Levomepromazine			S	Oral	Unk		Mylan	
Hypermotility; Loss Of	Metoclopramide			S	Oral	Unk		Mylan	
Consciousness;	Melperone			S	Oral	Unk		Mylan	
Poisoning; Toxicity To									
Various Agents									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15084704	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2018TUS020997			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Aggression;	Brintellix			S	Oral	5 Mg, Qd		Takeda	
Cardiac Failure;	Brintellix			S	Unknown	10 Mg, Unk		Takeda	
Compulsive Shopping;									

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Derealisation;	Brintellix	S	Unknown	15 Mg, Unk	Takeda
Disinhibition; Grandiosity;	Brintellix	S	Unknown	20 Mg, Unk	Takeda
Insomnia; Irritability;	Seroplex	S	Unknown	Unk	Not Reported
Mania; Myocardial	Lasilix /00032601/	C	Unknown	Unk	Not Reported
Infarction; Obsessive-Compulsive Disorder;	Aldactone 50 Hct	C	Unknown	Unk	Not Reported
Oedema; Persecutory	Kardegic	C	Unknown	Unk	Not Reported
Delusion; Stent	Depakote	C	Unknown	Unk	Not Reported
Placement; Suicidal	Xanax	C	Unknown	Unk	Not Reported
Ideation; Thinking	Inexium /01479302/	C	Unknown	Unk	Not Reported
Abnormal; Verbal Abuse;	Noctamide	C	Unknown	2 Mg, Unk	Not Reported
Weight Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15368174	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN-1843352US		58 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
Ineffective; Mental	Citalopram Hydrobromide - Bp			S	Unknown	Series Of Citalopram Infusions		Allergan
Disorder; Suicide Attempt	Aripiprazole			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk Unk,Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Ziprasidone			S	Unknown	Unk		Not Reported
	Clomipramine			S	Unknown			Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Memantine			C				Not Reported
	Melperone			C				Not Reported
	Tiapride			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

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Haloperidol		C		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15384319	EXPEDITED (15-DAY)		HO, LT, OT	FR-TEVA-2018-FR-954420		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram			S	Unknown	10 Milligram Daily; Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Ivax	
	Olanzapine			S	Unknown	15 Mg, Unk		Teva	
	Zopiclone			S	Oral	7.5 Milligram Daily; 1tab/Dy		Not Reported	
	Lepticur			S	Unknown	Unk		Not Reported	
	Methyl dopa			S	Oral	Unk		Not Reported	
	Abilify			S	Oral	10 Mg, Unk		Not Reported	
	Seroplex			S	Unknown	Unk		Not Reported	
	Depamide			S	Oral	300 Milligram Daily; 300 Mg, Oral Drug Unspecified Form		Not Reported	
	Seresta			S	Oral	50 Milligram Daily; Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported	
	Seroplex			S	Unknown	10 Milligram Daily; Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported	
	Anafranil			S	Oral	75 Milligram Daily; Daily Dose Increased. Oral Drug Unspecified Form		Not Reported	
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported	
	Seroplex			S	Unknown	5 Milligram Daily; 5 Mg, Qd		Not Reported	
	Imovane			S	Oral	7.5 Milligram Daily; 1tab/Dy, Oral Drug		Not Reported	

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Unspecified Form

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15384665	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-045284		25 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral	25 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15385495	EXPEDITED (15-DAY)		CA, DE	PHHY2018DE089083			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	Maternal Dose: 25 Mg Qd		Not Reported	
	Paroxetine			S	Transplacental	Maternal Dose: 30 Mg Qd		Not Reported	
	Levetiracetam			S	Transplacental	Maternal Dose: 1500 Mg Qd		Novartis	
	Escitalopram			S	Transplacental	Maternal Dose: 220 Mg Qd		Not Reported	
	Candesartan Cilexetil			S	Transplacental	Maternal Dose: 16 Mg Qd		Not Reported	
	L-Thyroxin			C	Transplacental	Unk		Not Reported	
	Cytotec			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15385781	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018369570		65 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Aspavor			S		40 Mg, Unk		Pfizer	
	Calciferol [Ergocalciferol]			S		50000 Iu, Unk		Not Reported	
	Arthrexin			S		25 Mg, Unk		Not Reported	

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Ciplasyl	S	40 Unk, Unk	Not Reported
Covocort	S	10 Mg, Unk	Not Reported
Dopaquel	S	5 Mg, Unk	Not Reported
Ecotrin	S	81 Mg, Unk	Not Reported
Eltroxin	S	100 Ug, Unk	Not Reported
Ferrimed [Ferric Hydroxide Polymaltose Complex]	S	Unk	Not Reported
Glucophage	S	500 Mg, Unk	Not Reported
Januvia	S	100 Mg, Unk	Not Reported
Lexamil	S	20 Mg, Unk	Not Reported
Omez [Omeprazole]	S	20 Mg, Unk	Not Reported
Puricos	S	300 Mg, Unk	Not Reported
Tamsul	S	0.4 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15386409	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA-2018SF12771		34 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Quetiapine Fumarate			S	Oral	12.5mg Unknown		Not Reported	
	Escitalopram			S				Not Reported	
	Novaminsulfon			C				Not Reported	
	Pantoprazol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387319	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1844529US		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery; Product Use Issue	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	
	Abilify			S	Unknown			Not Reported	
	Dihydroergotamine			S	Unknown	Unk, Unknown		Not Reported	
	Oxazepam			S	Unknown	Unk, Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Pipamperone	S	Unknown	Unk, Unknown	Not Reported
	Dipotassium Clorazepate	S	Unknown	Unk, Unknown	Not Reported
	Loprazolam	S	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387469	EXPEDITED (15-DAY)		HO, LT	JP-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00371		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Escitalopram			S	Unknown			Jubilant	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Adrenaline			S	Unknown	Unk, Once		Not Reported	
	Adrenaline			S	Unknown	Three Injections		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387491	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS- 2018M1067180		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Extrapyramidal Disorder; Mydriasis; Sinus Tachycardia; Suicide Attempt	Escitalopram			S	Oral	9 Mg, Total		Not Reported	
	Risperidone			S	Oral	36 Mg, Total		Not Reported	
	Theralene			C	Oral	Posologie Non Précisée		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387684	EXPEDITED (15-DAY)		DS	US-ALLERGAN- 1844528US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Withdrawal Syndrome	Escitalopram Oxalate Unk			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2018	14958508	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-028429			Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Oral	Unk		Aurobindo
	Bendamustine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bendamustine			S				Not Reported
	Bendamustine			S				Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Obinutuzumab			S				Not Reported
	Obinutuzumab			S				Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2018	15139435	EXPEDITED (15-DAY)		HO, LT	DE-HETERO CORPORATE-HET2018DE00645		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram			S	Unknown	5 Mg		Hetero
	Linezolid			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd, 2 Df Dosage Form Every Days		Not Reported
	Esomeprazol /01479301/			S	Unknown	40 Milligram		Not Reported
	Levetiracetam			C	Unknown	2 Dosage Form		Not Reported
	Ivabradina			C	Unknown	15 Milligram, Qd, 15 Mg Milligram(S) Every Days		Not Reported
	Cotrimoxazol			C	Intravenous (not otherwise specified)	2 Dosage Form, Qd 2 Df Dosage Form Every Days		Not Reported
	Naloxone, Tilidine			C	Unknown	10 Gtt		Not Reported
	Scopolamin			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported

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	Prednisolon	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Daily Dose: 1 Mg Milligram(S) Every Days	Not Reported
	L-Thyroxin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2018	15388210	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-045686		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk,Long Cours		Aurobindo
	Fenofibrate			S	Oral	Unk		Aurobindo
	Valaciclovir			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Loxapac /00401802/			S	Oral	Unk		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Milligram		Not Reported
	Levothyrox			S	Oral	Unk		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Milligram, Monthly		Not Reported
	Lorazepam			S	Oral	Unk, Long Cours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2018	15149903	EXPEDITED (15-DAY)		HO, LT	DE-TORRENT- 00008885		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Baclofen			C		Unknown		Unknown
	Cotrimoxazol			C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Unknown
	Ivabradin			C		Daily Dose: 15 Mg Milligram(S) Every Days		Unknown
	L-Thyroxin			C		Unknown		Unknown

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Levetiracetam	C	Daily Dose: 2 Df Dosage Form Every Days	Unknown
Lorazepam	C	Daily Dose: 1 Mg Milligram(S) Every Days	Unknown
Naloxone, Tilidine	C		Unknown
Prednisolon	C		Unknown
Scopolamin	C		Unknown
Escitalopram	S		Unknown
Esomeprazol	S		Unknown
Linezolid	S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15060339	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA- 2018_015891		14 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Abilify			S	Oral	10 Mg, Qd (Progressively Started 5 Mg In The Morning And Evening)		Otsuka	
	Tercian			S	Oral	25 Mg, Qd		Not Reported	
	Seroplex			S	Oral	10 Mg, Qd (In The Evening)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15126719	EXPEDITED (15-DAY)		CA, OT	DE- GLAXOSMITHKLINE- DE2018117785			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect;	Lorazepam			S	Unknown	Unk		Glaxosmithkline	
Autism Spectrum	Valaciclovir			S	Unknown	Unk		Glaxosmithkline	
Disorder; Camptodactyly	Mycophenolate Mofetil			S	Unknown	Unk		Glaxosmithkline	
Congenital; Clinodactyly;	Tacrolimus			S	Unknown	Unk		Glaxosmithkline	
Congenital Arterial	Colchicine			S	Unknown	Unk		Glaxosmithkline	
Malformation; Congenital	Cyclosporine			S	Unknown	Unk		Glaxosmithkline	
Central Nervous System									
Anomaly; Congenital									

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Renal Cyst; Dysplasia; External Auditory Canal Atresia; Foetal Exposure During Pregnancy; Foetal Malformation; Hydronephrosis; Meningocele; Microtia; Oesophageal Atresia; Premature Baby; Product Use Issue	Prednisolone Azathioprine Escitalopram Fosfomycin Abatacept Ursodeoxycholic Acid Acebutolol Prednisone Methyldopa Naproxen Zolpidem	S S S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk	Glaxosmithkline Glaxosmithkline Glaxosmithkline Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15154410	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1835498US		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Medication Error; Product Use In Unapproved Indication	Escitalopram Oxalate Unk			S	Oral	35 Gtt, Unk (In Total)		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15389627	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-955054		25 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram Oxalate			S	Oral	25 Mg		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15390096	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL		87 YR	Female	FRA

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Detailed Report

INDUSTRIES LTD-
2018RR-184641

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder; Pulmonary Fibrosis	Paracetamol		Y	S	Oral	1500 Mg, Daily		Ohm Lab
	Atorvastatine			S	Oral	10 Mg, Daily		Sun
	Ramipril			S	Oral	5 Mg, Daily		Ranbaxy
	Pantoprazole			S	Oral	20 Mg, Daily		Sun
	Amiodarone			S	Oral	200 Mg, Daily		Taro
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Levothyrox			S	Oral	Daily		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Df, Daily		Not Reported
	Caltrate Vitamine D3 600 Mg/400 Ui, Comprime Pellicule Secable			S	Oral	()		Not Reported
	Lorazepam			S	Oral	1 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15390175	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2018DE00910		76 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Rash	Escitalopram			S	Oral	5 Milligram, Qd		Hetero
	Candesartan			C	Unknown	8 Milligram, Qd		Not Reported
	Eliquis			C	Oral	10 Milligram, Qd		Not Reported
	Oestradiol			C	Oral	0.5 Milligram, Qd		Not Reported
	Novalgin /06276704/			C	Oral	1.5 Milligram, Qd		Not Reported
	Amlodipin /00972401/			C	Unknown	10 Milligram, Qd		Not Reported
	Sulfasalazin			C	Oral	2 Milligram, Qd		Not Reported

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Concor	C	Oral	5 Milligram, Qd	Not Reported
Kalinor /00031402/	C	Oral	600 Milligram, Qd	Not Reported
Cotrimoxazol	C	Oral	960 Milligram, Qd	Not Reported
Vigantoletten	C	Subcutaneous	1000 International Unit, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391041	EXPEDITED (15-DAY)		HO, LT, OT	JP-MACLEODS PHARMACEUTICALS US LTD- MAC2018016552			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Drug Ineffective; Eating Disorder; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Epinephrine			S	Unknown	Unk, Three Adrenaline Injections		Not Reported
	Epinephrine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391289	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2018164784		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Interaction; Labelled Drug- Drug Interaction	Nicorette 4mg Lozenge			S		4 Mg, Longer Than 12 Weeks		Glaxosmithkline
Medication Error; Mood Swings; Nicotine Dependence	Lorazepam			S		Unk		Glaxosmithkline
	Depakote			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391631	NON-EXPEDITED			US-TEVA-2018-US- 953911			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Skin Disorder		Escitalopram		S		Ivax			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392415	EXPEDITED (15-DAY)		HO, LT, OT	JP-OXFORD PHARMACEUTICALS, LLC-2018OXF00099		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity; Shock	Lorazepam			S	Unknown			Oxford Pharmaceuticals	
	Escitalopram			S	Unknown			Not Reported	
	Adrenaline			S	Unknown	Unk Unk, Once		Not Reported	
	Adrenaline			S	Unknown	Three Injections		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392987	EXPEDITED (15-DAY)		OT	IT-EISAI MEDICAL RESEARCH-EC-2018- 045065		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Intentional Self-Injury; Sluggishness	Pariet			S	Oral			Not Reported	
	Escitalopram			S	Oral	Unspecified Quantity		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15393170	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA- 2018TEU005040		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Lansoprazole			S	Oral	15 Mg, Qd		Takeda	
	Prograf			S	Oral	3 Mg, Qd		Not Reported	
	Atorvastatin			S	Oral	10 Mg, Qd		Not Reported	
	Fungizone			S	Buccal	Unk Unk, Qd		Not Reported	
	Amiodarone			S	Oral	Unk		Not Reported	
	Driptane			S	Oral	15 Mg, Qd		Not Reported	
	Bisoce			S	Oral	Unk Unk, Qd		Not Reported	

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	Lactulose	S	Oral	Unk Unk, Qd	Not Reported
	Trimebutine	S	Oral	300 Mg, Qd	Not Reported
	Trimebutine	S			Not Reported
	Repaglinide	S	Oral	2 Mg, Qd	Not Reported
	Repaglinide	S			Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15393842	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1845022US			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan	
	Heart Medication			C		Unk, Qpm		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	11885504	EXPEDITED (15-DAY)		HO	PHHY2015FR171590			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Ritaline			S	Oral	100 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis	
	Ritaline			S	Oral	90 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis	
	Ritaline			S	Oral	110 Mg, Qd (80 Mg In Morning And 20 Mg At 4:00 Pm)		Novartis	
	Quetiapine			S	Oral	400 Mg, Qd		Not Reported	
	Quetiapine			S				Not Reported	
	Quetiapine			S				Not Reported	
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported	
	Xeroquel			S				Not Reported	

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Xeroquel	S				Not Reported
Abilify	S	Oral	15 Mg, Qd		Not Reported
Abilify	S				Not Reported
Abilify	S				Not Reported
Seroplex	S	Oral	10 Mg, Qd		Not Reported
Seroplex	S				Not Reported
Seroplex	S				Not Reported
Laroxyl	S	Unknown			Not Reported
Laroxyl	S				Not Reported
Laroxyl	S				Not Reported
Lexapro	S	Oral	10 Mg, Qd		Not Reported
Lexapro	S				Not Reported
Lexapro	S				Not Reported
Lepticur	S	Unknown	15 Mg, Unk		Not Reported
Lepticur	S				Not Reported
Lepticur	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	11898605	EXPEDITED (15-DAY)	HO		FR-ASTRAZENECA-2016SE00976		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral	400 Mg Daily		Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Xeroquel			S	Oral			Astrazeneca
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seroplex			S	Oral	Lexapro, 10 Milligrams,		Not Reported

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			Daily	
Seroplex	S	Oral	Lexapro, 10 Milligrams, Daily	Not Reported
Seroplex	S	Oral	Lexapro, 10 Milligrams, Daily	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral	100 Mg (80 Mg In The Morning And 20 Mg At 4pm)	Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral		Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Ritaline	S	Oral	110 Mg Daily (80 Mg In The Morning And 20 Mg At 16:00)	Not Reported
Abilify	S	Oral		Not Reported
Abilify	S	Oral		Not Reported
Abilify	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Laroxyl	S	Oral		Not Reported
Lepticur	S	Unknown	15.0mg Unknown	Not Reported

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	Lepticur		S	Unknown	15.0mg	Unknown		Not Reported	
	Lepticur		S	Unknown	15.0mg	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	13289144	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP007448		28 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sialoadenitis	Escitalopram			S	Unknown	Unk		Apotex	
	Ondansetron			S	Unknown	Unk		Not Reported	
	Levetiracetam			C	Unknown			Not Reported	
	Temozolomide			C	Unknown	Unk		Not Reported	
	Temozolomide			C				Not Reported	
	Dexamethasone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	14875047	NON-EXPEDITED			US-PFIZER INC-2018189481		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Nexium			S		Unk		Unknown	
	Septra			S		Unk		Pfizer	
	Estrace			S		Unk		Not Reported	
	Flexeril			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Lotrel			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
	Niacin			S		Unk		Not Reported	
	Nickel			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	14879174	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US17516			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15293440	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-041631		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Movement Disorder	Aripiprazole			S	Unknown	Unk		Aurobindo	
	Escitalopram			S	Unknown	Unknown		Aurobindo	
	Lithium			S	Unknown	Unknown		Not Reported	
	Bupropion			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15306203	NON-EXPEDITED			US-PFIZER INC- 2018336323		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Drug Ineffective; Drug Intolerance; Personality Change; Tachyphrenia	Zoloft			S	Oral	Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15394378	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2018-046039		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown	Unk		Aurobindo	
	Melperone Hydrochloride			S	Unknown	Unk		Not Reported	

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Ciprallex /01588501/	S	Unknown	10 Milligram, Daily	Not Reported
Escitalopram	C	Unknown	Unk	Not Reported
L-Tyrosine	C	Unknown	Unk	Not Reported
Candesartan	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Mcp /00041901/	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Amlodipin /00972401/	C	Unknown	Unk	Not Reported
Kalinor /00031402/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15394414	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-184683		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Mirtazapine			S	Oral	Inconnue ()		Sun	
	Escitalopram			S	Oral	Inconnue ()		Not Reported	
	Alprazolam			S	Oral	Inconnue ()		Not Reported	
	Methadone			S	Oral	Inconnue ()		Not Reported	
	Havlane			S	Oral	Inconnue ()		Not Reported	
	Theralene			S	Oral	Inconnue ()		Not Reported	
	Tercian			S	Oral	Inconnue ()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15394432	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-045967		73 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Milligram, Once A Day		Aurobindo	
	Lorans			S	Oral	1 Dosage Form, Once A Day		Not Reported	

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Lorans	S	Oral	1 Unk	Not Reported
Carbolithium	S	Oral	1.5 Dosage Form, Once A Day	Not Reported
Metformin Teva	C	Unknown	Unk	Not Reported
Omeprazen /00661201/	C	Unknown	Unk	Not Reported
Nicetile	C	Unknown	Unk	Not Reported
Eskim	C	Unknown	Unk	Not Reported
Cipralext /01588501/	S	Oral	0.5 Dosage Form, Once A Day	Not Reported
Totalip	C	Unknown	Unk	Not Reported
Motilium /00498201/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15396400	EXPEDITED (15-DAY)		OT	ZA-MYLANLABS-2018M1068100			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Sleep Disorder	Escitalopram			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15396455	EXPEDITED (15-DAY)		OT	DE-TORRENT-00010002		76 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Rash	Candesartan			C		Unk			Unknown
	Eliquis			C	Oral	Unk			Unknown
	Oestradiol			C	Oral	Unk			Unknown
	Novalgine (Metamizole Sodium)			C	Oral	Unk			Unknown
	Amlodipine			C		Unk			Unknown
	Escitalopram			S	Oral	Unk			Unknown
	Sulfasalazine			C	Oral	Unk			Unknown
	Concor			C	Oral	Unk			Unknown

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	Kalinor (Potassium Chloride)	C	Oral			Unknown
	Cotrimoxazol	C	Oral	Unk		Unknown
	Vigantoletten	C	Subcutaneous	Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15396523	EXPEDITED (15-DAY)		OT	ZA-MYLANLABS-2018M1068105			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15399289	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1845021US		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown		Allergan	
	Loxapac			S	Oral	Unk, Unknown		Not Reported	
	Pantoprazole			S	Oral	Unk, Unknown (Long Cours)		Not Reported	
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Q Month		Not Reported	
	Levothyrox			S	Oral	Unk Unk, Unknown		Not Reported	
	Fenofibrate			S	Oral	Unk, Unknown		Not Reported	
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Q Month		Not Reported	
	Valaciclovir			S	Oral	Unk, Unknown		Not Reported	
	Lorazepam			S	Oral	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15405905	DIRECT	Y				64 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis	Escitalopram			S	Oral			Cipla
	Lansoprazole			C				Not Reported
	Levothyroxine 100mcg			C				Not Reported
	Rosuvastatin 20mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	14825575	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-066206		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Amlodipine			S	Oral	10 Mg, 1x/Day		Accord
	Bisoprolol			S	Oral	1.25 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral			Accord
	Irbesartan			S	Oral	300 Mg, 1x/Day		Accord
	Dafalgan			S	Oral	6 Df, 1x/Day		Not Reported
	Alprazolam			S	Oral	0.75 Mg, 1x/Day		Not Reported
	Mirtazapine			S	Oral	15 Mg, 1x/Day		Not Reported
	Nefopam			S	Oral	3 Df, 1x/Day		Not Reported
	Diffu K			S	Oral	3 Df, Unk		Not Reported
	Colchicine			S	Oral	1 Df, 1x/Day		Not Reported
	Xarelto			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Not Reported
	Metformine Pfizer			S	Oral	1000 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported
	Tavanic			S	Oral	30 Mg, 1x/Day		Not Reported
	Valium			S	Oral	3 Df, 1x/Day		Not Reported
	Terbutaline			S	Respiratory (inhalation)	1 Df,		Not Reported

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19-Sep-2018	14993667	EXPEDITED (15-DAY)		HO	FR-ABBVIE-18S-056-2382777-00		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Prescribed Underdose	Lipanthyl			S	Oral	145 Mg, Qd		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Esomeprazole			S	Oral	Unk		Not Reported	
	Decapeptyl [Gonadorelin]			S	Intramuscular	1 Df, Cycle		Not Reported	
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported	
	Amlor			S	Oral	Unk		Not Reported	
	Novonorm			S	Oral	Unk		Not Reported	
	Xtandi			S	Oral	120 Mg, Qd		Not Reported	
	Xtandi			S	Oral	40 Mg, Qd		Not Reported	
	Seroplex			S	Oral	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15014845	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-44627			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Tablets			S	Unknown	1 Df, Qd		Aurobindo	
	Enalapril+Hydrochlorothiazide			S	Unknown	1 Df, Qd		Not Reported	
	Escitalopram			S	Unknown	1 Df, Qd		Aurobindo	
	Escitalopram			S				Aurobindo	
	Naproxen			S	Unknown	1 Df, Bid		Aurobindo	
	Naproxen			S				Aurobindo	
	Omeprazole			S	Unknown	1 Df, Qd		Aurobindo	
	Paracetamol			S	Unknown	1 Df, Tid		Aurobindo	
	Simvastatin			S	Unknown	1 Df, Qd		Aurobindo	
	Simvastatin			S	Unknown	20 Mg, Unk		Aurobindo	

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Topiramate	S	Unknown	1 Df, Qd	Aurobindo
Topiramate	S	Unknown	0.5 Df, Qd	Aurobindo
Tramadol+Paracetamol	S	Unknown	1 Df, Tid	Aurobindo
Amitriptyline	S	Unknown	Unk, Qd	Not Reported
Amitriptyline	S	Unknown	25 Mg, Unk	Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
Diazepam	S	Unknown	0.5 Df, Qd	Not Reported
Diazepam	S	Unknown	Unk	Not Reported
Glibenclamide	S	Unknown	1 Df, Bid	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
Tepazepam	S	Unknown	Unk, Qd (1)	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15253608	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US20516			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspiration; Blood Pressure Increased; Burning Sensation; Drug Ineffective; Dry Mouth; Glossitis; Glossodynia; Hyperhidrosis; Lip Dry; Nausea; Nervousness; Pyrexia; Stress; Tongue Discomfort; Tremor; Weight Decreased; Wrong Technique In Product Usage Process	Escitalopram			S	Oral	10 Mg, Unk (Unknown Manufacturer)		Invagen
	Escitalopram			S	Oral	20 Mg, Qd		Invagen
	Escitalopram			S	Oral	30 Mg, Unk		Invagen
	Escitalopram			S	Oral	10 Mg, Unk		Invagen
	Valsartan			C	Unknown	120 Mg, Unk		Not Reported
	Irbesartan			C	Unknown	150 Mg, Qd		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Vitamin B12 /00056201/			C	Unknown	Unk, Qd		Not Reported
	Vitamin C /00008001/			C	Unknown	500 Mg, Qd		Not Reported
	Vitamin D /00107901/			C	Unknown	1000 Mcg, Qd		Not Reported
	Iron			C	Unknown	325 Mg, Qd		Not Reported
	Norethindrone /00044901/			C	Unknown	0.35 Mg, Unk		Not Reported

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Nicotine			C	Unknown	Unk	Not Reported			
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19-Sep-2018	15381962	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1843321US		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Inappropriate Schedule Of Product Administration	Restasis			S	Ophthalmic	2 Gtt, Bid		Allergan	
	Botox			S	Intravesical	100 Units, Single		Allergan	
	Bentyl Capsules			S	Oral	10 Mg, Bid		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Macrobid			C		Unk		Not Reported	
	Lipitor			C	Oral	Unk		Not Reported	
	Flonase			C	Nasal	Unk		Not Reported	
	Premarin			C	Topical	Unk		Not Reported	
	Calcium			C	Oral	Unk		Not Reported	
	Probiotic			C	Oral	Unk		Not Reported	
	Multivitamin			C	Oral	Unk		Not Reported	
	Fish Oil			C	Oral	Unk		Not Reported	
	Losartan			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15400005	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955915		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Teva	
	Valaciclovir			S	Oral			Teva	
	Escitalopram (Oxalate D')			S	Oral			Ivax	
	Fenofibrate			S	Oral			Not Reported	
	Loxapac			S	Oral			Not Reported	
	Bendamustine Accord			S	Intravenous (not			Not Reported	

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Levothyrox	S	otherwise specified)	Not Reported
Truxima	S	Intravenous (not otherwise specified)	Not Reported
Lorazepam	S	Oral Long Cours	Not Reported

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19-Sep-2018	15400676	EXPEDITED (15-DAY)		HO	FR-ACCORD-071837		24 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Disturbance In Attention; Overdose	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Codeine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401208	NON-EXPEDITED			US-DRREDDYS-USA/USA/18/0101806			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Rash Pruritic; Urticaria	Metoprolol Succinate			S	Unknown			Not Reported
	Metoprolol Succinate			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S				Not Reported
	Zoloft			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Flonase			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Baby Aspirin			C	Unknown			Not Reported

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	B Complex	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Calcium Citrate	C	Unknown	Not Reported
	Miralax	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401452	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-072481		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State; Suicide Attempt	Escitalopram			S	Oral			Not Reported	
	Paracetamol			S	Oral	12gr Dia		Accord	
	Exforge			S	Oral	5 Cps		Not Reported	
	Ibuprofen			S	Oral	400 Mg X 7 Cps		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401887	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001854		50 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion; Metabolic Encephalopathy	Escitalopram			S		Unknown		Unknown	
	Telmisartan			C		Unknown		Unknown	
	Acetylsalicylic Acid			C		For Previous 2 Years		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15402280	EXPEDITED (15-DAY)		HO	FR-ACCORD-072234		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
	Ibuprofen			S	Oral			Accord	
	Havlane			S	Oral			Not Reported	

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	Paroxetine		S	Oral				Not Reported	
	Dafalgan		S	Oral				Not Reported	
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19-Sep-2018	15402285	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-072372		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension; Suicide Attempt	Escitalopram			S	Oral			Not Reported	
	Paracetamol			S	Oral			Accord	
	Propranolol/Propranolol Hydrochloride/Propranolol			S	Oral			Accord	
	Phenobarbital								
	Lamotrigine			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Ibuprofen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15402524	EXPEDITED (15-DAY)		HO	FR-ACCORD-072194		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperleukocytosis; Pancreatitis; Renal Failure	Escitalopram			S	Oral			Not Reported	
	Ibuprofen			S	Oral			Accord	
	Paracetamol			S				Accord	
	Atarax			S	Oral			Not Reported	
	ColtramyI			S	Oral			Not Reported	
	Alprazolam			C	Oral			Not Reported	
	Cefuroxime			C	Oral			Not Reported	
	Brexin			C	Oral	Drug Intoxication		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15403024	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1845053US		30 YR	Male	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alexithymia; Decreased Appetite; Depression; Drug Ineffective; Erectile Dysfunction; Feeling Abnormal; Genital Disorder Male; Listless; Loss Of Libido; Mood Altered; Nausea; Off Label Use	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15404378	EXPEDITED (15-DAY)		HO	EE-BAUSCH-BL-2018-003957		46 YR	Female	EST

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Venlafaxine			S	Unknown	Increasing Dose		Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown	Increased Dose		Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Escitalopram			S	Unknown	After One Month, The Escitalopram Dose Was Increased To 20 Mg/Day,		Not Reported
	Agomelatine			C	Unknown			Not Reported
	Agomelatine			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Bupropion			C	Unknown	Increased Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15404602	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1834971US		19 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Overdose;	Escitalopram Oxalate Unk			S	Oral	280 Mg, Single		Allergan

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Sopor	Delorazepam	S	Unknown	Unk Unk, Unknown	Not Reported				
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20-Sep-2018	13983821	NON-EXPEDITED			US-APOTEX-2017AP009754		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Paroxetine Hydrochloride			S				Apotex	
	Fluoxetine Oral Solution Usp			S				Apotex	
	Sertraline Hydrochloride			S				Apotex	
	Escitalopram Oxalate			S				Apotex	
	Bupropion Hydrochloride			S				Apotex	
	Venlafaxine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	14338487	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2017-DE-838208		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour;	Aripiprazole			S	Unknown			Teva	
Accidental Overdose;	Aripiprazole			S	Oral			Teva	
Disinhibition; Drug	Cipralelex			S	Oral	5 Gtt Daily; Daily Dose: 5 Gtt Drop(S) Every Day		Not Reported	
Interaction; Drug	Cipralelex			S	Oral	20 Gtt Daily; Daily Dose: 20 Gtt Drop(S) Every Day		Not Reported	
Interaction;	Cipralelex			S	Oral	10 Gtt Daily; Daily Dose: 10 Gtt Drop(S) Every Day		Not Reported	
Hospitalisation; Mental	Cipralelex			S	Oral	1 Dosage Forms Daily; Daily Dose: 1 Df Dosage Form Every Day		Not Reported	
Disorder; Product Use									
Issue; Product Use Issue;									
Therapy Change									
	Calcium 600 Plus Vitamin D			C	Unknown			Not Reported	
	Calcium 600 Plus Vitamin D			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	14624261	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		88 YR	Female	FRA

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2018R1-165685

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Spironolactone			S	Oral	50 Mg, Daily		Mutual
	Seroplex 20 Mg, Comprime			S	Oral	1 Df, Daily		Not Reported
	Pellicule Secable							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	14950165	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-897008		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Unknown			Teva
	Quetiapine			S	Oral			Teva
	Quetiapine			S				Teva
	Laroxyl			S	Unknown			Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Xeroquel			S	Unknown			Not Reported
	Xeroquel			S	Oral	400 Milligram Daily;		Not Reported
	Xeroquel			S				Not Reported
	Seroplex			S	Oral	10 Milligram Daily; 10 Mg, Qd		Not Reported
	Seroplex			S				Not Reported
	Abilify			S	Unknown			Not Reported
	Abilify			S				Not Reported
	Abilify			S	Oral			Not Reported
	Ritaline			S	Oral	100 Mg, Unk		Not Reported
	Ritaline			S	Oral			Not Reported
	Ritaline			S				Not Reported
	Methylphenidate			S	Oral	110 Milligram Daily; 110		Not Reported

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					Mg, Qd	
Methylphenidate	S					Not Reported
Methylphenidate	S	Oral				Not Reported
Lexapro	S	Oral				Not Reported
Lexapro	S					Not Reported
Lexapro	S					Not Reported
Lepticur	S	Unknown		15 Mg, Unk		Not Reported
Lepticur	S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15114607	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2018-034015		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Zopiclone Tablet			S	Oral	1tab/Dy		Not Reported
	Olanzapine Tablet			S	Unknown	15 Mg, Unk		Aurobindo
	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Aripiprazole			S	Oral	10 Mg, Unk		Not Reported
	Lepticur			S	Intracardiac	Unk ()		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seroplex			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Dopamide			S	Oral	Unk ()		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Anafranil			S	Oral	Daily Dose Increased		Not Reported
	Anafranil			S	Oral	Daily Dose Increased. Oral Drug Unspecified Form		Not Reported

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Lexapro	S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy	Not Reported
Imovane	S	Oral	1tab/Dy, Oral Drug Unspecified Form	Not Reported
Methyldopa	S	Oral	Unk ()	Not Reported
Oxazepam	S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening ()	Not Reported
Tropatepine Hydrochloride	S	Unknown	Unk ()	Not Reported
Valpromide	S	Oral	Unk ()	Not Reported
Clomipramine Hydrochloride	S	Oral	75 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15403730	EXPEDITED (15-DAY)	DE, HO		FR-ALLERGAN-1000016239		83 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Inappropriate Schedule Of Product Administration; Melaena; Toxic Skin Eruption; Urticaria	Escitalopram Oxalate Unk			S	Oral	10 Mg, Bid		Allergan
	Previscan (Fluindione)			S	Oral	5 Mg, Qd		Not Reported
	Icaz			S	Oral	5 Mg, Qd		Not Reported
	Frisium			S	Oral	5 Mg, Qd		Not Reported
	Tadenan			S	Oral	50 Mg, Bid		Not Reported
	Diffu K			S	Oral	1 Df, Qd		Not Reported
	Fluindione			S		5 Mg, Qd		Not Reported
	Urbanyl			S	Oral	5 Mg, Qd		Not Reported
	Fucidine (Fusidic Acid)			C		Unk		Not Reported
	Kardegic			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15405290	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE00907			Unknown	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Escitalopram			S	Oral	30 Mg, Qd		Not Reported
	Diazepam			C	Oral	5 Mg, Qd		Not Reported
	Diazepam			C	Oral	10 Mg, Qd		Not Reported
	Pantozol /01263204/			C	Unknown	40 Mg, Qd		Not Reported
	Pantozol /01263204/			C	Unknown	20 Mg, Qd		Not Reported
	Prothipendyl			C	Oral	80 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15405432	EXPEDITED (15-DAY)		HO, LT, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-184915			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use; Suicide Attempt	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Sun
	Zopiclone			S	Oral	1tab/Dy		Not Reported
	Lepticur			S	Unknown	Unk ()		Not Reported
	Methyl dopa			S	Oral	Unk ()		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk ()		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Seroplex			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg.		Not Reported

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Seroplex	S	Unknown	1tab/Dy	Not Reported
Anafranil	S	Oral	5 Mg, Qd	Not Reported
Zyprexa	S	Unknown	Daily Dose Increased. Oral Drug Unspecified Form	Not Reported
Imovane	S	Oral	15 Mg, Unk	Not Reported
			1tab/Dy, Oral Drug Unspecified Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15405674	EXPEDITED (15-DAY)		DE, HO, OT	US-ZYDUS-026947		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anion Gap	Escitalopram			S	Unknown			Zydus Pharm
Abnormal; Atrioventricular Block; Bradycardia; Death; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Ventricular Arrhythmia	Lamotrigine			S	Unknown			Zydus Pharm
	Propranolol			S	Unknown			Zydus Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15409456	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1845762US		38 YR	Male	CHE

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusional Disorder, Unspecified Type; Depression; Mania; Overdose; Suicidal Ideation; Therapeutic Product Effect Incomplete	Escitalopram Oxalate - Bp			S	Unknown	50 Mg, Unk		Allergan	
	Abilify Maintena			S	Unknown	400 Mg, Q Month		Not Reported	
	Brintellix			S	Unknown	10 Mg, Unk		Not Reported	
	Abilify/Aripiprazole			S	Oral	15 Mg, Qd		Not Reported	
	Abilify/Aripiprazole			S				Not Reported	
	Lithium			C	Unknown	2 X 1.5 I.E 1/2 Daily		Not Reported	
	Wellbutrin			C	Unknown	300 Mg, Unk		Not Reported	
	Trittico			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15429149	DIRECT		OT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral; Uveitis	Escitalopram 10mg		Y	S	Oral	Quantity:1 Tablet(S);		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15429881	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Cyst; Respiratory Tract Neoplasm	Cosentyx Pen			S	Subcutaneous			Not Reported	
	Benadryl			C				Not Reported	
	Botox			C				Not Reported	
	Epipen			C				Not Reported	
	Flonase			C				Not Reported	
	Hydroxyz Pam			C				Not Reported	
	Lexapro			S				Not Reported	
	Neurontin			C				Not Reported	
	Singulair			C				Not Reported	
	Tiazac			C				Not Reported	
	Topamax			S				Not Reported	
	Traxodone			C				Not Reported	
	Ventolin Hfa Aer			C				Not Reported	

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Zyrtec			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	14266937	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR- APL-2017-44385		45 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Therapeutic Product Effect Incomplete	Sertraline Film-Coated Tablet			S	Oral	Unk		Aurobindo	
	Sertraline Film-Coated Tablet			S				Aurobindo	
	Escitalopram			S	Oral	Unk		Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	14797831	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-000232			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine Tablets			S	Unknown	1 Df, Qd		Aurobindo	
	Enalapril+Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Not Reported	
	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Aurobindo	
	Naproxen			S	Unknown	1 Df, Bid		Aurobindo	
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Aurobindo	
	Paracetamol			S	Unknown	1 Df, Tid		Aurobindo	
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Aurobindo	
	Simvastatin			S	Unknown	20 Mg, Unk		Aurobindo	
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Aurobindo	
	Topiramate			S	Unknown	.5 Dosage Forms Daily;		Aurobindo	
	Tramadol+Paracetamol			S	Unknown	1 Df, Daily, 3 Dosage Forms Daily; 1 Df = 37.5/325 Mg		Aurobindo	

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Amitriptyline	S	Unknown	Qd	Not Reported
Amitriptyline	S	Unknown	12.5 Mg, Qd	Not Reported
Glibenclamide	S	Unknown	2 Dosage Forms Daily;	Not Reported
Diazepam W/Sulpiride	S		Unk, Once A Day (Qd)	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
Diazepam	S	Unknown	.5 Dosage Forms Daily; 5 Mg	Not Reported
Diazepam	S	Unknown	Unk ()	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15324164	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-156511		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Sertraline			S	Oral	100 Mg, Daily		Sun
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Qd		Sun
	Brintellix			S	Unknown	15 Mg, Daily		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	5 Mg, Daily		Not Reported
	Duloxetine Hydrochloride			S	Unknown	60 Mg, Qd		Not Reported
	Ramipril/Idroclorotiazide			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Ezetimibe			C	Unknown	10 Mg, Qd		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Daily		Not Reported
	Simvastatin			C	Unknown	20 Mg, Qd		Not Reported
	Amiodarone			C	Unknown			Not Reported
	Alprazolam			C	Unknown	2 Mg, Qd		Not Reported
	Triatec Hct			C	Unknown	15 Mg, Qd		Not Reported

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Cordarone	C	Unknown	200 Mg, Unk	Not Reported
Coumadin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15412240	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-06717		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Duloxetine Hydrochloride			S	Oral	60 Mg, Qd		Alkem
	Duloxetine Hydrochloride			S	Oral	30 Mg, Qd		Alkem
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	Aspirin			C	Oral	325 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg, Qd		Not Reported
	Gabapentin			C	Oral	300 Mg, Tid		Not Reported
	Hydrocodone/Acetaminophen			C	Oral	7.5/500 Mg Every Six Hours As Needed		Not Reported
	Olmesartan			C	Oral	20 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Phenytoin			C	Oral	100 Mg, Bid		Not Reported
	Ropinirole			C	Oral	2 Mg, Bedtime		Not Reported
	Simvastatin			C	Oral	20 Mg, Bedtime		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15413290	EXPEDITED (15-DAY)		DE, LT, OT	US-MYLANLABS- 2018M1067562		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anion Gap Abnormal; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level	Propranolol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported

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Of Consciousness;
Dystonia;
Electrocardiogram Qrs
Complex Prolonged;
Electrocardiogram Qt
Prolonged; Heart Injury;
Hyperreflexia;
Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Toxicity To Various
Agents; Tremor;
Ventricular Arrhythmia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15413430	EXPEDITED (15-DAY)		OT	CH-TAKEDA- 2018TUS027783		38 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug	Brintellix			S	Unknown	10 Mg, Unk		Takeda
Ineffective; Overdose;	Abilify Maintena			S	Unknown	400 Mg, Q4weeks		Not Reported
Suicidal Ideation;	Ciprallex /01588501/			S	Unknown	50 Mg, Unk		Not Reported
Therapeutic Product Effect	Abilify			S	Oral	15 Mg, Qd		Not Reported
Incomplete	Abilify			S				Not Reported
	Lithium			C	Unknown	660 Mg, Qd		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Unk		Not Reported
	Trittico			C	Unknown	200 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15415141	EXPEDITED (15-DAY)		OT	JP-ALLERGAN- 1846006US		64 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Depas (Etizolam)			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15424098	DIRECT						Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Treatment Failure	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15430807	DIRECT	Y	HO			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral		10 YR	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2018	15415621	EXPEDITED (15-DAY)		DE, HO	FR-ACCORD-072668		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Disorder; Pulmonary Fibrosis	Atorvastatin/Atorvastatin			S	Oral			Not Reported	
	Calcium								
	Escitalopram			S	Oral			Not Reported	
	Ramipril			S	Oral			Accord	
	Paracetamol			S	Oral			Accord	
	Pantoprazole			S	Oral			Not Reported	
	Levothyrox			S	Oral	Dose 1 Unk Unit		Not Reported	
	Kardegic			S	Oral			Not Reported	
	Caltrate Vitamine D3			S	Oral			Not Reported	
Amiodarone			S	Oral			Not Reported		

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Lorazepam			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2018	15416251	EXPEDITED (15-DAY)		OT	US-BAXTER-2018BAX024154			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Human Herpesvirus 6 Infection	Ondansetron Injection, Usp-Single Dose			S	Unknown			Claris	
	Sertraline			S	Unknown	Initial Two Trimesters		Not Reported	
	Escitalopram			S	Unknown	Final Trimester		Not Reported	
	Progesterone			S	Unknown	High-Dose Progesterone Administered During Twin Pregnancy		Not Reported	
	Progesterone			S	Unknown	High-Dose Progesterone From 16 Weeks Of Gestation		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2018	15416253	EXPEDITED (15-DAY)		DE, OT	US-BAXTER-2018BAX024312		4 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congestive Cardiomyopathy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Human Herpesvirus 6 Infection	Ondansetron Injection, Usp-Single Dose			S	Transplacental			Claris	
	Sertraline			S	Transplacental	(Mother Dose: Initial Two Trimesters)		Not Reported	
	Escitalopram			S	Transplacental	(Mother Dose: Final Trimester)		Not Reported	
	Progesterone			S	Transplacental	(Mother Dose: High-Dose Progesterone From 16 Weeks Of Gestation)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15165989	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2018125155		35 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Apathy; Asthenia	Lamotrigine			S	Oral	100 Mg, Qd		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Glaxosmithkline
	Seroquel			S	Oral	1 Df, Qd		Not Reported
	Seroquel			S	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15253628	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APU-2018-033894		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asphyxia; Eye Swelling; Gait Inability; Haemorrhage; Nightmare; Rhinorrhoea	Escitalopram Tablets Usp 10mg			S		10 Milligram, Two Times A Day		Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo
	Stalevo /01530202/			C		Unk		Not Reported
	Nexpro /01479302/			C		Unk		Not Reported
	Amantadine			C		Unk		Not Reported
	Cobal /00056201/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15417985	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS- 2018M1068584		73 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardiogenic Shock; Haemodynamic Instability; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Epinephrine			S	Unknown	3 Injections		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	14687806	EXPEDITED (15-DAY)		DE	FI-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-168411			Unknown	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ventricular Fibrillation	Escitalopram			S	Unknown	Unknown		Not Reported	
	Ciprofloxacin			S	Oral	Unk		Ranbaxy	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	14933313	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2018-03933		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Hypotension; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Somnolence; Toxicity To Various Agents; Unresponsive To Stimuli	Escitalopram Tablets			S		Unk		Not Reported	
	Escitalopram Tablets			S				Not Reported	
	Lamotrigine Tablets 100 Mg			S	Oral	Unk		Lupin	
	Lamotrigine Tablets 100 Mg			S				Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15314742	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-042718		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Atorvastatin			S	Oral	10 Milligram, Daily		Not Reported	
	Amiodarone			S	Oral	Inconnue		Aurobindo	
	Lactulose			S	Oral	2 Dosage Form, Daily		Not Reported	

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Lansoprazole	S	Oral	15 Milligram, Daily	Not Reported
Trimebutine	S	Oral	300 Milligram, Daily	Not Reported
Repaglinide	S	Oral	2 Milligram, Daily	Aurobindo
Escitalopram	S	Oral	10 Milligram, Daily	Aurobindo
Prograf	S	Oral	3 Milligram, Daily	Not Reported
Bisocce	S	Oral	2 Dosage Form In Total	Not Reported
Fungizone	S	Buccal	3 Dosage Form, Daily	Not Reported
Driptane	S	Oral	3 Dosage Form, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15422477	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-185221		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours ()		Sun
	Fenofibrate			S	Oral	()		Sun
	Valaciclovir			S	Oral	()		Sun
	Loxapac			S	Oral	()		Not Reported
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Mg, Monthly		Not Reported
	Levothyrox			S	Oral	()		Not Reported
	Truxima			S	Intravenous (not otherwise specified)	720 Mg, Daily		Not Reported
	Lorazepam			S	Oral	Long Cours ()		Not Reported
	Escitalopram (Oxalate D')			S	Oral	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15424024	EXPEDITED (15-DAY)		CA, OT	DE- GLAXOSMITHKLINE- DE2018170258		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Atrial Septal Defect;	Lamictal	S	Transplacental	125 Unk, Unk	Glaxosmithkline
Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal;	Quetiapine	S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D	Glaxosmithkline
Ventricular Septal Defect	Cipralelex	S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D	Not Reported
	Folic Acid	C	Transplacental	Unk	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15424507	EXPEDITED (15-DAY)		OT	GB-TORRENT-00017905		81 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Product Dispensing Error	Escitalopram			S	Oral	Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15424877	EXPEDITED (15-DAY)		OT	DE-ROCHE-2188523		59 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Uric Acid Increased;	Rivotril			S	Unknown			Not Reported
Catatonia; Dental Caries;	Zoloft			S	Unknown			Not Reported
Disorientation; Dyskinesia;	Cipralelex			S	Unknown			Not Reported
Fatigue; Infection; Muscle Spasms; Off Label Use;	Remergil			S	Unknown			Not Reported
Product Use In	Seroquel			S	Unknown			Not Reported
Unapproved Indication;	Allopurinol			C	Unknown			Not Reported
Serotonin Syndrome;								
Suicidal Ideation; Tremor								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15425975	EXPEDITED (15-DAY)		CA, OT	PHHY2018DE104647		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine	S	Transplacental	Maternal Dose: 50 Mg, Qd (Varying Dosage Between 25 And 50 Mg/D)	Novartis
	Lamictal	S	Transplacental	Maternal Dose: 125 [Mg/D]/Slowly Reduced	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 20 Mg, Qd	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 10 Mg, Qd	Not Reported
	Cipralex	S	Transplacental	Maternal Dose: 5 Mg, Qd	Not Reported
	Femibion [Minerals Nos;Vitamins Nos]	C	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15426956	EXPEDITED (15-DAY)		OT	JP-ALLERGAN- 1846136US		15 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activation Syndrome; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	0.5 Mg, Qd		Allergan	
	Lunesta			C	Oral			Not Reported	
	Meilax			C	Oral	0.5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15150359	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT- 926980		19 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram Oxalate			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15302813	EXPEDITED (15-DAY)		OT	PHHY2018IT074689		35 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Lamotrigine			S	Oral	100 Mg, Qd		Novartis	

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	Seroquel		S	Oral		1 Df, Qd (1 Ug/Litre)			Not Reported
	Seroquel		S	Oral		1 Mg/L, Qd (1 Ug/Litre)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15428390	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0094605		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Interaction; Rash	Sumatriptan Succinate Tablets			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Synthroid			C	Unknown			Not Reported	
	Hydroxyurea			C	Unknown			Not Reported	
	Baby Aspirin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15428402	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.-2018GB21372			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Product Dispensing Error	Escitalopram			S	Oral	20 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15429342	EXPEDITED (15-DAY)		CA, DE, OT	DE-TORRENT-00010310			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 [Mg/D]		Unknown	
	Nepresol (Hydralazine Hydrochloride)			S	Transplacental	25 [Mg/D]		Unknown	
	L-Thyroxin 50			C	Transplacental	Unknown		Unknown	
	Escitalopram			S	Transplacental	20 [Mg/D]		Unknown	
	Cytotec			C	Transplacental	Unknown		Unknown	
	Candesartan			S	Transplacental	16 [Mg/D]		Unknown	

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Paroxetine			S		Transplacental		30 [Mg/D]		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
26-Sep-2018	15430293	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-MYLANLABS-2018M1070983		25 YR	Male	CZE	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Brain Death; Cardiac Fibrillation; Suicide Attempt; Toxicity To Various Agents; Ventricular Fibrillation	Escitalopram			S	Oral	Ingestion		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15430574	EXPEDITED (15-DAY)		OT	CH-TAKEDA-2018TUS020551			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Philadelphia Chromosome Positive; Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Iclusig			S	Oral	45 Mg, Qd		Takeda	
	Iclusig			S	Oral	15 Mg, Unk		Takeda	
	Iclusig			S	Oral	30 Mg, Unk		Takeda	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15432162	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1846447US		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd (0. - 40.2. Gestational Week)		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd (0. - 40.2. Gestational Week)		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd (0. - 40.2. Gestational Week)		Allergan	
	Lamictal			S	Transplacental	125 Mg, Qd Slowly		Not Reported	

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Quetiapine	S	Transplacental	Reduced (0. - 12.4. Gestational Week) 50 Mg, Qd (Varying Dosage Between 25 And 50 Mg/D/ 0. - 21.1. Gestational Week)	Not Reported
Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]	C	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15432415	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-PRINSTON PHARMACEUTICAL INC.-2018PRN01399		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Completed Suicide; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Nausea; Serotonin Syndrome; Syncope; Ventricular Fibrillation	Escitalopram			S	Oral	250 Mg, Once		Prinston Pharmaceutical
	Yew Leaves			S	Oral	50 G, Once		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15448342	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15448955	DIRECT	Y	OT			15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amenorrhoea	Lexapro			S	Oral			Not Reported

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27-Sep-2018	14374440	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159673		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Oral	400 Mg, Qd		Sun
	Laroxyl			S	Unknown	Unk		Not Reported
	Laroxyl			S				Not Reported
	Laroxyl			S				Not Reported
	Methylphenidate			S	Oral	110 Mg, Qd (80 Mg In The Morning And 20 Mg At 4pm)		Not Reported
	Methylphenidate			S	Oral	100 Mg, 80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Methylphenidate			S	Unknown	80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Lexapro			S	Oral	10 Mg, Qd		Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Xeroquel			S	Oral	400 Mg, Qd		Not Reported
	Xeroquel			S				Not Reported
	Xeroquel			S				Not Reported
	Seroplex			S	Oral	10 Mg, Qd		Not Reported
	Seroplex			S				Not Reported
	Seroplex			S				Not Reported
	Ritaline			S	Oral	100 Mg, Qd		Not Reported
	Ritaline			S	Oral	110 Mg, Qd		Not Reported
	Ritaline			S				Not Reported
	Lepticur			S	Unknown	15 Mg, Unk		Not Reported
	Lepticur			S				Not Reported
	Lepticur			S				Not Reported
	Abilify			S	Oral	15 Mg, Qd		Not Reported
	Abilify			S				Not Reported

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Abilify		S					Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	14908811	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR001671		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ondansetron			S	Oral	Unk		Novartis	
	Pantoprazole			S	Intravenous drip	Unk		Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Doxorubicin Hydrochloride			S	Intravenous drip	Unk		Not Reported	
	Methotrexate			S	Intravenous drip	Unk		Not Reported	
	Bromazepam			S	Oral	Unk		Not Reported	
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported	
	Furosemide			S	Oral	Unk		Not Reported	
	Valaciclovir			S	Oral	Unk		Not Reported	
	Prednisone			S	Intravenous drip	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Cyclophosphamide			S	Intravenous drip	Unk		Not Reported	
	Zarzio			S	Subcutaneous	Unk		Not Reported	
	Lidocaine			S	Buccal	Unk		Not Reported	
	Fungizone			S	Buccal			Not Reported	
	Exacyl			S	Intravenous drip			Not Reported	
	Eprex			S	Subcutaneous			Not Reported	
	Meropenem Anhydrous			S	Intravenous drip	Unk		Not Reported	
	Hextril			S	Buccal			Not Reported	
	Calciparine			S	Subcutaneous	Unk		Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	
	Voraxaze			S	Intravenous drip	Unk		Not Reported	
	Vincristine			S	Intravenous drip	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	14944550	EXPEDITED (15-DAY)		HO	ES-ROCHE-2129818			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Co-Trimoxazole			S	Unknown			Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	Most Recent Dose On 07/Mar/2018.		Not Reported
	Obinutuzumab			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	Most Recent Dose On 13/Mar/2018.		Not Reported
	Bendamustine Hydrochloride Incb050465			S				Not Reported
				S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15340384	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1842139US		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Acute; Septic Shock	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Atorvastatine			S	Oral	10 Mg, Qd		Not Reported
	Repaglinide			S	Oral	2 Mg, Qd		Not Reported
	Driptane			S	Oral	3 Df, Qd		Not Reported
	Amiodarone			S	Oral	Unk		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Bisocce			S	Oral	2 Df In Total		Not Reported
	Trimebutine			S	Oral	300 Mg, Qd		Not Reported
	Lactulose			S	Oral	2 Df, Qd		Not Reported

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Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
Fungizone	S	Buccal	3 Df, Qd	Not Reported

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27-Sep-2018	15344298	EXPEDITED (15-DAY)	LT, OT		JP-ALLERGAN-1842132US		73 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Off Label Use; Pulseless Electrical Activity	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S				Allergan
	Lorazepam			S	Unknown			Not Reported
	Lorazepam			S				Not Reported
	Epinephrine			S	Unknown	3 Df, Unk; Three Adrenaline Injections		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15388773	EXPEDITED (15-DAY)	HO		DE-TORRENT-00009932		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Haemorrhage; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Atorvastatin Calcium			C	Unknown	Unknown		Unknown
	Lorazepam			C	Unknown	In Crisis Situations With Temporary Effect		Unknown
	Opipramol Hydrochloride			C	Unknown	In Crisis Situations With Temporary Effect		Unknown
	Pregabalin			C		Unknown		Unknown
	Promethazine Hydrochloride			C	Unknown	Unknown		Unknown
	Aripiprazole			S	Unknown	5 Milligram Daily;		Unknown
	Escitalopram			S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg		Unknown
	Risperidone			S	Unknown	0.5 Mg		Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15432444	EXPEDITED (15-DAY)		CA, OT	DE-ASTRAZENECA-2018SF19958		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Zeneca	
	Cipralext			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported	
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Not Reported	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15432906	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-958737		39 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Feeling Abnormal; Feeling Hot; Hyperhidrosis; Paraesthesia; Urticaria	Escitalopram Teva			S	Unknown			Ivax	
	Escitalopram Teva			S				Ivax	
	Escitalopram Teva			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15433398	EXPEDITED (15-DAY)		HO, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185464		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Haemolytic Anaemia	Lorazepam			S	Unknown			Sun	
	Escitalopram			S	Unknown			Not Reported	

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27-Sep-2018	15433873	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2018-0059549		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Encephalopathy	Oxynormoro			S	Oral	5 Mg, Unk		Purdue	
	Topalgic Lp			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Amiodarone			S	Oral			Not Reported	
	Xanax			S	Oral			Not Reported	
	Kardegic			S	Oral	1 Df Daily, Strenght 75 Mg		Not Reported	
	Tazocilline			S	Intravenous (not otherwise specified)	3 Df Daily, Strenght 4g/500mg		Not Reported	
	Allopurinol			S	Oral			Not Reported	
	Ciclosporine			C	Oral			Not Reported	
	Mycophenolate Sodium			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15450918	DIRECT		DS, HO, LT, OT			56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Neoplasm; Blood Cholesterol Increased; Blood Pressure Increased; Cardiac Failure Congestive; Diabetes Mellitus; Gastrooesophageal Reflux Disease; Hyperglycaemia; Hyperlipidaemia; Neoplasm Malignant; Pancreatic Disorder; Parathyroid Tumour; Red Blood Cell Count	Seroquel			S				Unknown	
	Abilify			S				Not Reported	
	Actos			S				Not Reported	
	Metformin			S				Not Reported	
	Lexapro			S				Not Reported	

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Decreased; Thyroid
Neoplasm; Unevaluable
Event; Viral Infection;
White Blood Cell Count
Increased

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28-Sep-2018	15023859	EXPEDITED (15-DAY)		DE, OT	FR-FRESENIUS KABI-FK201802935		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Ondansetron (Manufacturer Unknown)			S	Oral			Not Reported	
	Ciprofloxacin (Manufacturer Unknown)			S	Intravenous drip	Unknown		Not Reported	
	Meropenem (Manufacturer Unknown)			S	Intravenous drip	Unknown		Not Reported	
	Pantoprazole			S	Intravenous drip	()		Not Reported	
	Fungizone			S	Buccal	()		Not Reported	
	Exacyl			S	Intravenous drip	()		Not Reported	
	Eprex			S	Subcutaneous	()		Not Reported	
	Zarzio			S	Subcutaneous	()		Not Reported	
	Hextril			S	Buccal	()		Not Reported	
	Furosemide			S	Oral	()		Not Reported	
	Lidocaine			S	Buccal	()		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Calciparine			S	Subcutaneous			Not Reported	
	Bisoprolol			S	Oral			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Cyclophosphamide			S	Intravenous drip			Not Reported	
	Prednisone			S	Intravenous drip			Not Reported	
	Vincristine			S	Intravenous drip			Not Reported	
	Methotrexate			S	Intravenous drip			Not Reported	
	Doxorubicin			S	Intravenous drip			Not Reported	

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Voraxaze	S	Intravenous drip	Not Reported
Valaciclovir	S	Oral	Not Reported
Bactrim	S	Oral	Not Reported
Bromazepam	S	Oral	Not Reported
Tranexamic Acid	S	Intravenous drip	Not Reported
Amphotericin B	S	Buccal	Not Reported
Epoetin Alfa	S	Subcutaneous	Not Reported
Sulfamethoxazole, Trimethoprim	S	Oral	Not Reported
Heparin Calcium	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15073839	EXPEDITED (15-DAY)		HO, OT	DE-HETERO CORPORATE- HET2018DE00571		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma; Haematoma; Haemorrhage; Menometrorrhagia; Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Escitalopram			S	Unknown	20 Mg, Qd (Morning)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S	Unknown	5 Mg, Qd		Hetero
	Risperidone			S	Unknown	0.5 Mg, Qd		Not Reported
	Risperidone			S				Not Reported
	Risperidone			S				Not Reported
	Pregabalin			C	Unknown	100 Mg, Qd Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Opipramol			C	Unknown	In Crisis Situations With Temporary Effect		Not Reported
	Lorazepam			C	Unknown	In Crisis Situations With Temporary Effect		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Promethazine			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15336125	EXPEDITED (15-DAY)		HO, OT	SK-ALLERGAN-1842008US		30 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Asthenia; Delusion; Depression; Disturbance In Social Behaviour; Hypomania; Mania; Mental Impairment; Product Use In Unapproved Indication; Sleep Disorder; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Pro Die		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Pro Die		Allergan	
	Olanzapine			S	Oral	Unk		Not Reported	
	Olanzapine			S	Oral	10 Mg, Pro Die		Not Reported	
	Olanzapine			S	Oral	15 Mg, Pro Die		Not Reported	
	Quetiapine			C	Unknown	500 Mg, Pro Die (Extended-Release Form)		Not Reported	
	Valproate			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15410126	EXPEDITED (15-DAY)		OT	CZ-AUROBINDO-AUR-APL-2018-025570		58 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Olanzapine			S	Unknown	Unk		Aurobindo	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Not Reported	
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported	
	Aripiprazole			S	Unknown	Unk		Not Reported	
	Citalopram			S	Unknown	Series Of Citalopram Infusions		Not Reported	
	Ziprasidone			S	Unknown	Unk		Not Reported	
	Clomipramine			S	Unknown	Unk		Not Reported	
	Melperone			C	Unknown	Unk		Not Reported	
	Tiaprider			C	Unknown	Unk		Not Reported	

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	Haloperidol	C	Unknown	Unk		Not Reported
	Propofol	C	Unknown	Unk		Not Reported
	Clonazepam	C	Unknown	Unk		Not Reported
	Memantine	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15438691	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-047404		81 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Product Dispensing Error	Escitalopram Tablets			S	Oral	20 Milligram		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15438888	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-047566			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15439323	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2018-047551		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D ()		Aurobindo
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced ()		Not Reported
	Cipralext /01588501/			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D ()		Not Reported

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Femibion /01597501/

C

Transplacental

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15440094	EXPEDITED (15-DAY)		HO, LT, OT	CZ-APOTEX-2018AP021192		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Loss Of Consciousness; Nausea; Serotonin Syndrome; Suicide Attempt; Syncope; Toxicity To Various Agents; Ventricular Dysfunction; Ventricular Fibrillation; Ventricular Hypokinesia; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk, Unk		Apotex
	Escitalopram			S	Unknown	250 Mg, Unk		Apotex
	Adenosine			C	Intravenous (not otherwise specified)	12 Mg, Unk		Not Reported
	Adenosine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15440318	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE102621		38 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Pancreatitis Acute; Thrombotic Thrombocytopenic Purpura	Quetiapine			S	Unknown	200 Mg, Unk(1 X 1 Per Day)		Novartis
	Quetiapine			S				Novartis
	Escitalopram			S	Unknown	10 Mg, Unk(1 X 1 Per Day)		Not Reported
	Escitalopram			S				Not Reported
	Venlafaxine Almus			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15440412	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1070271		1 DAY	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Not Reported	
	Grippe Impfstoff			C	Transplacental			Mylan	
	L-Thyroxin /00068002/			C	Transplacental	100 [Mg/D]/ Initial 75µg/D, Dosage Increase To 100µg/D From Week 34+2		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15442236	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-041340		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Oxycodone Hcl			S	Unknown	Unk Unknown, Unknown		Vintage	
	Hydralazine Hcl			S	Unknown	10 Mg, Unknown		Par	
	Isosorbide Mononitrate Er Tablets 30mg			S	Unknown	30 Mg, Unknown		Vintage	
	Lamictal			S	Unknown	25 Mg, Unknown		Not Reported	
	Lexapro			S	Unknown	20 Mg, Unknown		Not Reported	
	Depakote			S	Unknown	500 Mg, Unknown		Not Reported	
	Coreg			S	Unknown	3.125 Mg, Unknown		Not Reported	
	Lipitor			S	Unknown	10 Mg, Unknown		Not Reported	
	Glimepiride			S	Unknown	4 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15448147	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018016889			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Product Dispensing Error	Escitalopram 20mg Tablet			S	Oral	20 Milligram		Macleods	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2018	15440283	EXPEDITED (15-DAY)		CA, DE	DE-HETERO CORPORATE- HET2018DE00948			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Milligram, Qd		Hetero	
	Escitalopram			S	Transplacental	220 Milligram, Qd		Hetero	
	Paroxetine /00830801/			S	Transplacental	30 Milligram, Qd		Not Reported	
	Candesartan			S	Transplacental	16 Milligram, Qd		Not Reported	
	Nepresol /00007602/			S	Transplacental	25 [Mg/D]		Not Reported	
	L-Thyroxin 50			C	Transplacental	Unk		Not Reported	
	Cytotec			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2018	15448427	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018016890			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Qd		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2018	15448457	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR- APL-2018-048218		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness;	Escitalopram			S	Unknown	Unk		Aurobindo	
	Lamotrigine			S	Unknown	Unk		Aurobindo	
	Propranolol			S	Unknown	Unk		Not Reported	

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Dystonia;
Electrocardiogram Qrs
Complex Prolonged;
Electrocardiogram Qt
Interval; Hyperreflexia;
Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2018	15458233	DIRECT		LT, OT			31 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Chills; Dizziness; Dizziness; Muscle Twitching; Nausea; Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2018	15458541	DIRECT		OT			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Erectile Dysfunction; Erectile Dysfunction	Generic Lexapro			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	14067504	EXPEDITED (15-DAY)		HO, OT	IT-009507513- 1710ITA003705		50 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan Potassium	S	Oral	Unk (Also: "Dosage Form Unspecified")	Merck
	Delorazepam	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Haldol	S	Oral	Dosage Form: Solution	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15208475	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837104US			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	Unk		Allergan	
	Myslee			C	Transplacental	Unk		Not Reported	
	Yokukansan			C	Transplacental	Unk		Not Reported	
	Hirnamin			C	Transplacental	Unk		Not Reported	
	Horizon			C	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15218202	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-113481		71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Confusional State; Hyperglycaemia; Hypertension; Weight Increased	Nivolumab			S	Intravenous (not otherwise specified)	480 Mg, Unk		Bristol Myers Squibb	
	Amitriptyline			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Unknown	
	Prednisone			S	Unknown	Unk		Unknown	
	Methylprednisolone			S	Unknown			Unknown	
	Gabapentin			S	Unknown			Unknown	
	Oxycodone			S	Unknown			Not Reported	
	Denosumab			C	Unknown			Not Reported	
	Vantas			C	Unknown			Not Reported	

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Baby Aspirin	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Compazine /00013302/	C	Unknown	Not Reported
Flomax /00889901/	C	Unknown	Not Reported
Imodium	C	Unknown	Not Reported
Lamisil	C	Unknown	Not Reported
Levsin	C	Unknown	Not Reported
Multivitamin /00097801/	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Simvastatin	C	Unknown	Not Reported
Vitamin B 12	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Famotidine	C	Unknown	Not Reported
Fiber	C	Unknown	Not Reported
Flomax /00889901/	C	Unknown	Not Reported
Iron	C	Unknown	Not Reported
Lomotil /00034001/	C	Unknown	Not Reported
Remicade	C	Unknown	Not Reported
Vitamin C /00008001/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15361423	EXPEDITED (15-DAY)		HO, OT	PHHY2018SK088555		30 YR	Male	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia;	Valproate Sodium			S	Unknown			Not Reported
Asthenia; Delusion;	Escitalopram			S	Unknown	10 Mg, Per Day		Not Reported
Depression; Disturbance	Escitalopram			S	Unknown	5 Mg, Pro Die		Not Reported
In Social Behaviour; Drug	Escitalopram			S	Unknown	5 Mg, Per Day		Not Reported
Ineffective; Hypomania;								
Mania; Mental Impairment;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Off Label Use; Product Use In Unapproved Indication; Sleep Disorder; Weight Increased	Olanzapine	S	Oral	Unk (Dispersion)	Novartis
	Olanzapine	S	Oral	10 Mg, Pro Die	Novartis
	Olanzapine	S	Oral	15 Mg, Pro Die	Novartis
	Olanzapine	S	Unknown	15 Mg, Per Day	Novartis
	Sertraline	S	Unknown	Unk	Not Reported
	Quetiapine	C	Unknown	500 Mg, Pro Die (Extended-Release Form)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15375232	EXPEDITED (15-DAY)		HO, OT	FR- GLAXOSMITHKLINE- FR2018161036		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Unk		Glaxosmithkline
	Levothyrox			S	Oral	Unk		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	Unk		Glaxosmithkline
	Lorazepam			S	Oral	Long Cours		Glaxosmithkline
	Fenofibrate			S	Oral	Unk		Glaxosmithkline
	Valaciclovir			S	Oral	Unk		Glaxosmithkline
	Bendamustine			S	Intravenous (not otherwise specified)	346 Mg, Unk		Not Reported
	Loxapac			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	720 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15449371	EXPEDITED (15-DAY)		DE	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00645		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	Unk		Sciegen
	Propranolol			S	Unknown	Unk		Not Reported

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Escitalopram			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-Oct-2018	15449735	NON-EXPEDITED			US-APOTEX-2018AP016350		14 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Effective For Unapproved Indication; Rash; Sedation; Therapy Partial Responder	Citalopram			S	Oral	30 Mg, Daily		Apotex		
	Citalopram			S				Apotex		
	Bupropion			S	Oral	75 Mg, Daily		Apotex		
	Bupropion			S				Apotex		
	Fluvoxamine			S	Oral	50 Mg, Daily		Apotex		
	Fluvoxamine			S				Apotex		
	Lamotrigine			S	Unknown			Apotex		
	Quetiapine			S	Unknown			Apotex		
	Ziprasidone			S	Oral	20 Mg, Bid		Apotex		
	Lithium Carbonate			S	Unknown	750 Mg, Daily		Apotex		
	Lithium Carbonate			S				Apotex		
	Escitalopram			S	Oral	10 Mg, Q.H.S.		Apotex		
	Escitalopram			S				Apotex		
	Alprazolam			S	Oral	0.5 Mg, Daily		Apotex		
	Alprazolam			S				Apotex		
	Clonidine Extended Release Transdermal Film			S	Transdermal	0.1 Mg, 24 Hours		Apotex		
	Clonidine Extended Release Transdermal Film			S				Apotex		
	Clonidine Hydrochloride			S	Oral	Unk		Not Reported		
	Clonidine Hydrochloride			S	Oral	0.3 Mg, Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-Oct-2018	15450127	NON-EXPEDITED			US-PFIZER INC-2018393301			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anxiety; Depression;	Xanax			S		Unk		Pfizer		

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Diarrhoea	Otezla	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450358	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP021295		87 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Mg, Qd		Apotex	
	Heipram			S	Oral	10 Mg, Qd		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450495	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-ACCORD-072804		25 YR	Male	CZE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Brain Death; Cardiac Fibrillation; Suicide Attempt; Toxicity To Various Agents; Ventricular Fibrillation	Escitalopram			S	Oral			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450850	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1846628US		53 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Oxalate - Bp			S	Oral	Actual: Unknown Dose But Reported As Overdose		Allergan	
	Pariet			S	Oral	240 Mg, Qd		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450960	EXPEDITED (15-DAY)		CA, OT	DE-LUPIN PHARMACEUTICALS INC.-2018-06664		< 1 DAY	Male	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine	S	Transplacental	50 Mg/D Varying Dosage Between 25 And 50 Mg/D	Lupin
	Lamictal	S	Transplacental	125 Mg/D	Not Reported
	Lamictal	S	Transplacental	Slowly Reduced	Not Reported
	Cipralelex	S	Transplacental	20 Mg, Qd	Not Reported
	Cipralelex	S	Transplacental	10 Mg, Qd	Not Reported
	Cipralelex	S	Transplacental	5 Mg, Qd	Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]	C	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451046	EXPEDITED (15-DAY)		HO, LT	ES-APOTEX- 2018AP021356		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma	Escitalopram			S	Oral	Unk		Apotex	
	Enoxaparin Sodium			S	Subcutaneous	Unk		Not Reported	
	Sintrom			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451131	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2018-06701		92 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage	Aspirin			S	Unknown	Unk		Not Reported	
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Omeprazole			S	Unknown	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451132	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS		70 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ecchymosis; Gingival Bleeding; Haematuria	Escitalopram			S	Unknown	Unk		Lupin
	Aspirin			S	Unknown	Unk		Not Reported
	Fluindione			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451336	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1070807		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Mg, Qd		Not Reported
	Sertraline			C	Transplacental	150 Mg, Qd		Mylan
	Quetiapine			C	Transplacental	25 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451934	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00391		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Completed Suicide; Distributive Shock; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Nausea; Serotonin Syndrome; Syncope; Ventricular Fibrillation	Escitalopram			S	Oral	250 Mg, Once		Jubilant
	Yew Leaves			S	Oral	50 G, Once		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451996	EXPEDITED (15-DAY)		DE, OT	ZA-PFIZER INC-2018391836		63 YR	Male	ZAF

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Aspavor			S		40 Mg, Unk		Pfizer
	Cipralex [Escitalopram]			S		20 Mg, Unk		Not Reported
	Clopiwin			S		75 Mg, Unk		Not Reported
	Bezafibrate Sandoz			S		400 Mg, Unk		Not Reported
	Cardicor			S		2.5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15452022	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018392114		79 YR	Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Aspavor			S		10 Mg, Unk		Pfizer
	Bilocor			S		5 Mg, Unk		Not Reported
	Coveram			S		5/5 Mg		Not Reported
	Ecotrin			S		81 Mg, Unk		Not Reported
	Zytomil			S		10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15452624	NON-EXPEDITED			US-JAZZ-JPI-P-025983		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Sleep-Related Event; Chest Discomfort; Chest Pain; Dizziness; Enuresis; Head Discomfort; Headache	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Phentermine			C				Not Reported
	Naltrexone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15452951	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2018-DE-960085		1 DAY	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Teva
	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Not Reported
	Cipralext			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15453407	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2018M1071500		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Indapamide			S	Oral	2.5 Mg, Qd		Not Reported
	Lactulose			C		Unk		Mylan
	Perindopril			C		Unk		Mylan
	Enoxaparin Sodium			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15453448	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1847257US		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Blood Prolactin Increased; Hirsutism	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15425189	EXPEDITED (15-DAY)		HO	DE-MYLANLABS- 2018M1069764		79 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine			S	Oral	100 Mg, 0-0-0-1, Tablet		Not Reported
	Ciprallex 10mg /01588501/			S	Oral	10 Mg, 1-0-0-0, Tablets		Mylan
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tablets		Mylan
	Levothyroxin			C	Oral	75 Mg, 1-0-0-0, Tablets		Mylan
	Torasemid			C	Oral	10 Mg, 1-0-0-0, Tablets		Mylan
	Felodipine			C	Oral	10 Mg, 1-0-0-0, Tablets		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15454083	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP021485		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Drug Ineffective; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Somnolence; Tachycardia; Unresponsive To Stimuli	Lamotrigine			S	Unknown	Unk		Apotex
	Escitalopram Oxalate			S	Unknown	Unk		Apotex
	Midazolam			S	Unknown	Unk		Apotex
	Propofol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15454170	EXPEDITED (15-DAY)		HO, OT	US-UNICHEM PHARMACEUTICALS (USA) INC-UCM201809-000		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress	Lamotrigine			S				Unichem

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Syndrome; Agitation;
Bundle Branch Block Left;
Decreased Immune
Responsiveness;
Electrocardiogram Qrs
Complex Prolonged;
Endotracheal Intubation;
Hypotension; Overdose;
Pneumonia Aspiration;
Rhabdomyolysis;
Serotonin Syndrome;
Somnolence; Tachycardia;
Toxicity To Various
Agents; Unresponsive To
Stimuli

Escitalopram

S

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15454306	EXPEDITED (15-DAY)		OT	ES-ZYDUS-027736		83 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral			Zydus Pharm
	Trimetazidine			S	Oral			Not Reported
	Nifedipine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15456847	EXPEDITED (15-DAY)		DE	DE-MYLANLABS- 2018M1069897		19 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15457177	EXPEDITED (15-DAY)		HO	ZA-ALLERGAN- 1847460US			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Surgery	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
	Celebrex	C	Unknown	Unk	Not Reported
	Avamys	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Synaleve	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	14568851	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-016036			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Electrocardiogram Qt Prolonged; Pulmonary Embolism; Tricuspid Valve Incompetence	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Paracetamol			S	Unknown			Bristol Myers Squibb
	Clozapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Cholecalciferol			S	Unknown			Not Reported
	Fluticasone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Paliperidone			S	Unknown			Not Reported
	Desmopressin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	14853314	EXPEDITED (15-DAY)		HO	DE-TEVA-2017-DE- 830799		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax

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Aripiprazole	S	Oral	10 Milligram Daily;	Teva
Aripiprazole	S	Oral	5 Milligram Daily;	Teva
Candesartan Cilexetil	S	Oral	16 Milligram Daily;	Not Reported
L-Thyroxine	C	Oral	100 Microgram Daily;	Not Reported
Acetylsalicylic Acid	C	Oral	100 Milligram Daily;	Not Reported
Metformin	C	Oral		Not Reported
Atorvastatin	C	Oral	20 Milligram Daily;	Not Reported
Risperdal	C			Not Reported
Amisulpride	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15352229	EXPEDITED (15-DAY)		HO, OT	IT-ALLERGAN-1842825US		50 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan
	Delorazepam			S	Oral	1 Mg, Unk		Not Reported
	Losartan			S	Oral	Unk Mg, Unk		Not Reported
	Haldol			S	Oral	Unk Mg/ML, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15368192	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1843989US		57 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Contraindicated Product Administered; Drug Interaction; Drug Level Increased; Neuroleptic Malignant Syndrome; Product Administration Error; Wrong Dosage Formulation	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Zuclopenthixol Acetate			S	Intramuscular	100 Mg (Overdose: Medication Error)		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	5 Mg, Qd		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	40 Mg, Qd		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Mg, Q Month		Not Reported
	Cyamemazine			S	Unknown	25 To 50 Mg, Qd (Overdose)		Not Reported

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Cyamemazine	S	Unknown	50 To 100 Mg, Qd (Overdose)	Not Reported
Cyamemazine	S	Unknown	50 Mg, Qd (Overdose)	Not Reported
Cyamemazine	S	Unknown	750 Mg, Single (Overdose)	Not Reported
Lercanidipine	S	Unknown	300 Mg, Single (Overdose)	Not Reported
Lercanidipine	S	Unknown	Unk, Unknown	Not Reported
Bisoprolol	C	Unknown	Unk Unk, Unknown	Not Reported
Metformin	C	Unknown	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15396923	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018374843		56 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rib Fracture	Aspavor			S		20 Mg, Unk		Pfizer	
	Betapam			S		5 Mg, Unk		Not Reported	
	Epilizine Cr			S		500 Mg, Unk		Not Reported	
	Puricos			S		300 Mg, Unk		Not Reported	
	Rivotril			S		0.5 Mg, Unk		Not Reported	
	Stilpane [Caffeine;Codeine Phosphate;Meprobamate;Paracetamol]			S		Unk		Not Reported	
	Thiamine			S		100 Mg, Unk		Not Reported	
	Wellbutrin XL			S		300 Mg, Unk		Not Reported	
	Zytomil			S		20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15457785	EXPEDITED (15-DAY)		HO, LT	JP-SAPTALIS PHARMACEUTICALS LLC-2055616		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemolytic Anaemia; Left Ventricular Dysfunction;	Lorazepam			S	Unknown			Saptalis Pharmaceuticals	

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Pulseless Electrical Activity	Escitalopram	S	Unknown	Not Reported
	Adrenaline	S	Unknown	Not Reported

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03-Oct-2018	15458277	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-048147		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Film-Coated Tablets			S	Oral	Unspecified Quantity (1)		Aurobindo	
	Pariet			S	Oral	240 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15459253	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-LUPIN PHARMACEUTICALS INC.-2018-06779		25 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Cardiac Fibrillation; Distributive Shock; Electrocardiogram Qrs Complex; Intentional Overdose; Left Ventricular Dysfunction; Loss Of Consciousness; Serotonin Syndrome; Toxicity To Various Agents; Ventricular Fibrillation; Ventricular Hypokinesia	Escitalopram			S	Oral	250 Mg, Unk		Lupin	
	Escitalopram			S				Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15460478	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-960135		81 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Product Dispensing Error	Escitalopram			S	Oral			Ivax	

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03-Oct-2018	15461310	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1071910			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Ejaculation Disorder; Erectile Dysfunction; Poor Quality Sleep	Escitalopram			S	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Mylan	
	Kratom			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15208813	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-931209		35 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram Oxalate			S	Oral	20 Milligram Daily;		Ivax	
	Seroquel 300 Mg Compresse			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Rivestite Con Film Lamotrigine			S	Oral	100 Milligram Daily;		Not Reported	
	Seroquel 200 Mg Compresse A Rilascio Prolungato			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15209537	EXPEDITED (15-DAY)		OT	ZA-PRINSTON PHARMACEUTICAL INC.-2018PRN00442		59 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown	10 Mg		Prinston Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15221988	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1837299US		1 DAY	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Maternal Exposure During Breast Feeding	Escitalopram Oxalate - Bp	S	Transplacental	20 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S	Transmammary	20 Mg, Qd	Allergan
	Ethyl Loflazepate	C	Transplacental	Unk	Not Reported
	Ethyl Loflazepate	C	Transmammary	Unk	Not Reported
	Alprazolam	C	Transplacental	Unk	Not Reported
	Alprazolam	C	Transmammary	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15463182	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018016933			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram Tablet			S	Oral	1 Dosage Form, Qd (Unspecified Quantity, Film-Coated Tablet)		Macleods	
	Pariet			S	Oral	240 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15464014	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1847687US		66 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unknown		Allergan	
	Iberogast N			S	Oral	20 Gtt, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15464267	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-MACLEODS PHARMACEUTICALS US LTD- MAC2018017069			Unknown	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Cardiac Fibrillation; Toxicity To	Escitalopram Oxalate			S	Oral	Unk		Macleods	

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Various Agents; Ventricular Fibrillation		Yew	S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15464404	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1847429US		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Idaptan			S	Oral			Not Reported	
	Nifedipino			C	Oral	20 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15465567	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1072975		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15466213	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1847678US		77 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Haematuria	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Xarelto			S	Oral	15 Mg, Qd		Not Reported	
	Xarelto			S				Not Reported	
	Concor			C	Oral	1 Df, Qd		Not Reported	
	Adalat Crono			C	Oral	30 Mg, Qd		Not Reported	
	Aldactone			C	Oral	1 Df, Qd		Not Reported	
	Atorvastatin Pfizer			C	Oral	2 Df, Qd		Not Reported	
	Cardio Aspirin			C	Unknown	Unk		Not Reported	

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04-Oct-2018	15466454	EXPEDITED (15-DAY)		OT	DE-009507513-1810DEU001705		59 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Uric Acid Increased;	Remergil			S	Unknown			Merck	
Catatonia; Dental Caries;	Cipralex			S	Unknown			Not Reported	
Disorientation; Dyskinesia;	Rivotril			S	Unknown			Not Reported	
Fatigue; Infection; Muscle	Seroquel			S	Unknown			Not Reported	
Spasms; Off Label Use;	Zoloft			S	Unknown			Not Reported	
Product Use In	Allopurinol			C	Unknown			Not Reported	
Unapproved Indication;									
Serotonin Syndrome;									
Suicidal Ideation; Tremor									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	13288997	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20170226241			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Drug	Zyrtec		Y	S	Unknown			Not Reported	
Hypersensitivity; Epistaxis;	Zyrtec			S	Unknown			Not Reported	
Hepatitis Acute; Sinusitis;	Xyrem			S	Oral			Not Reported	
Sjogren'S Syndrome;	Xyrem			S	Oral			Not Reported	
Vomiting	Xyrem			S	Oral			Not Reported	
	Xyrem			S	Oral	Dose Adjustment		Not Reported	
	Xyrem			S	Oral	Dose Adjustment		Not Reported	
	Xyrem			S	Oral	Dose Adjustment		Not Reported	
	Xyrem			S	Oral			Not Reported	
	Xyrem			S	Oral			Not Reported	
	Xyrem			S	Oral			Not Reported	
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/MI); 5 Gm First Dose And 4 Gm		Not Reported	

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Xyrem	S	Oral	Second Dose Nightly (Dose Strength:500mg/ML); 5 Gm First Dose And 4 Gm Second Dose	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/ML); 5 Gm First Dose And 4 Gm Second Dose	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/ML)	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/ML)	Not Reported
Xyrem	S	Oral	Nightly (Dose Strength:500mg/ML)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/ML)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/ML)	Not Reported
Xyrem	S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/ML)	Not Reported
Lexapro	S	Unknown		Not Reported
Lexapro	S	Unknown		Not Reported
Trazodone	S	Unknown		Not Reported
Flovent	S	Unknown		Not Reported
Mometasone Furoate	S	Unknown		Not Reported
Promethazine	C	Unknown		Not Reported
Flaxseed Oil	C	Unknown		Not Reported
Metformin Hcl	C	Unknown		Not Reported
Metoprolol Succinate	C	Unknown		Not Reported
Oxycodone Hcl	C	Unknown		Not Reported
Psyllium Husk	C	Unknown		Not Reported
Ritalin	C	Unknown		Not Reported

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Wellbutrin	C	Unknown	Not Reported
Diclofenac Sodium Er	C	Unknown	Not Reported
Vicodin	C	Unknown	Not Reported
Provigil	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Tigan	C	Unknown	Not Reported
Clonazepam	C	Unknown	Not Reported
Zofran	C	Unknown	Not Reported
Zofran	C	Unknown	Not Reported
Epipen	C	Unknown	Not Reported
Cyclobenzaprine	C	Unknown	Not Reported
Adderall	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Fish Oil	C	Unknown	Not Reported
Fiber	C	Unknown	Not Reported
Diflunisal	C	Unknown	Not Reported
Albuterol Sulfate	C	Unknown	Not Reported
Methocarbamol	C	Unknown	Not Reported
Topiramate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	13768475	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_011716			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bruxism; Cogwheel Ridity; Depression; Ear Discomfort; Pain In Jaw; Weight Decreased	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	3 Mg, Qd		Otsuka
	Rexulti			S	Unknown	0.5 Mg, Qd (In The Morning For 7 Days)		Otsuka
	Rexulti			S	Unknown	1 Mg, Qd (In The Morning For 7 Days)		Otsuka

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Rexulti	S	Unknown	2 Mg,Qd (In The Morning)	Otsuka
Rexulti	S	Unknown	2 Mg, Unk	Otsuka
Lexapro	S	Unknown	Unk	Not Reported
Adderall	S	Unknown	1 Df, Bid	Not Reported
Adderall	S	Unknown	(5 To10 Mg), Bid (End Of October)	Not Reported
Adderall	S	Unknown	20 Mg, Bid	Not Reported
Pristiq	C	Unknown	200 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Unknown	25 Mg, Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Buspar	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Latuda	C	Unknown	40 Mg, Unk	Not Reported
Latuda	C	Unknown	60 Mg, Unk	Not Reported
Latuda	C	Unknown	80 Mg, Unk (At The End Of September And In Early October)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	14270855	EXPEDITED (15-DAY)		OT	US-OTSUKA-2017_015562			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bruxism; Cogwheel Rigidity; Depression; Weight Decreased	Abilify			S	Unknown	Unk		Otsuka
	Rexulti			S	Unknown	0.5 Mg, Qd		Otsuka
	Rexulti			S	Unknown	1 Mg, Qd		Otsuka
	Rexulti			S	Unknown	2 Mg, Qd		Otsuka
	Rexulti			S	Unknown	3 Mg, Qd		Otsuka
	Rexulti			S	Unknown	2 Mg, Qd		Otsuka

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Lexapro	S	Unknown	Unk	Not Reported
Cymbalta	S	Unknown	Unk	Not Reported
Trazodone	S	Unknown	Unk	Not Reported
Vitamin B12	S	Unknown	Unk	Not Reported
Pristiq	S	Unknown	200 Mg, Unk	Not Reported
Latuda	S	Unknown	40 Mg, Unk	Not Reported
Latuda	S	Unknown	60 Mg, Unk	Not Reported
Latuda	S	Unknown	80 Mg, Unk	Not Reported
Adderall	S	Unknown	1 Df, Bid	Not Reported
Adderall	S	Unknown	20 Mg, Bid	Not Reported
Buspar	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	14619097	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-012362		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S	Unknown	Unk		Aurobindo
	Xarelto			S	Unknown	20 Mg, Unk		Not Reported
	Zofenil			C	Unknown	Unk		Not Reported
	Carbidopa And Levodopa			C	Unknown	Unk		Not Reported
	Androtardyl			C	Unknown	Unk		Not Reported
	Amoxicillin Sodium And Potassium Clavulanate			C	Unknown	Unk		Not Reported
	Requip			C	Unknown	Unk		Not Reported
	Carbidopa, Levodopa			C		Unk ()		Not Reported
	Amoxicillin Sodium, Potassium Clavulanate			C		Unk ()		Not Reported
	Xarelto 20 Mg			S		20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15118608	NON-EXPEDITED			IT-LUPIN PHARMACEUTICALS		39 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

INC.-2018-04196

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clitoral Engorgement	Venlafaxine			S	Unknown	75 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15468913	EXPEDITED (15-DAY)		HO, OT	US- GLAXOSMITHKLINE- US2013000750			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Epistaxis; Hepatitis Acute; Sinusitis; Sjogren'S Syndrome; Vomiting	Zyrtec			S		Unk		Glaxosmithkline
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/MI)		Not Reported
	Xyrem			S	Oral	Dose Adjustments (Nightly (Dose Strength:500mg/MI)		Not Reported
	Xyrem			S	Oral	Nightly (Dose Strength:500mg/MI); 5 Gm First Dose And 4 Gm Second Dose		Not Reported
	Xyrem			S	Oral	2.25 G, Bid		Not Reported
	Xyrem			S	Oral	Dose Adjustment		Not Reported
	Xyrem			S	Oral	4.5 G, Bid		Not Reported
	Mometasone Furoate			S		Unk		Not Reported
	Fluticasone Propionate			S		Unk		Glaxosmithkline
	Trazodone Hydrochloride			S		Unk		Not Reported
	Lexapro (Escitalopram Oxalate)			S		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported

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Epi Pen	C		Not Reported
Flaxseed Oil	C	Unk	Not Reported
Methocarbamol	C	Unk	Not Reported
Metoprolol Succinate	C	Unk	Not Reported
Oxycodone Hydrochloride	C	Unk	Not Reported
Promethazine Hydrochloride	C	Unk	Not Reported
Psyllium Husk	C	Unk	Not Reported
Topiramate	C	Unk	Not Reported
Ritalin	C	Unk	Not Reported
Wellbutrin	C	Unk	Not Reported
Diclofenac Sodium Er	C	Unk	Not Reported
Vicodin	C	Unk	Not Reported
Provigil (Modafinil)	C	Unk	Not Reported
Omeprazole	C	Unk	Not Reported
Tigan	C	Unk	Not Reported
Clonazepam	C	Unk	Not Reported
Zofran (Ondansetron Hydrochloride)	C	Unk	Not Reported
Metformin Hydrochloride	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Plantago Ovata	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15468967	EXPEDITED (15-DAY)		HO	FR-LANNETT COMPANY, INC.-FR- 2018LAN001177		57 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Level Increased; Neuroleptic Malignant Syndrome; Potentiating Drug Interaction	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Lannett
	Zuclopenthixol Decanoate			S	Unknown	300 Mg, Monthly		Not Reported
	Zuclopenthixol Acetate			S	Intramuscular	100 Mg, Unk		Not Reported
	Zuclopenthixol Dihydrochloride			S	Unknown	5 To 40 Mg, Qd, Titrated Over Two Weeks		Not Reported

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	Cyamemazine	S	Unknown	50 Mg, Qd	Not Reported
	Cyamemazine	S	Unknown	25 Mg To 75 Mg, Qd	Not Reported
	Cyamemazine	S	Unknown	50 Mg To 100 Mg, Qd	Not Reported
	Lercanidipine	C		300 Mg, Unk	Not Reported
	Bisoprolol	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15469437	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1847692US		59 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Uric Acid Increased;	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Unknown		Allergan	
Catatonia; Dental Caries;	Rivotril			S	Unknown	Unk Unk, Unknown		Not Reported	
Disorientation; Dyskinesia;	Seroquel			S	Unknown	800 Mg, Unknown		Not Reported	
Fatigue; Infection; Muscle	Remergil			S	Unknown	60 Mg, Unknown		Not Reported	
Spasms; Off Label Use;	Zoloft			S	Unknown	Unk, Unknown		Not Reported	
Off Label Use; Overdose;	Allopurinol			C	Unknown	Unk, Unknown		Not Reported	
Serotonin Syndrome;									
Suicidal Ideation; Tremor									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15469459	EXPEDITED (15-DAY)		HO	ZA-JNJFOC-20180936849			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Surgery	Xarelto			S	Oral			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Avamys			S	Unknown			Not Reported	
	Ciprallex			S	Unknown			Not Reported	
	Stilpane (Acetaminophen/Caffeine/Codei ne/Phosphate/Meprobamate)			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15469743	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2018SF27600		59 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Uric Acid Increased;	Seroquel			S	Oral	800.0mg Unknown		Zeneca	
Catatonia; Dental Caries;	Ciprallex			S	Unknown	40.0mg Unknown		Not Reported	
Disorientation; Dyskinesia;	Rivotril			S	Unknown			Not Reported	
Fatigue; Infection; Muscle	Remergil			S	Unknown	60.0mg Unknown		Not Reported	
Spasms; Off Label Use;	Zoloft			S	Unknown			Not Reported	
Product Use In	Allopurinol			C				Not Reported	
Unapproved Indication;									
Serotonin Syndrome;									
Suicidal Ideation; Tremor									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15470085	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1073454		42 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Escitalopram			S	Oral	7 Df, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2018	15337438	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018016441			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional	Escitalopram Oxalate			S	Oral	20 Milligram, Coated Tablet		Macleods	
Overdose; Intentional	Losartan Potassium			S	Oral	Misuse, Unspecified		Macleods	
Product Misuse;	Haldol			S	Oral	Solution, Misuse		Not Reported	
Intentional Self-Injury;	Delorazepam			S	Oral	1 Milligram, Tablet		Not Reported	
Sopor									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2018	15471114	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-047950		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral	20 Milligram,		Aurobindo	
	Idaptan			S	Oral	20 Milligram		Not Reported	
	Nifedipine			C	Oral	20 Milligram, Two Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	8743310	EXPEDITED (15-DAY)		HO	FR-FRI-1000038112		89 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Lasilix			S	Oral	20 Mg, Qd		Not Reported	
	Avodart			C		Unk		Not Reported	
	Amiodarone Hydrochloride			C		Unk		Not Reported	
	Discotrine			C		Unk		Not Reported	
	Triatec (Ramipril)			C	Oral	Unk		Not Reported	
	Lantus			C	Subcutaneous	Unk		Not Reported	
	Eupressyl			C		Unk		Not Reported	
	Amlor			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	13398754	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1712671US		29 YR	Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphocyte Count Decreased; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan	
	Clozaril			S	Oral	400 Mg, Qd		Not Reported	

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Clozaril			S		Oral		Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Oct-2018	14084674	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-815671ACC		50 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Intentional Product Misuse; Intentional Self-Injury; Sopor	Losartan			S	Oral				Not Reported	
	Delorazepam			S	Oral				Not Reported	
	Haldol Janssen Cil			S	Oral				Not Reported	
	Escitalopram			S	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Oct-2018	15276892	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1839422US		44 YR	Male	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram Oxalate Unk			S	Oral	15 Mg, Qd			Allergan	
	Arlevertan			S	Oral	3 Df, Qd			Not Reported	
	Resilient			S	Oral	1 Df, Qd			Not Reported	
	Deniban			S	Oral	25 Mg, Qd			Not Reported	
	Valium			S	Oral	16 Gtt, Qd			Not Reported	
	Leponex			S	Oral	150 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Oct-2018	15426140	EXPEDITED (15-DAY)		DE, LT, OT	US-TEVA-2018-US-957625		33 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Agitation; Anion Gap Abnormal; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia;	Lamotrigine			S	Unknown				Teva	
	Escitalopram			S	Unknown				Ivax	
	Propranolol			S	Unknown				Not Reported	

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Electrocardiogram Qrs
Complex Prolonged;
Electrocardiogram Qt
Prolonged; Heart Injury;
Hyperreflexia;
Hyperthermia;
Hypoglycaemia;
Hypotension; Metabolic
Acidosis; Muscle Rigidity;
Myocardial Ischaemia;
Respiratory Depression;
Rhabdomyolysis; Seizure;
Tachycardia;
Thrombocytopenia;
Toxicity To Various
Agents; Tremor;
Ventricular Arrhythmia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15472091	EXPEDITED (15-DAY)		DE, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-186243		47 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Mirtazapin			S	Unknown	30 Mg, Daily		Sun	
	Cipralext			S	Oral	10 Mg, Daily		Not Reported	
	Olynth			C	Unknown	1 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15472340	EXPEDITED (15-DAY)		HO, OT	QA-ACCORD-073042		49 YR	Male	QAT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Liver Injury	Oxybutynin/Oxybutynin			S	Oral			Accord	
	Hydrochloride			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15473436	NON-EXPEDITED			US-TEVA-2018-US-960594			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Asthenia; Photopsia; Tremor	Escitab [Escitalopram Oxalate]			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15474690	EXPEDITED (15-DAY)		DE, OT	AU-COLLEGIUM PHARMACEUTICAL, INC.-AU- 2018COL014266			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Tapentadol Extended Release			S		Unk		Collegium	
Confusional State; Death;	Tramal			S		Unk		Pharmaceutical	
Delirium; Discomfort;	Duloxetine			S		Unk		Not Reported	
Dizziness; Drug	Venlafaxine			S		Unk		Not Reported	
Ineffective; Drug	Desvenlafaxine			S		Unk		Not Reported	
Interaction;	Amitriptyline			S		Unk		Not Reported	
Gastrointestinal Disorder;	Sertraline			S		Unk		Not Reported	
Hallucination; Malaise;	Escitalopram			S		Unk		Not Reported	
Mental Disorder; Nausea;									
Nervous System Disorder;									
Serotonin Syndrome;									
Tremor; Vomiting									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15475168	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2018M1073912		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Escitalopram			S	Oral	15 Mg, Qd		Not Reported	
	Plegridy			S	Subcutaneous			Mylan	
	Atacand			S	Oral	1 Df, Qd		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15475607	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1000001118		29 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Escitalopram Oxalate Unk			S	Unknown	10		Allergan	
	Salbutamol			S		Unk		Not Reported	
	Trimipramin Beta			S	Unknown	100		Not Reported	
	Tramadol			S	Unknown	Unk		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15475610	EXPEDITED (15-DAY)		HO	SI-ALLERGAN-1848208US		60 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Status Epilepticus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Ciprobay			S	Oral	1000 Mg, Qd		Not Reported	
	Ceftazidim Mylan			S	Intravenous (not otherwise specified)	1 G, Single		Not Reported	
	Mirzaten			S	Oral	30 Mg, Qd		Not Reported	
	Warfarin			C	Unknown	Unk		Not Reported	
	Apaurin			C	Unknown	5 Mg, Unk		Not Reported	
	Lanzul			C	Unknown	30 Mg, Qam		Not Reported	
	Dulcolax			C	Unknown	1 Df, Unk		Not Reported	
	Spiriva Respimat			C	Respiratory (inhalation)	2.5 Mg, Qam		Not Reported	
	Lekadol			C	Oral	500 Mg, Tid		Not Reported	
	Analgin (Metamizole Sodium Monohydrate)			C	Unknown	500 Mg, Unk		Not Reported	
	Clexane			C	Unknown	0.6 Mg, Q12h		Not Reported	
	Omnice Ocas			C	Unknown	0.4 Mg, Qam		Not Reported	

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	Folacin [Folic Acid]	C	Unknown	5 Mg, Qam	Not Reported
	Kreon	C	Unknown	3 Df, Qd	Not Reported
	Sorbisterit	C	Unknown	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15499699	DIRECT	Y	OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Ocular Discomfort; Product Quality Issue; Vibratory Sense Increased	Escitalopram			S	Oral		2 WEEK	Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15055180	EXPEDITED (15-DAY)		DE, HO	GB-ALLERGAN-1831849US		88 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
Haemorrhage;	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported	
Gastrointestinal Pain	Dihydrocodeine			C	Oral	120 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15455292	EXPEDITED (15-DAY)		HO	PHHY2018LT073001		62 YR	Male	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression;	Carbamazepine			S	Unknown	200 Mg, Tid		Not Reported	
Drug Ineffective; Off Label Use; Therapeutic Product Effect Incomplete	Carbamazepine			S	Unknown	600 Mg, Qd		Not Reported	
	Omeprazole			S	Unknown	20 Mg, Qd		Not Reported	
	Prednisolone			S	Unknown	30 Mg, Bid		Novartis	
	Prednisolone			S	Unknown	60 Mg, Qd		Novartis	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	

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		Pyridostigmine	C	Unknown	60 Mg, Qid			Not Reported	
		Fraxiparin	C	Unknown	0.3 MI, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15461106	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1072117		16 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Pressure Increased;	Escitalopram			S		20 Mg, Qd (1x Daily 2 Tablets)		Not Reported	
Diarrhoea; Diarrhoea Haemorrhagic;	Quetiapine			S		12.5 Mg, Qd (For The Night A Half Tablet)		Not Reported	
Haematochezia; Heart Rate Increased;	Quetiapine			S				Not Reported	
Hypertension; Tachycardia	Cholecalciferol			C		800 Iu, Qd (1 X 1)		Mylan	
	Melatonin			C		1 Mg, Qd (1 Mg 1 X 1)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15476736	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-028961		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Agitation;	Escitalopram			S	Oral			Zydus Pharm	
Bundle Branch Block Left; Clonus; Drug Level Above Therapeutic;	Lamotrigine			S	Oral			Zydus Pharm	
Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Sinus Tachycardia; Somnolence; Unresponsive To Stimuli									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15478180	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00010908			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Lamictal			S	Transplacental	125 [Mg/D]/ Slowly Reduced		Unknown	
	Cipralext			S	Transplacental	20 [Mg/D]/ Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Unknown	
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unknown		Unknown	
	Quetiapine			S	Transplacental	50 [Mg/D]/ Varying Dosage Between 25 And 50 Mg/D		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15478715	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1073873			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anxiety; Depression; Dizziness; Feeling Abnormal; Headache; Insomnia; Mood Altered; Nausea; Panic Attack; Suicidal Ideation	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15479865	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1072811		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Drug Ineffective;	Escitalopram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	

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Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Sodium Chloride	S	Other	Infusion	Not Reported
	Sodium Chloride	S	Other	Increase In The Infusion Rate	Not Reported
	Sodium Chloride	S	Unknown	An Additional 100 Meq Of Sodium Bicarbonate Was Also Given	Not Reported
	Sodium Chloride	S	Other	Repeated Boluses Of Bicarbonate	Not Reported
	Propofol	C	Unknown		Mylan
	Midazolam	C	Unknown		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15504463	DIRECT		DS			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Chest Pain; Depersonalisation/Derealisation Disorder; Depression; Eye Pain; Fear; Heart Rate Increased; Muscle Spasms; Muscle Twitching; Obsessive-Compulsive Disorder; Testicular Pain; Withdrawal Syndrome	Lexapro 20mg			S	Oral	Quantity:1 Capsule(S);	9 YR	Not Reported
	Multi Vitamins			C				Not Reported
	Melatonin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	14701337	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1816549US		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	

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10-Oct-2018	15190972	EXPEDITED (15-DAY)		OT	IT- ELI_LILLY_AND_COMP ANY-IT201807009722		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, Unknown		Not Reported	
	Tavor /00273201/			S	Oral	Unk Unk, Unknown		Not Reported	
	Escitalopram Oxalate			S	Oral	50 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15227242	EXPEDITED (15-DAY)			ZA-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00299		59 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Personal Independence In Daily Activities	Escitalopram			S	Unknown	10 Mg		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15243183	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1838606US		27 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Suicide Attempt	Escitalopram Oxalate Unk			S	Oral	15 MI In Total		Allergan	
	Delorazepam			S	Oral	10 MI In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15481484	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES- 962622		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral			Ivax	
	Idaptan			S	Oral			Not Reported	

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Nifedipino (3253a)			C	Oral		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15481976	EXPEDITED (15-DAY)		OT	BR-TORRENT-00004645		22 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Apparent Death; Crying; Feeling Of Relaxation; Hypertension; Insomnia; Obsessive Thoughts; Panic Reaction; Wrong Technique In Product Usage Process	Espran			S	Oral	One Tablet Daily		Torrent	
	Rivotril			C		0.25 Mg To 1.5 Mg Once Or Twice A Week		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15485441	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848657US		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15485673	EXPEDITED (15-DAY)		HO	JP-ANIPHARMA-2018-JP-000162		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam (Non-Specific)			S				Ani	
	Escitalopram			S				Not Reported	
	Adrenaline			S	Parenteral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15487161	DIRECT		HO, OT			58 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Emotional Distress; Intentional Self-Injury; Suicidal Ideation	Escitalopram	Y		S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	14372786	EXPEDITED (15-DAY)		HO	AT-TEVA-2018-AT-842917		19 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Parkinsonism	Aripiprazole			S	Oral			Teva	
	Aripiprazole			S	Oral			Teva	
	Escitalopram			S	Oral			Ivax	
	Escitalopram			S	Oral			Ivax	
	Escitalopram			S	Oral			Ivax	
	Cipralex			S	Oral	5 Milligram Daily;		Not Reported	
	Cipralex			S	Oral	15 Milligram Daily;		Not Reported	
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported	
	Cipralex			S	Oral			Not Reported	
	Abilify			S	Oral	5 Milligram Daily;		Not Reported	
	Abilify			S	Oral	2.5 Milligram Daily;		Not Reported	
	Atarax			C	Oral	25 Milligram Daily;		Not Reported	
	Atarax			C	Oral	25 Milligram Daily;		Not Reported	
	Methylprednisolone			C	Unknown	Unk		Not Reported	
	Probiotics			C	Unknown	Unk, Qd		Not Reported	
	Zoldem			C	Oral	10 Milligram Daily; Unk		Not Reported	
	Zoldem			C	Oral	5 Milligram Daily;		Not Reported	
	Atarax			C	Oral	25 Mg Qd		Not Reported	
	Sertraline Hydrochloride			C	Unknown	Unk		Not Reported	
	Seroquel			C	Unknown	Unk		Not Reported	

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Seroquel	C			Not Reported
Hova	C	Unknown	Unk	Not Reported
Temesta (Lorazepam)	C	Unknown	1-2 Mg, Qd	Not Reported
Mexalen	C	Unknown	Unk	Not Reported
Mexalen	C	Oral	500 Milligram Daily;	Not Reported
Aerius (Desloratadine)	C	Unknown	Unk	Not Reported
Praxiten	C	Unknown	Unk	Not Reported
Praxiten	C	Oral	15 Milligram Daily;	Not Reported
Praxiten	C	Oral	7.5 Milligram Daily;	Not Reported
Mexalen	C	Oral	500 Milligram Daily;	Not Reported
Mexalen	C	Oral	500 Milligram Daily;	Not Reported
Atarax	C	Oral	25-50 Mg Qd	Not Reported
Atarax	C	Oral	50 Milligram Daily;	Not Reported
Praxiten	C	Oral	15 Milligram Daily;	Not Reported
Atarax	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15486084	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SF29831		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Tagrisso			S	Oral			Astrazeneca
Confusional State;	Seroplex			S	Oral			Not Reported
Dermatitis Acneiform;	Kardegic			C	Oral			Not Reported
Hyponatraemia; Liver Injury; Nasal Obstruction; Throat Irritation	Lexomil			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15486508	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-058			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Hypersensitivity; Rash Pruritic	Escitalopram	S	Unknown	Hikma
	Escitalopram	S		Hikma
	Bupropion	S	Unknown	Not Reported
	Bupropion	S	Unknown	Not Reported
	Bupropion	S	Unknown	Not Reported
	Zoloft	S	Unknown	Not Reported
	Metoprolol Er	C	Unknown	Not Reported
	Metoprolol Er	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	B Complex	C	Unknown	Not Reported
	Loratadine	C	Unknown	Not Reported
	Flonase	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Calcium Citrate	C	Unknown	Not Reported
	Baby Aspirin	C	Unknown	Not Reported
	Walmart Miralax	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15487603	NON-EXPEDITED			US-TEVA-2018-US-961224		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Abnormal	Escitalopram			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15488901	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018404852		59 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Uric Acid Increased;	Zoloft			S	Unknown	Unk		Pfizer
Catatonia; Dental Caries;	Ciprallex [Escitalopram]			S	Unknown	40 Mg		Not Reported
Disorientation; Dyskinesia;	Rivotril			S	Unknown	Unk		Not Reported
Fatigue; Infection; Muscle	Seroquel			S	Unknown	800 Mg		Not Reported
Spasms; Off Label Use;	Remergil			S	Unknown	60 Mg		Not Reported
Product Use In	Allopurinol			C	Unknown			Not Reported
Unapproved Indication;								
Serotonin Syndrome;								
Suicidal Ideation; Tremor								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15489450	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848666US		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
Dermatitis Acneiform;	Tagrisso			S	Oral	80 Mg, Qd		Not Reported
Hyponatraemia; Liver	Kardegic			C	Oral	75 Mg, Qd		Not Reported
Injury	Lexomil			C	Oral	0.25 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15489482	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848716US		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd (Reported As 1-0-0)		Allergan
Haematoma Muscle	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15490382	EXPEDITED (15-DAY)		HO	PHHY2018FR120449		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Fall	Exforge	S	Oral	0.5 Df, Unk (0.5 Mg/L)	Novartis
	Atenolol	S	Oral	25 Mg, Unk	Not Reported
	Tramadol	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	1 Df, Unk (1 Mg/L)	Not Reported
	Hemigoxine Nativele	S	Oral	1 Df, Unk (1 Mg/L)	Not Reported
	Macrogol Stearate	C	Oral	2 Df, Unk (2 Mg/L)	Not Reported
	Caltrate	C	Oral	1 Df, Unk (1 Mg/L)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15490691	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848725US		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unk		Allergan
	Atenolol			S	Oral	25 Mg, Unk		Not Reported
	Exforge			S	Oral	0.5 Df, Unk		Not Reported
	Hemigoxine Nativele			S	Oral	1 Df, Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported
	Macrogol Stearate			C	Oral	2 Df, Unk		Not Reported
	Caltrate			C	Oral	1 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15490692	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848706US		90 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Forlax			C	Oral	Unk		Not Reported
	Lantus			C	Subcutaneous	14 Iu, Qd		Not Reported
	Previscan (Fluindione)			C	Unknown	0.5 Df, Qd		Not Reported
	Metformine			C	Oral	1000 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15027389	EXPEDITED (15-DAY)		DE, HO, OT	GB-AUROBINDO-AUR-APL-2018-031621		88 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo	
Haemorrhage;	Acetylsalicylic Acid			S	Oral	75 Milligram, Daily		Not Reported	
Gastrointestinal Pain	Dihydrocodeine			C	Oral	120 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15484792	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1848487US		93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan	
Hormone Secretion	Aspirin			C	Unknown	Unk, Unknown		Not Reported	
	Metoprolol			C	Unknown	Unk, Unknown		Not Reported	
	Amlodipine			C	Unknown	Unk, Unknown		Not Reported	
	Atorvastatin			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15492126	EXPEDITED (15-DAY)		CA, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-08264			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect;	Quetiapine Fumarate			S	Transplacental	Unknown		Alkem	
Congenital Choroid Plexus	Lamotrigine			S	Transplacental	Unknown		Alkem	
Cyst; Foetal Exposure	Cipraxel			S	Transplacental	Unknown		Not Reported	
During Pregnancy; Patent	Femibion [Minerals Nos;Vitamins Nos]			S	Transplacental	Unknown		Not Reported	
Ductus Arteriosus;									
Respiratory Disorder									
Neonatal; Ventricular									
Septal Defect									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15494009	EXPEDITED (15-DAY)		DE, OT	US-LANNETT COMPANY, INC.-US- 2018LAN001218		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anion Gap; Arrhythmia; Atrioventricular Block; Bradycardia; Coma; Delirium; Depressed Level Of Consciousness; Dystonia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperreflexia; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Muscle Rigidity; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Tremor	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Propranolol			S	Unknown	Unk		Not Reported	
	Lamotrigine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15494203	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018408189		62 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colon Cancer; Intestinal Obstruction	Avigra			S		100 Mg, Unk		Pfizer	
	Bilacor			S		5 Mg, Unk		Not Reported	
	Zytomil			S		20 Mg, Unk		Not Reported	
	Ecotrin			S		81 Mg, Unk		Not Reported	

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Topzole	S	40 Mg, Unk	Not Reported
Dormonox	S	2 Mg, Unk	Not Reported
Rivotril	S	0.5 Mg, Unk	Not Reported
Adco Mirteron	S	15 Mg, Unk	Not Reported
Aspen Trazodone	S	50 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2018	15034273	EXPEDITED (15-DAY)		DE, HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018014295			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Ulcer; Gastric Ulcer Haemorrhage; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral	20 Milligram, Qd		Macleods
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Dihydrocodeine			C	Oral	120 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2018	15410137	EXPEDITED (15-DAY)		HO, LT	BE-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2018- 12-00		85 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Computerised Tomogram Thorax Abnormal; Drug Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Pradaxa			S	Oral			Boehringer Ingelheim
	Cordarone			S	Oral			Not Reported
	Asaflow			S	Oral			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Sipralexa			S	Oral			Not Reported
	Forlax			C	Oral			Not Reported
	Prolopa Hbs			C	Oral			Not Reported
	Prolopa			C	Oral			Not Reported
	D-Vital Forte			C	Oral			Not Reported

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	Nexiam		C	Oral				Not Reported	
	Crestor		C	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2018	15495394	EXPEDITED (15-DAY)		HO	FR-ZYDUS-021334		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Lactulose/Paraffin/Liquid			S	Oral	Oral Jelly In Jar			Not Reported
	Amlodipine			S	Oral				Zydus Pharm
	Domperidone			S	Oral				Not Reported
	Escitalopram			S	Oral				Not Reported
	Carbonate De Calcium			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2018	15495398	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018017430			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Tramadol Hydrochloride			S	Unknown	Unk			Macleods
	Metoprolol			S	Unknown	Unk			Not Reported
	Ciprallex			S	Unknown	10			Not Reported
	Salbutamol			S	Unknown	Unk			Not Reported
	Trimipramine			S	Unknown	100			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	14321202	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT- 00007428		34 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Rash	Opipramol			C	Oral				Unknown
	Pantoprazole			C	Oral				Unknown

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Ramipril	C	Oral	Unknown
Escitalopram	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15408963	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2018M1068711		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Therapeutic Product Effective For Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Aripiprazole			S	Oral	20 Mg, Unk		Not Reported
	Abilify			S	Oral	20 Mg, Unk		Mylan
	Abilify			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15497515	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-050124		68 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Jaundice; Liver Disorder	Escitalopram			S	Oral	10 Milligram		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15497667	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-050229		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Atenolol			S	Oral	25 Milligram		Aurobindo
	Tramadol			S	Oral	Unk (Inconnue)		Aurobindo
	Seroplex			S	Oral	1 Dosage Form		Not Reported
	Exforge			S	Oral	0.5 Dosage Form		Not Reported
	Hemigoxine Nativelle			S	Oral	1 Dosage Form		Not Reported

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Macrogol Stearate	C	Oral	2 Dosage Form	Not Reported
Caltrate /00944201/	C	Oral	1 Dosage Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15498390	EXPEDITED (15-DAY)		HO, OT	IN-ACCORD-073329		50 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradykinesia;	Escitalopram			S				Not Reported
Encephalopathy;	Telmisartan			C				Not Reported
Hyperkalaemia;	Acetylsalicylic Acid			C				Not Reported
Hypertension;								
Hyponatraemia;								
Inappropriate Antidiuretic								
Hormone Secretion;								
Osmotic Demyelination								
Syndrome								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15498948	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1848906US		68 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Jaundice; Liver Disorder	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15498955	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1849060US		53 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Theralene			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15500079	EXPEDITED (15-DAY)		DE, OT	US-TARO PHARMACEUTICALS USA.,INC-		33 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anion Gap Increased; Atrioventricular Block; Bradycardia; Delirium; Depressed Level Of Consciousness; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Extrapyrimal Disorder; Hyperthermia; Hypoglycaemia; Hypotension; Metabolic Acidosis; Movement Disorder; Myocardial Ischaemia; Respiratory Depression; Rhabdomyolysis; Seizure; Tachycardia; Thrombocytopenia; Toxicity To Various Agents; Ventricular Arrhythmia	Lamotrigine			S	Unknown	Unk		Taro
	Escitalopram			S	Unknown	Unk		Taro
	Propranolol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15523067	DIRECT		OT			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Frustration Tolerance Decreased; Insomnia; Migraine; Panic Attack; Product Substitution Issue; Quality Of Life Decreased	Escitalopram 20 Mg.	Y		S	Oral	Quantity:6 Df Dosage Form;		Cipla
	Escitalopram 20 Mg.	Y		S				Cipla

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15524253	DIRECT	Y	OT			22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suppressed Lactation	Ortho-Cyclen			S				Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	9835582	EXPEDITED (15-DAY)		DE, LT	NO-TEVA-449104ISR		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drowning; Intentional Self- Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Vival			S	Unknown			Barr	
	Tramadol			S	Unknown	Unk		Teva	
	Diazepam			S	Unknown	Unk		Barr	
	Diazepam			S				Barr	
	Pinex Forte			S	Unknown	Strength: 500/30 Mg And Pandeine		Actavis	
	Nozinan			S	Unknown			Not Reported	
	Oxynorm			S	Unknown	10 Mg, Unk, Strength: 5 Mg-10 Mg		Not Reported	
	Oxynorm			S				Not Reported	
	Cipralex			S	Unknown			Not Reported	
	Sarotex			S	Unknown			Not Reported	
	Rivotril			S	Unknown	Unk		Not Reported	
	Orfiril			S	Unknown	Strength: 600 Mg-1200 Mg		Not Reported	
	Orfiril			S				Not Reported	
	Remeron			S	Unknown	Unk		Not Reported	
	Imovane			S	Oral	Unk		Not Reported	
	Atarax			S	Unknown			Not Reported	
	Truxal			S	Unknown	Unk		Not Reported	
	Truxal			S				Not Reported	

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Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
Seroquel	S	Unknown		Not Reported
Sobril	S	Unknown	Unk	Not Reported
Nobligan	S	Unknown	200 Mg, Unk, Strength: 50 Mg-200 Mg	Not Reported
Catapresan	S	Unknown	Strength 25 Mg, 50 Mg, Unk	Not Reported
Cipramil [Citalopram Hydrobromide]	S	Unknown		Not Reported
Hydroxyzine Hydrochloride	S	Unknown		Not Reported
Levomepromazine Maleate	S	Unknown		Not Reported
Forte	C		Unk	Not Reported
Diamorphine	C	Unknown	Unk	Not Reported
Heroin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	14390103	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2017IN29021			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Galactorrhoea	Escitalopram			S	Unknown	20 Mg, Per Day, For About 15 Days		Invagen	
	Sertraline			S	Unknown	50 Mg, Per Day, For About 15 Days		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15042745	EXPEDITED (15-DAY)		OT	DE-TORRENT-00008656		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram			S	Oral	Unknown		Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15115019	EXPEDITED (15-DAY)		DE, HO	GB-TEVA-2018-GB-922348		88 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer; Gastric Ulcer Haemorrhage; Gastrointestinal Haemorrhage; Gastrointestinal Pain	Acetylsalicylic Acid			S	Oral	75 Milligram Daily;		Not Reported	
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax	
	Dihydrocodeine			C	Oral	120 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15280077	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018318000		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor; Suicidal Ideation	Tavor (Lorazepam)			S	Oral	Unk		Pfizer	
	Escitalopram Oxalate			S	Oral	50 Mg, Total		Not Reported	
	Olanzapine			S	Oral	20 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15328313	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2018-FR-947859		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Atorvastatine			S	Oral	10 Milligram Daily;		Teva	
	Amiodarone			S	Oral	Unknown		Not Reported	
	Lactulose			S	Oral	2 Dosage Forms Daily;		Actavis	
	Lansoprazole			S	Oral	15 Milligram Daily;		Teva	
	Trimebutine			S	Oral	300 Milligram Daily;		Not Reported	
	Repaglinide			S	Oral	2 Milligram Daily;		Not Reported	
	Escitalopram			S	Oral	10 Milligram Daily;		Not Reported	
	Prograf			S	Oral	3 Milligram Daily;		Not Reported	
	Fungizone 10 Pour Cent,			S	Buccal	3 Dosage Forms Daily;		Not Reported	

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Suspension Buvable Driptane 5 Mg, Comprimé Sécable	S	Oral	3 Dosage Forms Daily;	Not Reported
Bisoce 1,25 Mg, Comprimé Pelliculé	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15507041	EXPEDITED (15-DAY)		DS	PHHY2018IT121680		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum Disorder	Escitalopram Oxalate			S	Oral	5 Gtt, Qd		Not Reported	
	Risperidone			S	Oropharyngeal	1 Mg, Qd		Novartis	
	Depakin			C	Oral	100 Mg, Qd		Not Reported	
	Rivotril			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15507258	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20181019904		29 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Trimipramine			S	Unknown			Not Reported	
	Metoprolol			S	Unknown			Not Reported	
	Ciprallex			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15507534	EXPEDITED (15-DAY)		DE, OT	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2018NSR000150		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anion Gap; Atrioventricular Block;	Propranolol Hydrochloride			S		Unk		Northstar	

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Bradycardia; Coma;	Escitalopram	S	Unk	Not Reported
Delirium; Depressed Level Of Consciousness;	Lamotrigine	S	Unk	Not Reported
Dystonia;				
Electrocardiogram Qrs Complex Prolonged;				
Electrocardiogram Qt Prolonged; Hyperreflexia;				
Hyperthermia;				
Hypoglycaemia;				
Hypotension; Metabolic Acidosis; Myocardial Ischaemia; Respiratory Depression;				
Rhabdomyolysis; Seizure;				
Tachycardia;				
Thrombocytopenia;				
Toxicity To Various Agents; Ventricular Arrhythmia				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15507539	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA283827		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Paracetamol/Tramadol Hydrochloride			S	Oral			Not Reported
	Coaprovel			S	Oral			Sanofi
	Escitalopram Oxalate			S	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15507580	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1849254US		37 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Drug Abuse; Drug Dependence; Drug	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd (1-0-0)		Allergan

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Dependence; Prescription	Ixprim	S	Oral	3 Df, Tid (1-1-1)	Not Reported
Form Tampering	Imovane	S	Oral	7.5 Mg, Qd (0-0-0-1)	Not Reported
	Xanax	S	Oral	0.75 Mg, Tid (1-1-1)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15508641	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-MYLANLABS-2018M1076056		37 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral	15 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Unk		Not Reported
	Metformin Hydrochloride			C				Mylan
	Nifedipine			C				Mylan
	Pregabalin			C				Mylan
	Nefopam			C				Mylan
	Tiotropium			C				Mylan
	Sodium Picosulfate			C				Mylan
	Cetirizine			C				Mylan
	Naproxen			C				Mylan
	Diazepam			C				Mylan
	Cassia Senna			C				Mylan
	Methotrexate Sodium			C				Mylan
	Budesonide W/Formoterol			C				Mylan
	Fumarate							
	Lansoprazole			C				Mylan
	Meptazinol			C				Mylan
	Quetiapine Fumarate			C				Mylan
	Temazepam			C				Mylan
	Montelukast			C				Mylan
	Pyridoxine			C				Mylan
	Folic Acid			C				Mylan
	Adcal D3			C				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15509341	DIRECT		OT			35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alopecia; Anxiety; Arthralgia; Bone Pain; Chest Pain; Dental Caries; Loss Of Personal Independence In Daily Activities; Suicidal Ideation	Escitalopram	Y	S	Oral				Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15511936	EXPEDITED (15-DAY)		OT	FR-TAKEDA- 2018TUS030050			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Drug Ineffective; Drug Intolerance; Dysuria	Brintellix			S	Unknown	5 Mg, Unk		Takeda
	Brintellix			S	Unknown	10 Mg, Unk		Takeda
	Brintellix			S	Unknown	15 Mg, Unk		Takeda
	Seroplex			S	Unknown	Unk		Not Reported
	Paroxetine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15514569	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1849271US		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Coaprovel			S	Oral	1 Df, Qd		Not Reported
	Ixprim			S	Oral	3 Df, Qd		Not Reported
	Omeprazole			C	Oral	40 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15514585	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1849415US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Drug Ineffective; Drug Intolerance; Dysuria	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
	Brintellix			S	Unknown	5 Mg, Unknown		Not Reported

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	Brintellix	S	Unknown	10 Mg, Unknown	Not Reported
	Brintellix	S	Unknown	15 Mg, Unknown	Not Reported
	Paroxetine	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	14140765	NON-EXPEDITED			US-AMGEN- USASP2017161996			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen	
	Arava			S	Unknown	Unk		Not Reported	
	Chantix			S	Unknown	Unk		Not Reported	
	Indocin			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Lithium			S	Unknown	Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	14986409	NON-EXPEDITED			US-ASTRAZENECA- 2018SE62879		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Nexium			S	Oral	Unk		Astrazeneca	
	Lexapro			S	Unknown	Unk		Not Reported	
	Estrace			S		Unk		Not Reported	
	Gabapentin			S		Unk		Not Reported	
	Flexeril			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
	Niacin			S		Unk		Not Reported	
	Lotrel			S		Unk		Not Reported	
	Septra			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15034582	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-911442		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Therapeutic Product Effective For Unapproved Indication	Abilify			S	Oral	Unk		Teva
	Abilify			S	Unknown	Unk		Teva
	Escitalopram			S	Oral	Unk		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15132168	EXPEDITED (15-DAY)		DE	PHHY2018IT043201		49 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Alprazolam			S	Oral	0.5 Mg, Qd		Novartis
	Alprazolam			S	Oral	0.75 Mg, Qd		Novartis
	Venlafaxine Hydrochloride			S	Oral	37.5 Mg, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Oral	75 Mg, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Oral	150 Mg, Qd		Not Reported
	Zolpidem Tartrate			S	Oral	10 Gtt, Qd		Not Reported
	Zolpidem Tartrate			S	Oral	15 Gtt, Qd		Not Reported
	Clonazepam			S	Oral	7 Gtt, Qd		Not Reported
	Cipralelex			S	Oral	2 Gtt, Qd		Not Reported
	Cipralelex			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515192	EXPEDITED (15-DAY)		HO, OT	IN-HETERO CORPORATE-		22 YR	Female	IND

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

HET2018IN01040

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemoglobin Decreased; Typhoid Fever	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Solopose Beta			C	Unknown	0.5 Mg, Qd		Not Reported
	Desilam			C	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515433	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-964775		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Haematoma Muscle	Clopidogrel Base			S	Oral	75 Milligram Daily;		Teva
	Escitalopram			S	Oral	5 Milligram Daily; 1-0-0		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515866	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US20279			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash Pruritic; Urticaria	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk, Dose Increased		Invagen
	Bupropion Hcl XI			S	Unknown	150 Mg, Daily		Not Reported
	Zoloft			S	Unknown	Unk, For Years		Not Reported
	Metoprolol			S	Unknown	25 Mg, Unk		Not Reported
	Metoprolol			S	Unknown	50 Mg, Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Flonase /00908302/			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Loratadine			C	Unknown	Unk		Not Reported

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	Baby Aspirin	C	Unknown	Unk		Not Reported
	B Complex /00322001/	C	Unknown	Unk		Not Reported
	Vitamin D /00107901/	C	Unknown	Unk		Not Reported
	Fish Oil	C	Unknown	Unk		Not Reported
	Calcium Citrate	C	Unknown	Unk		Not Reported
	Miralax	C	Unknown	Unk		Not Reported
	Multivitamins /00116001/	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515927	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US17958			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Product Quality Issue	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515952	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US00718			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sinusitis; Tooth Discolouration	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
	Escitalopram			S				Invagen	
	Amlodipine /00972402/	C			Unknown	5 Mg, Qd		Not Reported	
	Amlodipine /00972402/	C			Unknown	1.5 Mg, Qd		Not Reported	
	Amoxicillin /00249602/	C			Unknown	500 Mg, Qid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516114	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US21021			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram			S	Unknown	5 Mg, Unk		Invagen	
	Lisinopril			C	Unknown	20 Mg, Unk		Not Reported	

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		Temazepam	C	Unknown	15 Mg, Unk			Not Reported	
		Fondaparinux	C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516193	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US19565			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura	Escitalopram			S	Oral	20 Mg, Qd		Invagen	
	Rosuvastatin Calcium			C	Unknown	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516226	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US22153			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Product Administration Error	Escitalopram			S	Unknown	10 Mg, 1/2 Pill/Day		Invagen	
	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen	
	Escitalopram			S	Unknown	10 Mg, 1/2 Pill/Day		Invagen	
	Gabapentin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516243	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US08278			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extra Dose Administered	Escitalopram			S	Oral	10 Mg Tablets (Count Unknown, Beyond The Prescribed Dose)		Invagen	
	Alprazolam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516264	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US21089			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Decreased Appetite; Dizziness; Feeding Disorder; Feeling Abnormal; Malaise	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Xanax			C	Unknown	0.25mg Bid, Tablet (Twice A Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516265	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US16921			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Escitalopram			S	Oral	10 Mg, Once A Day		Invagen	
	Escitalopram			S				Invagen	
	Amitriptyline			C	Unknown	10 Mg, Once A Day		Not Reported	
	Diazepam			C	Unknown	5 Mg, Whenever Required		Not Reported	
	Myrbetriq			C	Unknown	25 Mg, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516270	EXPEDITED (15-DAY)			US-CIPLA LTD.-2018US16598			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective	Escitalopram			S	Unknown	20 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516317	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1074594		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Drug Ineffective	Escitalopram			S	Unknown	Every Other Day		Not Reported	
	Xarelto			S	Oral	15 Mg, Unk		Mylan	
	Xarelto			S	Oral	20 Mg, Qd		Mylan	
	Xarelto			S	Oral	Restarted On Rivaroxaban Therapy After One Year		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aspirin /00002701/

C

Oral

1 Year With Rivaroxaban
Followed By 2 Months As
Monotherapy

Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516332	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US16599			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Escitalopram			S	Oral	10 Mg, Qd		Invagen	
Drug Ineffective; Fatigue;	Telmisartan			C	Unknown	75 Mcg, Unk		Not Reported	
Head Titubation;	Synthroid			C	Unknown	160 Mg, Unk		Not Reported	
Headache; Product Substitution Issue									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516351	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US21205			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective;	Escitalopram			S	Oral	10 Mg, Unk, 2 Years		Invagen	
Malaise; Migraine;	Escitalopram			S	Oral	10 Mg, Unk, Brand New Sealed Bottle		Invagen	
Nausea; Palpitations; Panic Attack; Product Quality Issue; Stress	Escitalopram			S	Unknown	Unk, New Bottle Different Lot		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516374	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US19551			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Escitalopram			S	Oral	20 Mg, 3 Tablets Once A Day		Invagen	
Headache; Insomnia; Nausea; Product Substitution Issue	Escitalopram			S	Unknown	Unk, Brand Lexapro Manufactured By Actavis		Invagen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516384	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US01287			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Incorrect Dose Administered	Escitalopram			S	Oral	5 Mg, Unk		Invagen	
	Escitalopram			S	Oral	2.5 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516389	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US22592			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Therapeutic Response Unexpected; Tinnitus	Escitalopram			S	Oral	5 Mg, Qd		Invagen	
	Escitalopram			S				Invagen	
	Cartia Xt			C	Unknown	300 Mg, Qd		Not Reported	
	Liothyronine Sodium (T3)			C	Unknown	5 Mg, Unk		Not Reported	
	Levothyroxine /00068002/			C	Unknown	Unk, 2 Tablets 3 Times A Week And One Tablet 4 Times A Week		Not Reported	
	Metoprolol			C	Unknown	45 Mg, Qd		Not Reported	
	Cardizem /00489701/			C	Unknown	180 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516401	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US17325			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anger; Hypersensitivity	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Levothyroxine			C	Unknown	75 Mcg, Qd, Every Day		Not Reported	
	Centrum /02217401/			C	Unknown	Unk		Not Reported	

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17-Oct-2018	15516962	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1075916		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported	
	Escitalopram			S	Oral	140 Mg, Total		Not Reported	
	Alprazolam			S	Oral	15 Ml, Total		Not Reported	
	Prozin /00011902/			S	Oral	1200 Mg, Total		Mylan	
	Zitromax			S	Oral	1500 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15518425	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-965149		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Liver Disorder	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	12159585	EXPEDITED (15-DAY)		OT	CA-FRI-1000082991		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Serotonin Syndrome	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Unknown	30 Mg, Qd		Allergan	
	Escitalopram Teva			S	Unknown	20 Mg, Qd		Not Reported	
	Escitalopram Teva			S	Unknown	30 Mg, Qd		Not Reported	
	Abilify			S	Oral	2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15414965	EXPEDITED (15-DAY)		HO, OT	PHHY2018CO006004			Male	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Back Pain; Blood Pressure Decreased; Choking; Headache; Heart Rate Decreased; Malaise; Neck Pain; Spinal Pain	Gilenya	S	Oral	0.5 Mg, Qd	Novartis
	Gilenya	S	Unknown	Unk	Novartis
	Escitalopram	S	Unknown	20 Mg, Qd (In The Morning)	Not Reported
	Lebrina	S	Unknown	Unk	Not Reported
	Vigia	C	Unknown	100 Mg, Qd	Not Reported
	Lyrice	C	Unknown	75 Mg, Qhs	Not Reported
	Trazodone	C	Unknown		Not Reported
	Vitamins Nos	C	Unknown		Not Reported
	Fampridine	C	Oral	10 Mg, Bid	Not Reported
	Omeprazole	C	Unknown		Not Reported
	Prednisolone	C	Unknown	50 Mg, Unk (Daily)	Not Reported
	Vitamin D2	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15518069	DIRECT						Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Lexapro			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15525691	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1078085		77 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Encephalopathy	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
	Amiodarone			S	Oral	200 Mg, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Mylan
	Topalgic Lp			S	Oral	3 Df, Qd		Mylan
	Oxynormoro			S	Oral	5 Mg, Unk		Mylan
	Xanax			S	Oral	0.38 Mg, Qd		Mylan

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Kardegic	S	Oral	1 Df, Qd	Mylan
Tazocilline	S	Intravenous (not otherwise specified)	3 Df, Qd	Mylan
Mycophenolate Sodium	C	Oral	360 Mg, Qd	Mylan
Ciclosporine	C	Oral	100 Mg, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15530381	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2018-US-963664		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Drug Ineffective; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Oral			Ivax
	Lamotrigine			S	Oral			Teva
	Sodium Bicarbonate			S	Other	Infusion		Not Reported
	Sodium Bicarbonate			S	Other	Increase In The Infusion Rate		Not Reported
	Sodium Bicarbonate			S	Unknown	An Additional 100 Meq Of Sodium Bicarbonate Was Also Given		Not Reported
	Sodium Bicarbonate			S	Other	Repeated Boluses Of Bicarbonate		Not Reported
	Propofol			C	Unknown			Not Reported
	Midazolam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	14995516	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1829373US			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Aripiprazole			S	Oral	2 Mg, Unk		Not Reported
	Teva Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Serax			C	Unknown	Unk		Not Reported

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19-Oct-2018	15305723	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-945279		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Product Substitution Issue	Escitalopram Abz 20 Mg			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15441206	EXPEDITED (15-DAY)		HO, LT	BE-SAKK-2018SA266773AA		85 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Computerised Tomogram Thorax Abnormal; Drug Interaction; Haemoptysis; Hepatojugular Reflux; Hypoventilation; Lymphadenopathy; Pleural Effusion; Pulmonary Alveolar Haemorrhage	Clexane			S	Subcutaneous	80 Mg, Qd		Sanofi	
	Acetylsalicylic Acid			S	Oral	80 Mg, Qd		Not Reported	
	Cordarone			S	Oral	200 Mg, Qd		Not Reported	
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported	
	Sipralexa			S	Oral	10 Mg, Qd		Not Reported	
	Prolopa Hbs			C	Oral	1 Df, Qd		Not Reported	
	Forlax			C	Oral	1 Df, Qd		Not Reported	
	Prolopa			C	Oral	7 Df, Qd		Not Reported	
	Nexiam [Esomeprazole Magnesium]			C	Oral	20 Mg, Qd		Not Reported	
	Crestor			C	Oral	20 Mg, Qd		Not Reported	
	D Vital Forte			C	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15525240	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-966092		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Atenolol			S	Oral			Not Reported	
	Tramadol Base			S	Oral	Unknown		Teva	

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	Seroplex 5 Mg, Comprimé Pelliculé	S	Oral	Not Reported
	Exforge	S	Oral	Not Reported
	Hemigoxine Nativelle 0,125 Mg, Comprimé	S	Oral	Not Reported
	Macrogol (Stearate De)	C	Oral	Not Reported
	Caltrate	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15525507	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-966131		48 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Tonic-Clonic Seizure	Prednisolone			S	Oral	20 Milligram Daily;		Actavis
	Rhinofluimucil, Solution Pour Pulvérisation Nasale			S	Nasal			Not Reported
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported
	Alprazolam Mylan 0,25 Mg, Comprimé Sécable			C	Oral	1 Dosage Forms Daily;		Not Reported
	Tussipax			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15532084	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US22773			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Spasms; Musculoskeletal Stiffness	Escitalopram			S	Oral	10 Mg, Qd, In The Morning		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15532089	EXPEDITED (15-DAY)			US-CIPLA LTD.-2017US17739			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Hyperhidrosis; Vertigo	Escitalopram			S	Oral	10 Mg, Qd		Invagen
	Escitalopram			S				Invagen

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Metformin	C	Unknown	500 Mg, Qd	Not Reported
Januvia	C	Unknown	40 Mg, Qd	Not Reported
Clopidogrel	C	Unknown	75 Mg, Qd	Not Reported
Pravastatin	C	Unknown	20 Mg, Qd	Cipla
Metoprolol	C	Unknown	Unk	Not Reported
Alprazolam	C	Unknown	10 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15532146	EXPEDITED (15-DAY)		OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-07287			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colon Cancer; Large Intestinal Obstruction	Bilcor Tablets			S	Oral	05 Mg, Unk		Not Reported	
	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin	
	Avigra			S	Oral	100 Mg, Unk		Not Reported	
	Ecotrin			S	Oral	81 Mg, Unk		Not Reported	
	Topzole			S	Oral	40 Mg, Unk		Not Reported	
	Dormonox			S	Oral	02 Mg, Unk		Not Reported	
	Rivotril			S	Oral	0.5 Mg, Unk		Not Reported	
	Adco-Mirteron			S	Oral	15 Mg, Unk		Not Reported	
	Aspen Trazodone			S	Oral	50 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15533499	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2018M1078434		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Malaise; Sinus Bradycardia	Escitalopram			S	Oral	10 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2018	15264067	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-041285		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Lichen Planus	Lamotrigine			S	Oral	Unk		Aurobindo
	Perindopril			S	Oral	2 Milligram		Aurobindo
	Esomeprazole			S	Oral	Unk		Aurobindo
	Atorvastatin			S	Oral	20 Milligram		Not Reported
	Esidrex			S	Oral	25 Milligram		Not Reported
	Aldactone /00006201/			S	Oral	Unk		Not Reported
	Xeroquel			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Verapamil			S	Oral	240 Milligram		Not Reported
	Teralithe			S	Oral	Unk		Not Reported
	Seroplex			S	Oral	Unk		Not Reported
	Macrogol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2018	15535994	DIRECT	Y	OT			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Product Substitution Issue; Somnolence; Somnolence	Escitalopram			S	Oral			Camber

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2018	15536332	DIRECT	Y	OT			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Hypertension; Migraine;	Escitalopram			S	Oral			Torrent

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Product Substitution Issue

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	14849361	EXPEDITED (15-DAY)		DE	IT-ROCHE-2117792		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Clonazepam			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Zolpidem Tartrate			S	Oral			Not Reported	
	Zolpidem Tartrate			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Ciprallex			S	Oral			Not Reported	
	Ciprallex			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	14895102	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-892132		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram			S	Oral			Ivax	
	Escitalopram			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15440278	EXPEDITED (15-DAY)		HO	DE-HETERO CORPORATE-HET2018DE00900			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia;	Escitalopram			S	Unknown			Hetero	
	Duloxetine			S	Unknown			Hetero	

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Myoclonus	Aripiprazole	S	Unknown	Unk	Hetero
	Aripiprazole	S			Hetero
	Mirtazapine	S	Unknown		Not Reported
	Biperiden	S	Unknown		Not Reported
	Oxazepam	S	Unknown	At Different Doses	Not Reported
	Fluoxetine	S	Unknown	Unk	Not Reported
	Bupropion	S	Unknown	Unk	Not Reported
	Promethazine	S	Unknown	Unk	Not Reported
	Promethazine	S			Not Reported
	Amisulpride	S	Unknown	Unk	Not Reported
	Amisulpride	S			Not Reported
	Risperidone	S	Unknown	Unk	Not Reported
	Venlafaxine	S	Oral		Not Reported
	Olanzapine	S	Unknown	Unk	Not Reported
	Olanzapine	S			Not Reported
	Clozapine	S	Unknown		Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported
	Quetiapine	S	Oral	Unk	Not Reported
	Oxcarbazepine	C	Unknown	Unk	Not Reported
	Zonisamide	C	Unknown	Up To 100mg	Not Reported
	Brivaracetam	C	Unknown	200-250mg; Received Over One Year	Not Reported
	Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported
	Clobazam	C	Unknown	Up To 20mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15534487	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-051384		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo	
	Coaprovel			S	Oral	1 Dosage Form, Once A		Not Reported	

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Ixprim	S	Oral	Day	Not Reported
Omeprazole	C	Oral	3 Dosage Form, Once A Day	Not Reported
			40 Milligram, Once A Day	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15534711	NON-EXPEDITED			US-APOTEX-2018AP022382		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Mg Per Day		Apotex	
	Escitalopram			S	Unknown	20 Mg		Apotex	
	Escitalopram			S	Unknown	10 Mg, Prn		Apotex	
	Clonazepam			S	Unknown	0.5 Mg, Prn		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15536113	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP022750		40 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thyroid Mass	Escitalopram			S	Oral	20 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15537156	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1078884		85 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Olanzapine			S	Oral	Unk		Not Reported	
	Venlafaxine			S	Oral	1 Df, Qd		Not Reported	
	Delorazepam			S	Oral	Unk		Not Reported	
	Cipralext /01588501/			S	Oral	Unk		Mylan	
	Donepezil			C		Unk		Mylan	
	Bisoprolol Fumarate			C		Unk		Mylan	

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	Madopar		C		Unk		Mylan		
	Terazosin Hydrochloride		C		Unk		Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15539970	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN HEALTHCARE (UK) LIMITED-2018-07285			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Zytomil			S	Oral	20 Mg, Unk		Lupin	
	Pearinda Plus			S	Oral	4/1.25 Mg, Unk		Not Reported	
	Wellbutrin			S	Oral	150 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15540115	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-188516		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Atenolol			S	Oral	25 Mg, Unk		Sun	
	Tramadol			S	Oral	Inconnue ()		Sun	
	Exforge			S	Oral			Not Reported	
	Hemigoxine Nativelle 0,125 Mg, Comprime			S	Oral	1 Df, Unk		Not Reported	
	Seroplex 5 Mg, Comprime			S	Oral	1 Df, Unk		Not Reported	
	Pellicule								
	Macrogol (Stearate De)			C	Oral	2 Df, Unk		Not Reported	
	Caltrate			C	Oral	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15540325	NON-EXPEDITED			US-PFIZER INC- 2018419469		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Chantix			S		Unk		Pfizer	

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Arava	S	Unk	Not Reported
Indocin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Lithium	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541321	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP023248		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Prescription Drug Used Without A Prescription; Serotonin Syndrome	Tramadol			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541455	NON-EXPEDITED			US-TORRENT-00005631			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Escitalopram			S				Unknown
	Fondaparinux Sodium			C	Subcutaneous	Ndc: 5511167802 Once Daily In The Stomach		Not Reported
	Lisinopril			C				Unknown
	Temazepam			C				Unknown
	Iron			C				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541458	NON-EXPEDITED			US-TORRENT-00005662		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mental Disorder; Nausea; Wrong Technique In Product Usage Process	Escitalopram			S		Cutting The Tablet Into Quarter And Takes 5 Mg (From Unspecified Date)		Torrent

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23-Oct-2018	15541459	NON-EXPEDITED			US-TORRENT-00005974			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Drug Ineffective	Escitalopram			S				Unknown	
	Escitalopram			C		Lot No: Pw03047, Ndc: 16729-0168-01 (Accord)		Unknown	
	Fosamax			C				Unknown	
	Lexapro			C				Unknown	
	Lorazepam			C				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541461	NON-EXPEDITED			US-TORRENT-00006148		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Drug Intolerance; Mood Altered; Product Substitution Issue	Escitalopram Oxalate Tablet			S		Always In The Morning		Torrent	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541462	NON-EXPEDITED			US-TORRENT-00006162			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Intolerance; Headache	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541463	NON-EXPEDITED			US-TORRENT-00006263			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Rigidity	Escitalopram			S		5 Mg Tablet		Unknown	

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23-Oct-2018	15541464	NON-EXPEDITED			US-TORRENT-00006228		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Height Decreased; Product Prescribing Error; Wrong Technique In Product Usage Process	Escitalopram			S		5 Mg Of The Tablet Reduce It To Half I.E. 2.5 Mg.		Torrent	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541476	NON-EXPEDITED			US-TORRENT-00006265			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Escitalopram			S		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541477	NON-EXPEDITED			US-TORRENT-00006739			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Drug Ineffective; Fatigue; Somnolence; Yawning	Escitalopram			S		Unknown		Torrent	
	Escitalopram			C		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541478	NON-EXPEDITED			US-TORRENT-00006485			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash Pruritic	Escitalopram			S		Unknown		Torrent	
	Bupropion Hydrochloride			S		Round Shape, White Color, Imprint 144: Rx 7087916		Unknown	
	Atorvastatin Calcium			C		Unknown		Unknown	

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Flonase	C	Unknown	Unknown
Levothyroxine Sodium	C	Unknown	Unknown
Loratadine	C	Unknown	Unknown
Aspirin	C	Unknown	Unknown
Vitamin B Complex	C	Unknown	Unknown
Vitamin D3	C	Unknown	Unknown
Fish Oil	C	Unknown	Unknown
Calcium Citrate	C	Unknown	Unknown
Miralax	C	Unknown	Unknown
Metoprolol	S	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15542946	EXPEDITED (15-DAY)		HO	ZA-JNJFOC-20181030317			Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospitalisation	Tramacet			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Disprin			S	Unknown			Not Reported
	Atacand Plus			S	Unknown			Not Reported
	Diagluclide			S	Unknown			Not Reported
	Glucophage			S	Unknown			Not Reported
	Cipralax			S	Unknown			Not Reported
	Urbanol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15543061	EXPEDITED (15-DAY)		HO, LT	BE-PFIZER INC-2018430765		85 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Computerised Tomogram	Cordarone			S	Oral	200 Mg, 1x/Day		Pfizer
Thorax Abnormal; Drug	Clexane			S	Subcutaneous	80 Mg, 1x/Day		Not Reported

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Interaction; Haemoptysis;	Asaflow	S	Oral	80 Mg, 1x/Day	Not Reported
Hepatojugular Reflux;	Pradaxa	S	Oral	110 Mg, 1x/Day	Not Reported
Hypoventilation;	Sipralexa	S	Oral	10 Mg, 1x/Day	Not Reported
Lymphadenopathy; Pleural	Prolopa Hbs	C		Unk	Not Reported
Effusion; Pulmonary	Forlax	C		Unk	Not Reported
Alveolar Haemorrhage	Prolopa	C		Unk	Not Reported
	Nexiam [Esomeprazole	C	Oral	20 Mg, Unk	Not Reported
	Magnesium]				
	Crestor	C	Oral	20 Mg, Unk	Not Reported
	D Vital Forte	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15543597	EXPEDITED (15-DAY)		HO, LT	BE-ALLERGAN-1850052US		85 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Computerised Tomogram	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
Thorax; Drug Interaction;	Cordarone			S	Oral	200 Mg, Qd		Not Reported
Haemoptysis;	Asaflow			S	Oral	80 Mg, Qd		Not Reported
Hepatojugular Reflux;	Clexane			S	Subcutaneous	80 Mg, Qd		Not Reported
Hypoventilation;	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
Lymphadenopathy; Pleural	Forlax			C	Oral	1 Df, Qd		Not Reported
Effusion; Pulmonary	Prolopa Hbs			C	Oral	1 Df, Qd		Not Reported
Alveolar Haemorrhage	Prolopa 250			C	Oral	7 Df, Qd		Not Reported
	D-Vital Forte			C	Oral	1 Df, Qd		Not Reported
	Nexiam 20 Mg			C	Oral	20 Mg, Qd		Not Reported
	Crestor 20 Mg			C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15543743	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1773548US		90 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Escitalopram Oxalate - Bp	S	Unknown	5 Mg, Unk	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
	Duloxetine Mylan	S	Unknown	15 Mg, Unk	Not Reported
	Duloxetine Mylan	S	Unknown	Unk	Not Reported
	Venlafaxine Mylan	S	Unknown	37.5 Mg, Unk	Not Reported
	Venlafaxine Mylan	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15546474	DIRECT		DS, HO, OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Depression; Diarrhoea; Dizziness; Impaired Work Ability; Nausea; Product Substitution Issue	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo
	Lexapro			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	11455120	NON-EXPEDITED			US-ACTELION PHARMACEUTICALS US, INC.-A-NJ2015- 1185		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Acne; Anxiety; Burning Sensation; Chest Discomfort; Depression; Dizziness; Fatigue; Gastric Ulcer; Headache; Hypoaesthesia; Insomnia; Laryngitis; Nasal Congestion; Nasopharyngitis; Nausea; Neuralgia; Oral Candidiasis; Paraesthesia Oral; Somnolence;	Tracleer			S	Oral	Unk		Actelion
	Tracleer			S	Oral	125 Mg, Bid		Actelion
	Clonazepam			S	Unknown			Not Reported
	Remeron			S	Unknown	7.5 Mg, Qd		Not Reported
	Remeron			S	Unknown	10 Mg, Qd		Not Reported
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Sildenafil			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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Unevaluable Event;
Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	14111334	EXPEDITED (15-DAY)		OT	US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00354		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Bradycardia; Chest Discomfort; Chest Pain; Diarrhoea; Feeling Abnormal; Hypertensive Urgency; Malaise; Mental Impairment	Escitalopram Hydrochlorothiazide Dexilant Potassium Folic Acid			S C C C C	Oral	10 Mg, 1x/Day		Jubilant Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	14908534	EXPEDITED (15-DAY)		DE, OT	FR-JNJFOC- 20180309197		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Hextril Eprex Doxorubicin Exacyl Pantoprazole Ciprofloxacin Zarzio Meropenem Furosemide Lidocaine Rituximab Calciparine Bisoprolol		Y	S S S S S S S S S S S S S S	Buccal Subcutaneous Intravenous drip Intravenous drip Intravenous drip Intravenous drip Subcutaneous Intravenous drip Oral Buccal Intravenous drip Subcutaneous Oral			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Intravenous drip	Not Reported
Methotrexate	S	Intravenous drip	Not Reported
Voraxaze	S	Intravenous drip	Not Reported
Valaciclovir	S	Oral	Not Reported
Cyclophosphamide	S	Intravenous drip	Not Reported
Prednisone	S	Intravenous drip	Not Reported
Ondansetron	S	Oral	Not Reported
Vincristine	S	Intravenous drip	Not Reported
Bactrim	S	Oral	Not Reported
Bromazepam	S	Oral	Not Reported
Escitalopram	S	Oral	Not Reported
Fungizone	S	Buccal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544241	EXPEDITED (15-DAY)		DS	IT-TEVA-2018-IT-967676		19 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autism Spectrum Disorder	Escitalopram Oxalate			S	Oral	5 Gtt Daily;		Ivax
	Risperidone			S	Oropharyngeal	1 Milligram Daily;		Pliva
	Depakin			C	Oral	100 Milligram Daily;		Not Reported
	Rivotril 2,5 Mg/ML Gocce Orali Soluzione			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544551	EXPEDITED (15-DAY)		HO	FR-ACCORD-073782		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Malaise; Potentiating Drug Interaction	Escitalopram			S	Oral			Not Reported
	Rulid			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544568	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-177867			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chest Pain; Drug Interaction; Insomnia	Amphetamine Mixed Salts			S	Unknown	20 Mg In Morning And 10 Mg In Evening		Mutual	
	Lexapro			S	Unknown	Unk		Not Reported	
	Trinessa			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544710	EXPEDITED (15-DAY)		HO	FR-ACCORD-073889		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Amlodipine			S	Oral			Accord	
	Escitalopram			S	Oral			Not Reported	
	Transulose			S	Oral			Not Reported	
	Domperidone			S	Oral			Not Reported	
	Calcium Carbonate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544826	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-189028		24 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cycloplegia; Nausea; Somnolence	Duloxetine			S	Unknown	30 Mg, Daily		Sun	
	Escitalopram			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544839	NON-EXPEDITED			US-APOTEX-2018AP017646			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Rash Pruritic	Escitalopram			S	Unknown	Unk		Apotex	
	Escitalopram			S				Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15545443	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00526		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hypotension; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Sinus Tachycardia; Somnolence	Lamotrigine Tablets 100mg			S	Unknown	Unk		Taro	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15545727	EXPEDITED (15-DAY)		OT	FI-MYLANLABS-2018M1079226			Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antipsychotic Drug Level Increased; Blood Pressure Increased;	Leponex			S		450 Mg, Qd		Mylan	
Electrocardiogram Qt Prolonged;	Leponex			S		Unk		Mylan	
Hyperparathyroidism; Hypokalaemia;	Cipralex /01588501/			S		30 Mg, Qd		Mylan	
	Cipralex /01588501/			S		10 Mg, Qd		Mylan	

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Detailed Report

Parathyroid Tumour
Benign

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15546017	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018418427		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Abuse; Drug Dependence; Drug Dependence; Prescription Form Tampering	Xanax			S	Oral	0.75 Mg, 1x/Day (1-1-1)		Pfizer	
	Ixprim			S	Oral	3 Df, 1x/Day (1-1-1)		Not Reported	
	Imovane			S	Oral	7.5 Mg, 1x/Day (0-0-0-1)		Not Reported	
	Seroplex			S	Oral	20 Mg, 1x/Day (1-0-0)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	14648303	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2018106685		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Pantoprazole			S	Intravenous drip	Unk		Pfizer	
	Ciprofloxacin			S	Intravenous drip	Unk		Unknown	
	Meropenem			S	Intravenous drip	Unk		Pfizer	
	Doxorubicin Hcl			S	Intravenous drip	Unk		Pfizer	
	Vincristine Sulfate			S	Intravenous drip	Unk		Unknown	
	Fungizone			S	Buccal	Unk		Not Reported	
	Exacyl			S	Intravenous drip	Unk		Not Reported	
	Exacyl			S	Intravenous drip	Unk		Not Reported	
	Eprex			S	Subcutaneous	Unk		Not Reported	
	Zarzio			S	Subcutaneous	Unk		Not Reported	
	Hextril			S	Buccal	Unk		Not Reported	
	Hextril			S	Unknown	Unk		Not Reported	
	Furosemide			S	Oral	Unk		Not Reported	
	Lidocaine			S	Buccal	Unk		Not Reported	

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Lidocaine	S	Buccal	Unk	Not Reported
Methotrexate	S	Intravenous drip	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Voraxaze	S	Intravenous drip	Unk	Not Reported
Valaciclovir Hydrochloride	S	Oral	Unk	Not Reported
Cyclophosphamide	S	Intravenous drip	Unk	Not Reported
Prednisone	S	Intravenous drip	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported
Escitalopram	S	Oral	Unk	Not Reported
Escitalopram	S			Not Reported
Bactrim	S	Oral	Unk	Not Reported
Calciparine	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Bisoprolol	S	Oral	Unk	Not Reported
Bisoprolol Fumarate	S	Oral	Unk	Not Reported
Tranexamic Acid	S	Intravenous drip	Unk	Not Reported
Amphotericin B	S	Buccal	Unk	Not Reported
Epoetin Alfa	S	Subcutaneous	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Oral	Unk	Not Reported
Heparin Calcium	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	14873010	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2018-024653		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Alprazolam Tablets			S	Oral	0.75 Milligram, Once A Day		Aurobindo	
	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Not Reported	
	Zolpidem Tartrate			S	Oral	10 Gtt, Daily		Not Reported	

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		Zolpidem Tartrate	S	Oral	15 Gtt, Once A Day	Not Reported
		Venlafaxine Hydrochloride	S	Oral	37.5 Milligram, Once A Day	Not Reported
		Venlafaxine Hydrochloride	S	Oral	75 Milligram, Once A Day	Not Reported
		Venlafaxine Hydrochloride	S	Oral	150 Milligram, Once A Day	Not Reported
		Ciprallex /01588501/	S	Oral	2 Gtt, Once A Day	Not Reported
		Clonazepam	S	Oral	7 Gtt, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15201350	EXPEDITED (15-DAY)		OT	DE-TORRENT-00009064		19 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy; Overdose; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram			S	Unknown	Unknown		Unknown
	Quetiapine			S		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15548699	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-934702		27 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuser; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Escitalopram Oxalate			S				Ivax
	Delorazepam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15548767	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US21945			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage Intracranial; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Invagen

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Tramadol			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
25-Oct-2018	15550422	EXPEDITED (15-DAY)		OT	FR- GLAXOSMITHKLINE- FR2018181487			Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Pain; Amnesia; Arthralgia; Blood Thyroid Stimulating Hormone Abnormal; Diarrhoea; Dry Skin; Eye Burns; Fatigue; Feeling Hot; Feeling Jittery; Insomnia; Irritability; Muscle Spasms; Myalgia; Nasal Dryness; Paraesthesia; Pruritus; Urticaria; Vertigo; Vision Blurred	Diclofenac Sodium			S	Unknown	2 Df, Qw		Glaxosmithkline		
	Simvastatin			S	Unknown	20 Mg, Qd		Glaxosmithkline		
	Imovane			S	Unknown	0.5 Df, Qd		Glaxosmithkline		
	Uvedose			S	Unknown	1 Df, Q3mo		Glaxosmithkline		
	Seresta			S	Unknown	12.5 Mg, Qd		Glaxosmithkline		
	Amlor			S	Unknown	1 Df, Qd		Glaxosmithkline		
	Zyloric			S	Unknown	1 Df, Qd		Glaxosmithkline		
	Levothyrox			S	Oral	1 Df, Qd		Glaxosmithkline		
	Cotareg			S	Unknown	1 Df, Qd		Not Reported		
	Atenolol			S	Unknown	50 Ug, Qd		Not Reported		
	Seroplex			S	Unknown	1 Df, Qd		Not Reported		
	Endotelon			S	Unknown	2-3 Tablets, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
25-Oct-2018	15551195	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018432736		73 YR	Female	ZAF	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cataract	Aspavor			S		20 Mg, Unk		Pfizer		
	Ivedal			S		10 Mg, Unk		Not Reported		
	Lexamil			S		5 Mg, Unk		Not Reported		
	Pritor [Lacidipine]			S		40 Mg, Unk		Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15551586	EXPEDITED (15-DAY)		OT	PHHY2018CA136999			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx			S	Subcutaneous	150 Mg, Unk		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk Unk, Qd		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Diclofenac Diethylamine			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15554211	DIRECT					71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fear; Paraesthesia; Peripheral Coldness	Escitalopram 5 Mg			S	Oral	Quantity:2 Tablet(S);		Torrent
	Lexapro			C				Not Reported
	Xanax			C				Not Reported
	Miftazipine			C				Not Reported
	Anoro Inhaler			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Zyrtec			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	13869396	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2017348063		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Oral Lichen Planus	Aldactone	S	Oral	Unk	Pfizer
	Atorvastatin Calcium	S	Oral	20 Mg, Daily	Pfizer
	Esomeprazole Magnesium	S	Oral	Unk	Unknown
	Lamotrigine	S	Oral	Unk	Not Reported
	Teralithe	S	Oral	400 Mg, Unk	Not Reported
	Teralithe	S	Oral	800 Mg, Unk	Not Reported
	Teralithe	S	Oral	600 Mg, Unk	Not Reported
	Kardegic	S	Oral	Unk	Not Reported
	Perindopril	S	Oral	2 Mg, Daily	Not Reported
	Hydrochlorothiazide	S	Oral	25 Mg, Daily	Not Reported
	Verapamil Hydrochloride	S	Oral	240 Mg, Daily	Not Reported
	Macrogol	S	Oral	Unk	Not Reported
	Seroplex	S	Oral	Unk	Not Reported
	Xeroquel	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	13887760	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1735280US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Prolactin-Producing Pituitary Tumour	Lexapro			S	Unknown	20 Mg, Unk		Allergan
	Rexulti			S	Unknown	1 Mg, Unk		Not Reported
	Abilify			S	Unknown	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	13893658	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1735893US		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Lichen Planus	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Hydrochlorothiazide			S	Oral	25 Mg, Unk		Not Reported
	Aldactone			S	Oral	Unk		Not Reported

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Lamotrigine	S	Oral		Not Reported
Xeroquel	S	Oral		Not Reported
Perindopril	S	Oral	2 Mg, Qd	Not Reported
Kardegic	S	Oral	Unk	Not Reported
Esomeprazole	S	Oral		Not Reported
Verapamil	S	Oral	240 Mg, Qd	Not Reported
Atorvastatine	S	Oral	20 Mg, Unk	Not Reported
Teralithe	S	Oral	Unk	Not Reported
Macrogol	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	14899290	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2018US17810			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Cipla
	Escitalopram			S	Oral	Unk		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	14955900	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR- APL-2018-027650		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs	Escitalopram Tablets Usp 20mg			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets Usp 20mg			S				Aurobindo
	Lamotrigine Tablets 100 Mg			S	Unknown	Unk		Aurobindo
	Lamotrigine Tablets 100 Mg			S				Aurobindo

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Complex Prolonged;
Hypotension; Overdose;
Pneumonia Aspiration;
Rhabdomyolysis;
Serotonin Syndrome;
Sinus Tachycardia;
Toxicity To Various
Agents; Unresponsive To
Stimuli

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15442896	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC- 2018387763		56 YR	Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Spinal Fracture	Bilcor			S		5 Mg, Unk		Not Reported
	Co-Diovan			S		Unk		Not Reported
	Mylan Pantoprazole			S		40 Mg, Unk		Not Reported
	Lexamil			S		20 Mg, Unk		Not Reported
	Celebrex			C		200 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15553903	NON-EXPEDITED		OT	FR-APOTEX- 2018AP023369		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytopenia	Paroxetine			S	Unknown	10 Mg, Qd		Glaxosmithkline
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Zopiclone			C	Oral	7.5 Mg, Qd		Not Reported
	Valium			C	Oral	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15554039	EXPEDITED (15-DAY)		OT	ZA-ROCHE-2203977			Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Colon Cancer; Gastrointestinal Disorder	Rivotril	S	Unknown	Not Reported
	Bilacor	S	Unknown	Not Reported
	Zytomil	S	Unknown	Not Reported
	Avigra	S	Unknown	Not Reported
	Ecotrin	S	Unknown	Not Reported
	Topzole	S	Unknown	Not Reported
	Dormonox	S	Unknown	Not Reported
	Adco-Mirteron	S	Unknown	Not Reported
	Aspen Trazodone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15554210	NON-EXPEDITED			US-PFIZER INC- 2018428655			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Nausea	Sertraline Hcl			S		Unk		Pfizer	
	Sertraline Hcl			S				Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Bupropion			S		Unk		Not Reported	
	Bupropion			S				Not Reported	
	Fluoxetine			S		Unk		Not Reported	
	Levothyroxine			C	Oral	100 Ug, Daily		Not Reported	
	Alprazolam			C	Oral	1 Mg, Daily		Not Reported	
	Alprazolam			C		0.5 Mg, Daily		Not Reported	
	Gabapentin			C	Oral	100 Mg, 2x/Day (100mg Capsule In The Morning, And One 100mg Capsule At Night)		Not Reported	
	Gabapentin			C	Oral	100 Mg, Daily		Not Reported	
	Gabapentin			C		Unk (Can Take Up To 3 Capsules Daily)		Not Reported	

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Esomeprazole Magnesium	C	Oral	1 Capsule, Daily	Not Reported
Ranitidine	C	Oral	300 Mg, 1 Tablet Taken Once Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15554602	NON-EXPEDITED			US-PFIZER INC- 2018438211		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Effexor			S		Unk		Pfizer	
	Celexa [Citalopram Hydrobromide]			S		Unk		Not Reported	
	Prozac			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Trazodone			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15556329	EXPEDITED (15-DAY)		OT	PHEH2018US044851			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Headache; Rectal Haemorrhage	Gilenya			S	Oral	0.5 Mg, Qd		Novartis	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15556649	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 968683		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Coaprovel 300 Mg/12,5 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Ixprim 37,5 Mg/325 Mg, Comprimé Pelliculé			S	Oral	3 Dosage Forms Daily;		Not Reported	

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Omeprazole			C	Oral	40 Milligram Daily;			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15556903	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1850481US			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hypertonia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transmammary	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15557358	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1850791US		14 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Product Use Issue; Somnolence; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Qd		Allergan	
	Rivotril			S	Oral	Unk Unk, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2018	15558416	EXPEDITED (15-DAY)		OT	HR-ROCHE-2206226		14 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Somnolence; Suicide Attempt	Rivotril			S	Oral	Date Of Most Recent Dose: 27/Jul/2018		Not Reported	
	Cipralext			S	Oral	Date Of Most Recent Dose: 27/Jul/2018		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	13703596	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2017-IPXL-01859		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Erectile Dysfunction; Loss Of Libido; Treatment Noncompliance	Lamotrigine Odt	S	Unknown	100 Mg, Tid	Impax
	Lamotrigine Odt	S			Impax
	Mirtazapine Odt	S	Unknown	22.5 Mg, Qhs	Impax
	Escitalopram	S	Unknown	20 Mg, Bid	Not Reported
	Alprazolam	S	Unknown	1 Mg, Tid, Prn	Not Reported
	Enalapril	S	Unknown	20 Mg, Qam (Everyday Before Noon)	Not Reported
	Lansoprazole	S	Unknown	30 Mg, Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	13881566	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE82010		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Lichen Planus	Esomeprazole Magnesium			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Teralithe			S	Oral	400.0mg Unknown		Not Reported
	Teralithe			S	Oral	800.0mg Unknown		Not Reported
	Teralithe			S	Oral	600.0mg Unknown		Not Reported
	Aldactone			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Perindopril			S	Oral			Not Reported
	Verapamil Hydrochloride			S	Oral			Not Reported
	Macrogol			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	14151979	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-38840		53 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Escitalopram Tablets Usp 10mg			S	Unknown	Three And Half Tablet Daily		Aurobindo
	Belsomra			C	Unknown			Not Reported
	Clorazepate			C	Unknown			Not Reported
	Doxepine			C	Unknown			Not Reported
	Hydroxyzine			C	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Linzess			C	Unknown			Not Reported
	Novolog			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	14324545	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1073700			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Paracetamol			S	Unknown	1 Df, Tid		Not Reported
	Paracetamol/Tramadol			S	Unknown	1 Df, Tid,(37.5/325 Mg)		Not Reported
	Enalapril/Hydrochlorothiazide			S	Unknown	1 Df, Qd,(20/12.5 Mg)		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Omeprazole			S	Unknown	1 Df, Qd		Not Reported
	Simvastatin			S	Unknown	1 Df, Qd		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Simvastatin			S		20 Mg, Unk		Not Reported
	Lormetazepam			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	1 Df, Qd		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Not Reported
	Tepazepam			S	Unknown	Unk, Qd		Mylan

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Glibenclamide	S	Unknown	1 Df, Bid	Not Reported
Naproxen	S	Unknown	1 Df, Bid	Mylan
Diazepam	S	Unknown	0.5 Df, Qd	Mylan
Diazepam	S	Unknown	Unk	Mylan
Amitriptyline	S	Unknown	5 Mg, Qd	Mylan
Amitriptyline	S	Unknown	12.5 Mg, Qd	Mylan
Amitriptyline	S		25 Mg, Unk	Mylan
Amitriptyline	S		25 Unk, Unk	Mylan
Metoclopramide	C	Unknown	1 Week Treatment	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15534216	EXPEDITED (15-DAY)	HO		US-JNJFOC-20181016212		13 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Suicide Attempt; Weight Increased	Risperidone			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Risperdal			S	Oral	Dose: 3 - 4 Mg		Not Reported
	Risperdal			S	Oral	Dose: 3 - 4 Mg		Not Reported
	Adderall			S	Unknown	Dose: 10 - 30 Mg		Not Reported
	Lexapro			S	Unknown	Dose: 20 - 30 Mg		Not Reported
	Intuniv			S	Unknown	Dose: 1 - 4 Mg		Not Reported
	Sertraline			S	Unknown	Dose: 50 - 150 Mg		Not Reported
	Vyvanse			S	Unknown	Dose: 40 - 70- Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15552628	EXPEDITED (15-DAY)		OT	FR-FRESENIUS KABI-FK201810999		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Maculo-Papular	Linezolid Kabi			S	Intravenous (not otherwise specified)	1200mg/Day		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	300mg/Day		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	400mg/Day		Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Imipenem Monohydrate/Cilastatin Sodium			S	Intravenous (not otherwise specified)	500/500 Milligrammes 3 Fois Par Jour		Not Reported	
	Sulfamethoxazole/Trimethoprim			C				Not Reported	
	Ponatinib			C				Not Reported	
	Trimebutine			C				Not Reported	
	Heparin Sodium			C				Not Reported	
	Valaciclovir			C				Not Reported	
	Phloroglucinol/Trimethylphloroglucinol			C				Not Reported	
	Fenofibrate			C				Not Reported	
	Paraffin, Liquid			C				Not Reported	
	Lansoprazole			C				Not Reported	
	Entecavir Monohydrate			C				Not Reported	
	Sodium Bicarbonate/Potassium Chloride/Sodium Chloride/Macrogol 3350			C				Not Reported	
	Hydroxyzine			C				Not Reported	
	Hydrocortisone			C				Not Reported	
	Zopiclone			C				Not Reported	
	Calcium Folate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15558926	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2018AU22092			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Urine Present	Escitalopram	S	Unknown	Unk	Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559021	EXPEDITED (15-DAY)		HO	ZA-CIPLA LTD.- 2018ZA22066			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event	Escitalopram			S	Unknown	Unk		Invagen
	Difluzole			S	Unknown	Unk		Not Reported
	Adco-Atenolol			S	Unknown	Unk		Not Reported
	Amloc /00550802/			S	Unknown	Unk		Not Reported
	Zartan Co			S	Unknown	Unk		Not Reported
	Menacal7			S	Unknown	Unk		Not Reported
	Aspavor			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559153	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2018-007087			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue	Escitalopram Tablets Usp 20mg			S	Unknown			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559158	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2018-021367			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Photophobia; Visual Impairment; Vitreous Floaters	Escitalopram Tablets Usp 10mg			S	Unknown	Unk Unk, Once A Day		Aurobindo
	Escitalopram Tablets Usp 10mg			S				Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559169	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2017-43557			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abnormal Behaviour	Escitalopram Tablets Usp 10mg			S	Unknown			Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559178	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-43694			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Escitalopram 5 Mg			S	Unknown			Aurobindo	
	Fondaparinux Sodium			C	Subcutaneous	2.5/ 0.5 Mg/MI		Not Reported	
	Lisinopril			C	Unknown			Not Reported	
	Temazepam			C	Unknown	15 Mg, Unk		Not Reported	
	Iron			C	Unknown	Unk, As Necessary		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559180	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2017-45316		42 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Sleep Disorder	Escitalopram Tablets Usp 20mg			S	Unknown	Unk, 1 Tab Per Day		Aurobindo	
	Escitalopram Tablets Usp 20mg			S				Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559194	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-002169			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Headache	Escitalopram Tablets Usp 5mg			S	Unknown	Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559196	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-004876		53 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Dizziness; Headache	Escitalopram Tablets Usp 20mg	S	Unknown	Unk Unk, Once A Day	Aurobindo				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559203	NON-EXPEDITED			US-AUROBINDO-AUR- APU-2018-018839			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Flatulence	Escitalopram Tablets Usp 5mg			S	Unknown	5 Milligram, Once A Day, (One Tablet Per Day)		Aurobindo	
	Meloxicam			C	Unknown	Unk		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Diacerein			C	Unknown	Unk		Not Reported	
	Norco			C	Unknown	Direction Depend On Pain		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559324	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US22251			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen	
	Sertraline			S	Unknown	100 Mg, Unk For 4 Months		Invagen	
	Sertraline			S	Unknown	200 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560305	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00403			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Tinnitus	Escitalopram			S		Unk		Jubilant	
	Fondaparinux			S	Subcutaneous	Unk, 1x/Day		Not Reported	
	Lisinopril			C				Not Reported	
	Temazepam			C				Not Reported	
	Iron			C		As Needed		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560306	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00105		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Tachyphrenia	Escitalopram			S	Oral	40 Mg, 1x/Day		Jubilant	
	Ibuprofen			S	Oral	600 Mg, 3x/Day		Not Reported	
	Atorvastatin			C				Not Reported	
	Unspecified Dietary Supplements			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560307	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00291			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash Pruritic	Escitalopram			S		Unk		Jubilant	
	Escitalopram			S		Increased Dose		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560399	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX- 2018AP023271		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Dexametasona /00016001/			S	Oral	0.25 Mg, Qd		Not Reported	
	Hidroaltesona			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	14344530	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS- 2017M1083628		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Zolpidem	S	Oral	10 Mg, Qd At Bedtime	Not Reported
	Zolpidem	S			Not Reported
	Clarithromycin	S	Oral	Unk, Two 10 Day Courses	Not Reported
	Atorvastatin	S	Oral	(Bed Time)	Not Reported
	Tramadol	S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago	Not Reported
	Tramadol	S			Not Reported
	Escitalopram	S	Oral	10 Mg, Hs, Doctor Switched The Patient From Sertraline To Escitalopram	Not Reported
	Escitalopram	S		10 Mg, Unk	Not Reported
	Escitalopram	S			Not Reported
	Perindopril	S	Oral	Unk	Not Reported
	Sertraline	S	Oral	50 Mg, Qd	Not Reported
	Sertraline	S	Oral	50 Mg, Qd, In The Morning	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Doxepin	S	Oral	25 Mg, Qd Qhs, At Bedtime	Not Reported
	Concor	S	Unknown	Unk	Mylan
	Concor	S	Unknown	Unk	Mylan
	Trosicam	S	Oral	Unk	Mylan
	Trosicam	S	Oral	Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago	Mylan
	Polisen	S	Oral	10 Mg, Hs At Bedtime	Mylan
	Atorvastatin	C		Unk	Mylan
	Perindopril	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15121381	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2018M1048454		46 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram			S	Oral	300 Mg, Total		Not Reported	
	Lexotan 6			S	Oral	20 Ml, Total		Mylan	
	Efexor XI			S	Oral	7 Df, Total		Mylan	
	Lamictal			S	Oral	1400 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15453428	EXPEDITED (15-DAY)		DS	DE-MYLANLABS- 2018M1071005			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Gait Disturbance; Hyperhidrosis; Hypoaesthesia; Insomnia; Malaise; Muscle Twitching; Off Label Use; Palpitations; Paraesthesia; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd(Took On 16.11.2017 Escitalopram 20 Mg)		Not Reported	
	Oxazepam			S	Oral	10 Mg, Hs,(At Night)		Not Reported	
	Monostep			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15543570	EXPEDITED (15-DAY)			US-ALLERGAN- 1849899US		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Rexulti			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15565033	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2018-052486			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Headache	Escitalopram Film-Coated Tablets			S	Unknown	15 Mg, Qhs (Every Bedtime)		Aurobindo	

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Mirtazapine Film-Coated Tablet	S	Unknown	30 Mg, Unk	Aurobindo
Levocarb 1 A Pharma	S	Unknown	0.5 Df, Unk	1a Pharma
Acetylsalicylic Acid	C	Unknown	100 Milligram, Once A Day	Not Reported
Atorvastatin	C	Unknown	300 Mg, Qhs	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15565088	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-07495			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pemphigoid	Zartan (Losartan Potassium)			S	Oral	100 Mg, Unk		Lupin
	Novomix			S	Unknown	100 Iu, Unk (30 Flexpen)		Not Reported
	Eltroxin			S	Oral	150 Mcg, Unk		Not Reported
	Lexamil			S	Oral	10 Mg, Unk		Not Reported
	Glucophage			S	Oral	1000 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15565730	EXPEDITED (15-DAY)		OT	NL-APOTEX- 2018AP023258		16 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea Haemorrhagic; Hypertension; Tachycardia	Quetiapine			S	Unknown	Voor De Nacht Een Halve Tablet		Apotex
	Quetiapine			S				Apotex
	Escitalopram			S	Unknown	1x Daags 2 Tabletten		Not Reported
	Cholecalciferol			C	Unknown	1 X 1		Not Reported
	Melatonine			C	Unknown	1 Mg 1 X 1		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15565986	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-100226			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Haemorrhagic Stroke	Eliquis	S	Unknown	Unavailable	Bristol Myers Squibb
	Lexapro	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15567192	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-APOTEX-2018AP023301			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine			S	Transplacental	5 Mg, Qd		Apotex
	Pantoprazole			S	Unknown	Unk		Apotex
	Theophylline			S	Unknown	Unk		Not Reported
	Nucala			S	Transplacental	100 Mg, Unk		Not Reported
	Fluticasone Furoate			S	Transplacental	Unk Unk, Qd		Not Reported
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported
	Vilanterol Trifenatate			S	Transplacental	1 Df, Qd		Not Reported
	Seretide			S	Transplacental	Unk		Not Reported
	Pantomed (Pantoprazol)			S	Transplacental	Unk		Not Reported
	Flixotide			S	Transplacental	250 Ug, Bid		Not Reported
	Ventolin /00139501/			S	Transplacental	100 Ug, Unk		Not Reported
	Avamys			S	Transplacental	Unk Unk, Bid		Not Reported
	Relvar Ellipta			S	Transplacental	1 Df, Qd		Not Reported
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported
	Xyzall			S	Transplacental	5 Mg, Qd		Not Reported
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15567371	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1850860US		18 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; No Adverse Event; Suicide	Escitalopram Oxalate - Bp			S	Oral	Overdose: 210mg		Allergan

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Attempt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15567771	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1080695		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral	5 Mg, Qd		Not Reported
	Aldactazine			S	Oral	1 Df, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15567830	EXPEDITED (15-DAY)		DS	PHHY2018IT141480		19 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Novartis
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	30 Gtt, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15569474	DIRECT		OT			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Depression; Drug Withdrawal Syndrome	Lexapro			S	Oral			Forest

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	12539373	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2016-08916		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Bromazepam Escitalopram Lormetazepam Venlafaxine	S S S S	Oral Oral Oral Oral	180 Milligram In Total 840 Milligram In Total 14 Milligram In Total 7875 Milligram In Total	Not Reported Aurobindo Not Reported Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	13716378	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1727471US		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Jittery; Gastrointestinal Disorder; Lethargy; Libido Decreased; Mental Impairment; Mental Impairment; Nervousness; Off Label Use; Restlessness; Sexual Dysfunction; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Escitalopram Oxalate - Bp Citalopram Hydrobromide - Bp Trintellix Trintellix Trintellix			S S S S S S S	Oral Oral Oral Oral Unknown Oral Oral	10 Mg, Unk 7.5 Mg (One And One-Half 5mg Tablet), Unk 5 Mg, Unk 2.5 Mg, Unk Unk 10 Mg, Qd 5 Mg, Qd		Allergan Allergan Allergan Allergan Allergan Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	14726623	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US14460			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiogenic Shock; Drug Ineffective; Electrocardiogram Qrs	Amlodipine Escitalopram			S S	Oral Oral	Unk Unk		Invagen Invagen

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Complex Prolonged; Muscle Necrosis; Overdose; Prescription Drug Used Without A Prescription; Rhabdomyolysis; Seizure	Atorvastatin	S	Oral	Unk	Invagen
	Calcium	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Oral	Unk	Not Reported
	Atropine	S	Unknown	Unk	Not Reported
	Venlafaxine	S	Oral	Unk	Not Reported
	Fluoxetine	S	Oral	Unk	Not Reported
	Glucagon	S	Unknown	Unk	Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/ Buspirone	S	Oral	Unk	Not Reported
		S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15313577	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-946668		72 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Lichen Planus	Lamotrigine			S	Oral			Teva
	Perindopril			S	Oral	2 Mg		Not Reported
	Verapamil (Chlorhydrate De)			S	Oral	240 Mg		Actavis
	Atorvastatine			S	Oral	20 Mg		Teva
	Esomeprazole			S	Oral			Teva
	Hydrochlorothiazide			S	Oral			Not Reported
	Aldactone 25 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Teralithe			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Macrogols			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15357529	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC-2018357943		73 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam			S		Unk		Pfizer
	Lorazepam			S				Pfizer
	Epinephrine			S		Three Adrenaline Injections		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15397226	EXPEDITED (15-DAY)		OT	US-TAKEDA- 2018TUS027019		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Confusional State; Dizziness; Feeling Abnormal; Muscle Spasms; Pain; Paraesthesia; Suicidal Ideation; Urinary Tract Infection	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Lexapro			S	Unknown	20 Mg, Unk		Not Reported
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Tramadol			C	Oral	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Carvedilol			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15568458	EXPEDITED (15-DAY)		HO, LT	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00688			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Bundle Branch Block; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Toxicity To Various Agents	Lamotrigine Tablets			S	Unknown	100 Mg, Unk		Sciegen
	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15568636	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2018US22217			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Major Depression; Somatic Delusion; Treatment Noncompliance	Escitalopram			S	Unknown	5 Mg, Daily		Invagen	
	Escitalopram			S	Unknown	10 Mg, Daily Increased After 3 Days		Invagen	
	Escitalopram			S		10 Mg, Daily, Resatrted At Month 14		Invagen	
	Escitalopram			S	Unknown	20 Mg, Increased At Month 15 After The Initial Consultation		Invagen	
	Haloperidol			S	Unknown	1 Mg, At Bedtime		Not Reported	
	Haloperidol			S	Unknown	2 Mg, At Bedtime (Increased After 3 Days)		Not Reported	
	Haloperidol			S	Unknown	2 Mg, At 27 Month After The Initial Consultation		Not Reported	
	Haloperidol			S	Unknown	3 Mg, Increased At 28 Month After The Initial Consultation		Not Reported	
	Trazodone			S	Unknown	25 Mg, Start At 28 Month		Not Reported	
	Carvedilol			C	Unknown	Unk		Not Reported	
	Digoxin			C	Unknown	Unk		Not Reported	
	Digoxin			C				Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
	Glipizide			C	Unknown	Unk		Not Reported	
	Insulin Aspart			C	Unknown	Unk		Not Reported	
	Insulin Glargine			C	Unknown	Unk		Not Reported	
	Metolazone			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Potassium Chloride			C	Unknown	Unk		Not Reported	

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Rivaroxaban	C	Unknown	Unk	Not Reported
Spironolactone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15569920	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2018-07546		20 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cycloplegia; Nausea; Somnolence	Sertraline			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	30 Mg, Qd		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15570086	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS- 2018GMK037998		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Lamotrigine			S	Unknown	150 Mg, Qd		Glenmark
	Lamotrigine			S	Unknown	100 Mg, Qd		Glenmark
	Lithium			S	Unknown	600 Mg, Od (Every Bedtime)		Glenmark
	Escitalopram			S	Unknown	5 Mg, Od (Every Morning)		Not Reported
	Escitalopram			S	Unknown	20 Mg, Od		Not Reported
	Escitalopram			S	Unknown	10 Mg, Od (Every Morning)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Od (Every Morning)		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Unknown	20 Mg, Od (Extended Release, Every Morning)		Not Reported
	Dextroamphetamine Saccharate, Amphe/01345401/			S	Unknown	10 Mg, Od (Extended Release, Every Morning)		Not Reported
	Testosterone			S	Topical	Unk, Od (50 Mg/5 G Every Morning On The Right)		Not Reported

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			Upper Extremity)	
Lurasidone	S	Unknown	40 Mg, Od (After Dinner)	Not Reported
Lorazepam	S	Unknown	0.5 Mg, Tid (As Necessary)	Not Reported
Lorazepam	S	Unknown	1 Mg, Tid (As Necessary)	Not Reported
Bupropion	S	Unknown	150 Mg, Od (Every Morning)	Not Reported
Bupropion	S	Unknown	200 Mg, Od (Every Morning)	Not Reported
Bupropion	S	Unknown	300 Mg, Od (Every Morning)	Not Reported
Buspirone	S	Unknown	15 Mg, Bid (Every 12 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	10 Mg, Od	Not Reported
Buspirone	S	Unknown	17.5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	15 Mg, Od	Not Reported
Buspirone	S	Unknown	2.5 Mg, Od	Not Reported
Buspirone	S	Unknown	22.5 Mg, Od	Not Reported
Buspirone	S	Unknown	5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Od	Not Reported
Buspirone	S	Unknown	7.5 Mg, Bid (Every 12 Hours)	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid (Every 8 Hours)	Not Reported
Buspirone	S	Unknown	20 Mg, Od	Not Reported
Aripiprazole	S	Unknown	4 Mg, Od (Every Bedtime)	Not Reported

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Aripiprazole	S	Unknown	2 Mg, Od (Every Bedtime)	Not Reported
Benzotropine Mesylate	C	Unknown	0.5 Mg, Bid (As Necessary)	Not Reported

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31-Oct-2018	15570702	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181042844		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Tramadol Hydrochloride			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Atenolol			S	Oral			Not Reported
	Exforge			S	Oral			Not Reported
	Hemigoxine Nativelle			S	Oral			Not Reported
	Caltrate			C	Oral			Not Reported
	Macrogol			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15571281	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1081339		30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anorgasmia; Impaired Quality Of Life; Treatment Noncompliance	Escitalopram			S	Unknown	Every Morning		Not Reported
	Gabapentin			S	Unknown	Total Daily Dose		Not Reported
	Nortriptyline			S	Unknown	Every Bedtime		Not Reported
	Alprazolam			S	Unknown	Extended Release; Total Daily Dose		Not Reported
	Alprazolam			S	Unknown	Total Daily Dose (1mg-0.5mg-1mg); Extended Release		Not Reported
	Lisdexamfetamine Dimesylate			S	Unknown	Every Morning		Mylan

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31-Oct-2018	15572534	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1081408		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperkalaemia; Hypoglycaemia; Hyponatraemia	Omeprazole Mylan 20 Mg, Gélule Gastro-Résistante			S	Oral	20 Mg, Qd		Mylan	
	Ramipril Mylan 5 Mg, Comprimé			S	Oral	5 Mg, Qd		Mylan	
	Sécable			S	Oral	5 Mg, Qd		Not Reported	
	Escitalopram			C	Oral	70 Mg, 1 Second		Mylan	
	Acide Alendronique /01220301/			C	Oral	2.5 Mg, Qd		Mylan	
	Icaz Lp			C	Oral	40 Mg, Qd		Mylan	
	Ceris			C	Oral	500 Mg, Qd		Mylan	
	Calperos D3			C	Oral	10 G, Qd		Mylan	
	Lactulose								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15572710	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1851564US		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depressed Mood; Insomnia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Rivotril			S	Oral	30 Gtt, Qd		Not Reported	
	Risperidone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15572745	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1851574US			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	100 Mg, Unk		Allergan	
	Lithium			S	Oral	6 G, Unk		Not Reported	
	Seroquel			S	Oral	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	13692000	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US10855			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Disturbance In Attention; Memory Impairment; Physical Product Label Issue	Amlodipine			S	Oral	10 Mg, Qd		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	
	Neurozac			C	Unknown	Unk, Tablet		Not Reported	
	Zentel			C	Unknown	Unk, Tablet		Not Reported	
	Levothyroxine			C	Unknown	Unk, Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	14355524	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-ABBVIE-18S-129- 2213282-00		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Condition Aggravated; Depression; Drug Abuse; Drug Ineffective; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Clarithromycin			S	Oral	Unk, Two 10 Day Courses		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd At Bedtime		Not Reported	
	Atorvastatin			S	Oral	Unk		Not Reported	
	Atorvastatin			S	Oral	Unk, Pm (Bed Time)		Not Reported	
	Atorvastatin			S	Oral	Unk		Not Reported	
	Tramadol			S	Unknown	Unk		Not Reported	
	Tramadol			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago		Not Reported	
	Escitalopram			S	Oral	10 Mg, Hs, Doctor Switched The Patient From Sertraline To Escitalopram		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S				Not Reported	
	Sertraline			S	Oral	50 Mg, Qd		Not Reported	

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Sertraline	S	Oral	50 Mg, Qd, In The Morning	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Doxepin	S	Oral	25 Mg, Qd Qhs, At Bedtime	Not Reported
Concor	S	Unknown	Unk	Not Reported
Concor	S	Unknown	Unk	Not Reported
Trosicam	S	Oral	Unk	Not Reported
Trosicam	S	Oral	Unk, Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
Polisen	S	Oral	10 Mg, Hs At Bedtime	Not Reported
Perindopril	S	Oral		Not Reported
Perindopril	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	14535767	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2018-007041		41 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents; Unresponsive To Stimuli	Paracetamol Tablet			S	Oral	Unk		Aurobindo
	Escitalopram			S	Oral	Unk		Aurobindo
	Dextropropoxyphene			S	Oral	Unk		Not Reported
	Baclofen			S	Oral	Unk		Not Reported
	Baclofen			S				Not Reported
	Valpromide			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15368319	EXPEDITED (15-DAY)		HO, LT, OT	JP-BAUSCH-BL-2018-024688		73 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left	Lorazepam			S	Unknown			Not Reported

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Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Lorazepam	S							Not Reported
	Epinephrine	S	Unknown	Three Adrenaline Injections					Not Reported
	Escitalopram	S	Unknown						Not Reported
	Escitalopram	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15553251	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US21976			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Cortisol Increased	Escitalopram			S	Oral	5 Mg, Qd (Half Of Escitalopram 10mg)		Invagen
	Escitalopram			S	Oral	10 Mg, Qd, Whole Tablet		Invagen
	Clonazepam			C	Unknown	0.25 Mg, Qd (0.5mg Was Prescribed However, Consumer Stated She Is Taking 0.25mg)		Not Reported
	Lyrica			C	Unknown	75 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15573346	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22182			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Amnesia; Aphasia; Chills; Diarrhoea; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Escitalopram			S	Unknown	5 Mg, Every Mornig		Invagen
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Escitalopram			S	Unknown	10 Mg, Every Morning		Invagen
	Escitalopram			S	Unknown	15 Mg, Every Morning Followed By A Gradual Taper (2.5 Mg/Week)		Invagen
	Buspirone			S	Unknown	7.5 Mg, Bid		Not Reported
	Buspirone			S	Unknown	15 Mg, Tid		Not Reported
	Buspirone			S	Unknown	7.5 Mg, Tid		Not Reported

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Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Lorazepam	C	Unknown	0.5 Mg, Prn, Twice Daily	Not Reported
Bupropion	C	Unknown	150 Mg, Every Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15573708	EXPEDITED (15-DAY)		HO, LT, OT	CZ-APOTEX-2018AP023322			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea;	Ibuprofen			S	Unknown			Apotex	
Electrocardiogram Qt Prolonged;	Escitalopram			S	Oral	Unk		Apotex	
Electrocardiogram Qt Shortened; Epilepsy;	Olanzapine			S	Oral	Unk		Apotex	
Gastrointestinal Hypermotility; Loss Of Consciousness; Poisoning	Venlafaxine			S	Oral	Unk		Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Metoclopramide			S	Oral	Unk		Not Reported	
	Levopromazine			S	Oral	Unk		Not Reported	
	Melperone			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15574600	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA-2018SF40665			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Suicide Attempt	Seroquel			S	Oral	Once Daily		Zeneca	
	Ciprallex			S	Oral	100.0mg Unknown		Not Reported	
	Lithium			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15574631	EXPEDITED (15-DAY)		OT	US-TORRENT-00007134		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Amnesia;	Lorazepam			C		As Necessary		Unknown	

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Aphasia; Chills; Diarrhoea; Feeling Abnormal; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Buspirone Escitalopram Bupropion	S S C	Unknown Unknown Every Morning	Unknown Unknown Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15575077	DIRECT		DS, HO, LT			20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Depressed Mood; Depression; Discomfort; Disturbance In Attention; Drug Dependence; Fall; Fatigue; Feeling Abnormal; Feeling Hot; Insomnia; Loss Of Libido; Nicotine Dependence; Product Complaint; Speech Disorder; Therapy Cessation; Visual Impairment	Fluoxetine Alprazolam Sertaline Venlafaxine Escitalopram Wellbutrin			S S S S S C			6 YR	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15575299	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2018M1081467		68 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia	Fenofibrate Escitalopram Irbesartan Pregabalin Bromazepam Levothyroxine Sodique			S S S S S S	Oral Oral Oral Oral Oral Oral	67 Mg, Unk 20 Mg, Unk 75 Mg, Unk 150 Mg, Unk 18 Mg, Unk 75 G, Unk		Not Reported Not Reported Not Reported Not Reported Not Reported Mylan

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Naproxene /00256201/

S

Oral

1100 Mg, Unk

Mylan

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01-Nov-2018	15575901	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-970760		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Maculo-Papular	Escitalopram Arrow			S	Oral	10 Milligram Daily;		Ivax
	Vfend			S	Intravenous (not otherwise specified)	300 Milligram Daily;		Not Reported
	Linezolid Kabi			S	Intravenous (not otherwise specified)	1200 Milligram Daily;		Not Reported
	Imipenem Cilastatine Mylan			S	Intravenous (not otherwise specified)	500/500 Milligrams 3 Times Daily		Not Reported
	Vfend 200 Mg, Poudre Pour Solution Pour Perfusion			S		400 Milligram Daily;		Not Reported
	Bactrim Forte, Comprimé			C	Unknown			Not Reported
	Ponatinib			C	Unknown			Not Reported
	Trimebutine			C	Unknown			Not Reported
	Heparine Sodique			C	Unknown			Not Reported
	Valaciclovir			C	Unknown			Not Reported
	Spasfon (Phloroglucinol\Trimethylphloroglucinol)			C	Unknown			Not Reported
	Lipanthyl			C	Unknown			Not Reported
	Lansoyl			C	Unknown			Not Reported
	Ogastoro			C	Unknown			Not Reported
	Movicol			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15576039	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1851634US			Unknown	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15576123	EXPEDITED (15-DAY)		DE, HO	GB-MYLANLABS-2018M1081835		88 YR	Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Ulcer;	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
Gastrointestinal Haemorrhage;	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Mylan
Gastrointestinal Pain	Dihydrocodeine			C	Oral	120 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15576738	EXPEDITED (15-DAY)		DS	IT-BAUSCH-BL-2018-029275		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dysgraphia;	Venlafaxin			S	Unknown			Not Reported
Dyskinesia; Therapeutic Product Effect Decreased;	Sertraline			S	Unknown			Not Reported
Tremor	Sertraline			S	Unknown	Dose Reduced		Not Reported
	Valproic Acid			S	Unknown			Not Reported
	Quetiapine			S	Oral			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15578259	DIRECT						Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Migraine	Celexa	S	Not Reported
	Lexapro	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	13183771	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2016-01223		85 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Metoclopramide			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Metoclopramide			S				Not Reported
	Amiodarone Hydrochloride			S	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Losartan			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Betahistine			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Simvastatin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Bisoprolol			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Acenocoumarol			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Metformin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported
	Iron Sulfate			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	13709967	EXPEDITED (15-DAY)		OT	CA-TAKEDA- 2017TUS014200		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Agitation; Anxiety; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Feeling Abnormal; Feeling Jittery; Gastrointestinal Disorder; Lethargy; Mental Impairment; Mental Impairment; Nervousness;	Trintellix			S	Oral	5 Mg, Qd		Takeda
	Trintellix			S	Oral	10 Mg, Qd		Takeda
	Trintellix			S	Unknown	Unk		Takeda
	Cipralext /01588501/			S	Oral	5 Mg, Qd		Not Reported
	Cipralext /01588501/			S	Oral	10 Mg, Unk		Not Reported
	Cipralext /01588501/			S	Oral	7.5 Mg, Unk		Not Reported
	Cipralext /01588501/			S	Oral	2.5 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use Issue; Restlessness; Sexual Dysfunction; Wrong Technique In Product Usage Process	Celexa /00582602/	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	14165183	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1763512US		94 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Melaena	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Pradaxa			S	Oral	110 Mg, Qd		Not Reported
	Singulair			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Aldactone			C		Unk		Not Reported
	Bilaska			C		Unk		Not Reported
	Cardensiel			C	Unknown	Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Hemigoxine Nativelle			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	14340017	EXPEDITED (15-DAY)		OT	ES-TEVA-2017-ES-832259			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Amlodipine			S	Unknown	1 Dosage Forms Daily; 5 Mg		Teva
	Paracetamol			S	Unknown	3 Dosage Forms Daily; 1 G		Not Reported
	Tramadol W/Paracetamol			S	Unknown	3 Dosage Forms Daily; 1		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enalapril/Hydrochlorothiazide	S	Unknown	Df = 37.5/325 Mg 1 Dosage Forms Daily; 1 Df = 20/12.5 Mg	Teva
Escitalopram	S	Unknown	1 Dosage Forms Daily; 10 Mg	Ivax
Omeprazole	S	Unknown	1 Dosage Forms Daily; 20 Mg	Actavis
Simvastatin	S	Unknown	1 Dosage Forms Daily; 40 Mg	Ivax
Simvastatin	S	Unknown	20 Mg	Ivax
Simvastatin	S	Unknown	20 Mg	Ivax
Lormetazepam	S	Unknown	1 Dosage Forms Daily; 1 Mg	Not Reported
Topiramate	S	Unknown	1 Dosage Forms Daily; 50 Mg	Teva
Topiramate	S		.5 Dosage Forms Daily; 100 Mg	Teva
Naproxen	S	Unknown	2 Dosage Forms Daily; 500 Mg	Teva
Tepazepam	S	Unknown	Qd	Not Reported
Glibenclamida	S	Unknown	2 Dosage Forms Daily; 5 Mg	Teva
Diazepam	S	Unknown	.5 Dosage Forms Daily; 5 Mg	Barr
Diazepam	S	Unknown	5 Mg	Barr
Amitriptyline 10 Mg	S	Unknown	Qd	Not Reported
Amitriptyline 25 Mg	S	Unknown	12.5 Milligram Daily; 25 Mg	Not Reported
Amitriptyline 25 Mg	S	Unknown	25 Milligram Daily; 25 Mg	Not Reported
Amitriptyline 25 Mg	S	Unknown	25 Unk	Not Reported
Diazepam, Sulpiride	S	Unknown		Not Reported
Amitriptyline Hydrochloride	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metoclopramide			C	Unknown	1 Week Treatment			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	14913216	EXPEDITED (15-DAY)	DE		FR-TEVA-2018-FR-892337		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ciprofloxacin			S	Intravenous drip			Not Reported	
	Methotrexate			S	Intravenous drip			Barr	
	Valaciclovir			S	Oral			Teva	
	Furosemide			S	Oral			Ivax	
	Ondansetron			S	Oral			Teva	
	Bromazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Ivax	
	Doxorubicin			S	Intravenous drip			Actavis	
	Vincristine			S	Intravenous drip			Teva	
	Pantoprazole			S	Intravenous drip			Teva	
	Bisoprolol			S	Oral			Duramed	
	Prednisone			S	Intravenous drip			Actavis	
	Rituximab			S	Intravenous drip			Not Reported	
	Calciparine			S	Subcutaneous			Not Reported	
	Lidocaine			S	Buccal			Not Reported	
	Fungizone			S	Buccal			Not Reported	
	Voraxaze			S	Intravenous drip			Not Reported	
	Zarzio			S	Subcutaneous			Not Reported	
	Cyclophosphamide			S	Intravenous drip			Not Reported	
	Exacyl			S	Intravenous drip			Not Reported	
	Bactrim			S	Oral			Not Reported	
	Hextril			S	Buccal			Not Reported	
	Eprex			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem Anhydrous			S		Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15204078	EXPEDITED (15-DAY)		DS, HO, OT	GB-ALLERGAN-1837053US		31 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Off Label Use; Pollakiuria	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15271331	EXPEDITED (15-DAY)		DS, HO, OT	GB-TORRENT-00017024		31 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15350971	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183466		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Lichen Planus	Atorvastatine			S	Oral	Unk		Sun	
	Esomeprazole			S	Oral	Unk		Sun	
	Perindopril			S	Oral	Unk		Not Reported	
	Aldactone 25 Mg, Comprime Pellicule Secable			S	Oral	Unk		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Kardegic			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Macrogols			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Teralithe			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Verapamil (Chlorhydrate De)	S	Oral	Unk	Not Reported
Xeroquel	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15578071	EXPEDITED (15-DAY)		HO	FR-ACCORD-090556		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	1-0-0		Not Reported
	Irbesartan			S	Oral	1-0-0		Accord
	Furosemide			S	Oral	1-0-0		Accord
	Pantoprazole			S	Oral	0-0-1		Not Reported
	Seresta			C	Oral	0-0-1		Not Reported
	Duphalac			C	Oral	1-1-1		Not Reported
	Havlane			C	Oral	0-0-1 Si Besoin		Not Reported
	Kardegic			C	Oral	0-1-0, 160 Mg Powder For Oral Solution In Sachet		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15579415	EXPEDITED (15-DAY)		HO	JP-LANNETT COMPANY, INC.-JP- 2018LAN001260		73 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardiogenic Shock; Haemodynamic Instability; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Lannett
	Lorazepam			S	Unknown	Unk		Not Reported
	Adrenaline /00003901/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15579891	EXPEDITED (15-DAY)		DE	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-101076		85 YR	Female	FRA

FDA Adverse Event Reporting System

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Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis; Iron Deficiency Anaemia	Eliquis			S	Oral	5 Mg, Daily		Bristol Myers Squibb	
	Seroplex			S	Oral	5 Gtt, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15580791	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1851899US		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinal Vein Occlusion	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Rebif			S	Subcutaneous	66 Mg, Q Week		Not Reported	
	Inexium			C	Oral	20 Mg, Qd		Not Reported	
	Neurontin			C	Oral	400 Mg, Qd		Not Reported	
	Levothyrox			C	Oral	75 Mg, Qd		Not Reported	
	Dedrogyl			C	Oral	6 Gtt, Qd		Not Reported	
	Furosemide			C	Oral	40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15580924	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-029895		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Aripiprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15584795	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-971458		18 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; No Adverse Event; Suicide	Escitalopram			S	Oral	210 Milligram Daily;		Ivax	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Attempt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15584930	EXPEDITED (15-DAY)		OT	US-TORRENT-00007150		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Breast Tenderness; Gynaecomastia	Escitalopram			S		Every Morning		Unknown
	Amphetamine, Dextroamphetamine			S		Extended Release, Every Morning		Unknown
	Testosterone 50mg/5g - Gel			S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity		Unknown
	Lithium			S		Every Bedtime		Unknown
	Benzotropine Mesylate			C		As Necessary		Unknown
	Lurasidone			S		After Dinner		Unknown
	Lamotrigine			S				Unknown
	Lorazepam			S		As Necessary		Unknown
	Bupropion			S		Every Morning		Unknown
	Buspirone			S		Unknown		Unknown
	Aripiprazole			S		Every Bedtime		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15584990	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1851971US			Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antipsychotic Drug Level Increased; Blood Pressure Increased; Electrocardiogram Qt Prolonged; Hyperparathyroidism; Hypokalaemia; Overdose; Parathyroid Tumour Benign	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd (Overdose)		Allergan
	Leponex			S	Unknown	Unk		Not Reported
	Leponex			S	Unknown	450 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15585108	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1851959US		92 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Pradaxa			S	Oral	Unk		Not Reported	
	Irbesartan			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2018	15582815	EXPEDITED (15-DAY)		DS	IT-AUROBINDO-AUR-APL-2018-053149		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Aurobindo	
	Escitalopram			S	Oral	Unk		Aurobindo	
	Rivotril			S	Oral	30 Gtt, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2018	15583296	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD-MAC2018018446			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Amnesia; Aphasia; Chills; Diarrhoea; Feeling Abnormal; Headache; Hyperhidrosis; Piloerection; Pyrexia; Restlessness; Withdrawal Syndrome	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods	
	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd, Every Morning		Macleods	
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd, Every Morning		Macleods	
	Buspirone			S	Unknown	15 Milligram, Tid		Not Reported	
	Buspirone			S	Unknown	7.5 Milligram, Bid		Not Reported	
	Buspirone			S	Unknown	7.5 Milligram, Tid		Not Reported	
	Bupropion			C	Unknown	150 Milligram, Qd, Every		Not Reported	

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Lorazepam	C	Unknown	Morning 0.5 Milligram, Bid, As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2018	15583310	EXPEDITED (15-DAY)		OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2018018448			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Escitalopram Oxalate			S		5 Milligram, Qd, Every Morning		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd, Every Morning		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd, Every Morning		Macleods
	Aripiprazole			S	Unknown	4 Milligram, Qd, Every Bedtime		Macleods
	Aripiprazole			S	Unknown	2 Milligram, Qd, Every Bedtime		Macleods
	Amfetamine/Dexamfetamine			S	Unknown	20 Milligram, Qd, Extended Release, Every Morning		Not Reported
	Amfetamine/Dexamfetamine			S	Unknown	10 Milligram, Qd, Extended Release, Every Morning		Not Reported
	Testosterone 50mg/5g			S	Topical	Unk, Qd, 50 Mg/5 G Every Morning On The Right Upper Extremity		Not Reported
	Lithium			S	Unknown	600 Milligram, Qd, Every Bedtime		Not Reported
	Lurasidone			S	Unknown	40 Milligram, Qd, After Dinner		Not Reported
	Lamotrigine			S	Unknown	150 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lamotrigine	S	Unknown	100 Milligram, Qd	Not Reported
Lorazepam	S	Unknown	0.5 Milligram, Tid, Every 8 Hour, As Necessary	Not Reported
Lorazepam	S	Unknown	1 Milligram, Tid, Every 8 Hour, As Necessary	Not Reported
Bupropion	S		1.5 Milligram, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	200 Milligram, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	300 Milligram, Qd, Every Morning	Not Reported
Buspirone	S	Unknown	15 Milligram, Bid, Every 12 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Tid, Every 8 Hour	Not Reported
Buspirone	S	Unknown	10 Milligram, Qd	Not Reported
Buspirone	S	Unknown	17.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Qd, Every 8 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Tid, Every 8 Hour	Not Reported
Buspirone	S	Unknown	15 Milligram, Qd	Not Reported
Buspirone	S	Unknown	2.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	22.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Qd	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Bid	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Tid	Not Reported
Buspirone	S	Unknown	20 Milligram, Qd	Not Reported
Benzotropine Mesylate	C	Unknown	0.5 Milligram, Bid, As Necessary	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2018	13929999	EXPEDITED (15-DAY)		LT, OT	PL-PFIZER INC-2017377512		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Atorvastatin Calcium			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Escitalopram Oxalate			S				Not Reported	
	Perindopril			S		Unk		Not Reported	
	Tramadol Hcl			S		Unk		Not Reported	
	Tramadol Hcl			S				Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	
	Meloxicam			C		Unk		Not Reported	
	Meloxicam			C				Not Reported	
	Clarithromycin			C		Unk		Not Reported	
	Doxepin			C		25 Mg, 1x/Day At Bedtime		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2018	14333109	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2017370709		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Atorvastatin Calcium			S	Oral	Unk Unk, 2x/Day		Pfizer	
	Sertraline Hcl			S	Oral	50 Mg, 1x/Day(In The Morning)		Pfizer	
	Zolpidem Pfizer			S	Oral	10 Mg At Bedtime		Not Reported	
	Zolpidem Pfizer			S				Not Reported	
	Escitalopram Oxalate			S	Oral	10 Mg, Before Sleeping		Not Reported	
	Escitalopram Oxalate			S				Not Reported	
	Escitalopram Oxalate			S				Not Reported	
	Doxepin			S	Oral	25 Mg, 1x/Day(At Bedtime)		Not Reported	
	Doxepin			S				Not Reported	
	Tramadol Hcl			S	Oral	Unk, 2x/Day		Not Reported	

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	Tramadol Hcl		S					Not Reported	
	Meloxicam		S	Oral	Unk, 2x/Day			Not Reported	
	Clarithromycin		S	Oral	Unk, 2x/Day (Two 10 Day Courses)			Not Reported	
	Perindopril		C		Unk			Not Reported	
	Bisoprolol		C	Oral	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2018	14598973	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-PFIZER INC-2018084248			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affective Disorder; Condition Aggravated; Impaired Work Ability; Insomnia; Intentional Overdose; Intentional Product Misuse; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Overdose; Product Use In Unapproved Indication; Suicide Attempt; Tinnitus	Atorvastatin Calcium			S	Oral	Unk, 1x/Day (Bedtime)		Pfizer	
	Sertraline Hcl			S	Oral	50 Mg, Od, (In The Morning), 1x/Day		Pfizer	
	Sertraline Hcl			S				Pfizer	
	Polsen			S	Unknown	10 Mg, Od, At Bed Time, 1x/Day		Not Reported	
	Atoris			S	Unknown	Unk		Not Reported	
	Clarithromycin			S	Oral	Unk (Bedtime), Two, 10-Day Treatment Cycles Courses		Not Reported	
	Perindopril			S	Oral	Unk		Not Reported	
	Tramadol			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam For About Two Years Ago		Not Reported	
	Tramadol			S				Not Reported	
	Meloxicam			S	Oral	Unk (Bedtime), Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported	
	Meloxicam			S				Not Reported	
	Concor			S	Unknown	Unk		Not Reported	
Trosicam			S	Unknown	Unk		Not Reported		

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	Escitalopram	S							Not Reported
	Escitalopram	S	Oral		10 Mg, 1x/Day Hs				Not Reported
	Escitalopram	S							Not Reported
	Zolpidem	S	Oral		10 Mg, 1x/Day Od				Not Reported
	Zolpidem	S							Not Reported
	Doxepin	S	Oral		25 Mg, 1x/Day Od, At Bed Time				Not Reported
	Doxepin	S							Not Reported
	Doxepin	S							Not Reported
	Bisoprolol	S	Oral						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	13512660	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-139414		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Poisoning Deliberate; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported	
	Paracetamol		Y	S	Oral	Unk		Ohm Lab	
	Baclofen			S	Oral	Unk		Not Reported	
	Baclofen			S				Not Reported	
	Dextropropoxyphen			S	Oral	Unk		Not Reported	
	Valpromide			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	14849654	EXPEDITED (15-DAY)		DE, OT	FR- GLAXOSMITHKLINE- FR2018076854		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Ciprofloxacin			S	Intravenous drip	Unk		Glaxosmithkline	
	Methotrexate			S	Intravenous drip	Unk		Glaxosmithkline	
	Methotrexate			S	Intravenous drip	Unk		Glaxosmithkline	
	Lidocaine			S	Other	Unk		Glaxosmithkline	

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Valaciclovir	S	Oral	Unk	Glaxosmithkline
Furosemide	S	Oral	Unk	Glaxosmithkline
Bactrim	S	Oral	Unk	Glaxosmithkline
Pantoprazole	S	Intravenous drip	Unk	Glaxosmithkline
Bromazepam	S	Oral	Unk	Glaxosmithkline
Escitalopram	S	Oral	Unk	Glaxosmithkline
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S			Not Reported
Calciparine	S	Subcutaneous	Unk	Not Reported
Bisoprolol	S	Oral	Unk	Not Reported
Doxorubicine	S	Intravenous drip	Unk	Not Reported
Fungizone	S	Other	Unk	Not Reported
Prednisone	S	Intravenous drip	Unk	Not Reported
Zarzio	S	Subcutaneous	Unk	Not Reported
Cyclophosphamide	S		Unk	Not Reported
Exacyl	S		Unk	Not Reported
Eprex	S	Subcutaneous	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Vincristine	S	Intravenous drip	Unk	Not Reported
Hextril	S	Other	Unk	Not Reported
Meropenem	S	Intravenous drip	Unk	Not Reported
Voraxaze	S	Intravenous drip	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15550551	EXPEDITED (15-DAY)		OT	US- GLAXOSMITHKLINE- US2018193757		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Escitalopram			S	Unknown	Every Morning		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, Qd		Glaxosmithkline

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Escitalopram	S	Unknown	10 Mg, Qd	Glaxosmithkline
Escitalopram	S	Unknown	15 Mg, Qd	Glaxosmithkline
Lithium	S	Unknown	Every Bedtime	Glaxosmithkline
Lamotrigine	S	Unknown	150 Mg, Qd	Glaxosmithkline
Lamotrigine	S	Unknown	100 Mg, Qd	Glaxosmithkline
Lorazepam	S	Unknown	0.5 Mg, Unk	Glaxosmithkline
Lorazepam	S	Unknown	1 Mg, Unk	Glaxosmithkline
Bupropion	S	Unknown	150 Mg, Qd	Glaxosmithkline
Bupropion	S	Unknown	200 Mg, Qd	Glaxosmithkline
Bupropion	S	Unknown	300 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	10 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	17.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	15 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	2.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	22.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	5 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Qd	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	7.5 Mg, Unk	Glaxosmithkline
Buspirone Hydrochloride	S	Unknown	20 Mg, Qd	Glaxosmithkline
Amphetamine + Dextroamphetamine	S	Unknown	Extended Release, Every Morning	Not Reported
Amphetamine + Dextroamphetamine	S	Unknown	10 Mg, Qd	Not Reported
Testosterone Gel	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported

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Lurasidone	S	Unknown	After Dinner	Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Aripiprazole	S	Unknown	2 Mg, Qd	Not Reported
Benzotropine Mesylate	C	Unknown	As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15581296	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2018US22437			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Drug Ineffective	Citalopram			S	Unknown	40 Mg, Unk		Invagen
	Citalopram			S				Invagen
	Citalopram			S				Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Lamotrigine			S	Unknown	100 Mg, Daily		Cipla
	Lamotrigine			S	Unknown	Unk, Dose Tapered		Cipla
	Sertraline			S	Unknown	300 Mg, Unk		Invagen
	Sertraline			S				Invagen
	Sertraline			S				Invagen
	Bupropion			S	Unknown	150 Mg, Unk		Invagen
	Bupropion			S				Invagen
	Bupropion			S				Invagen
	Venlafaxine			S	Unknown	375 Mg, Daily		Not Reported
	Venlafaxine			S				Not Reported
	Venlafaxine			S				Not Reported
	Venlafaxine			S				Not Reported
	Mirtazapine			S	Unknown	7.5 Mg, Nightly		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Nightly		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Haloperidol /00027402/			S	Unknown	0.5 Mg, Unk		Not Reported

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Haloperidol /00027402/	S				Not Reported
Haloperidol /00027402/	S				Not Reported
Haloperidol /00027402/	S				Not Reported
Junel Fe 1/20	C	Oral		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583391	EXPEDITED (15-DAY)		OT	FR-ABBVIE-18S-056-2541618-00		68 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia	Fenofibrate			S	Oral	67 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Irbesartan			S	Oral	75 Mg, Unk		Not Reported
	Pregabalin			S	Oral	150 Mg, Unk		Not Reported
	Bromazepam			S	Oral	18 Mg, Unk		Not Reported
	Levothyroxine Sodique			S	Oral	75 G, Unk		Not Reported
	Naproxene			S	Oral	1100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583523	NON-EXPEDITED			US-ACCORD-063139			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Night Sweats	Escitalopram			S		Strength: 15 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583524	NON-EXPEDITED			US-ACCORD-063237		44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Drug Ineffective; Feeling Abnormal; Tachyphrenia; Wrong Technique In Product Usage Process	Escitalopram Accord			S	Oral	Strength: 10 Mg		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583526	NON-EXPEDITED			US-ACCORD-064531			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation; Headache	Escitalopram Accord			S		Strength: 10 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583529	NON-EXPEDITED			US-ACCORD-059959		40 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event; Drug Ineffective	Escitalopram Accord			S		Strength: 10 Mg		Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583531	NON-EXPEDITED			US-ACCORD-060202		53 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue; Feeling Abnormal; Headache; Insomnia; Product Size Issue	Escitalopram			S	Oral	Strength: 20 Mg		Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583532	NON-EXPEDITED			US-ACCORD-059228		62 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alopecia; Neuralgia; Sensitisation; Withdrawal Syndrome	Escitalopram			S	Oral	Strength: 20 Mg, White Tablet With '20'		Accord	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15583533	NON-EXPEDITED			US-ACCORD-061390			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Injection Site Pain; Tinnitus	Escitalopram			S		Strength: 5 Mg		Accord	
	Fondaparinux Sodium Dr. Reddy'S			S		Strength: 2.5 Mg/0.5 MI		Not Reported	
	Lisinopril			C		Strength: 20 Mg		Not Reported	
	Temazepam			C		Strength: 15 Mg		Not Reported	
	Iron			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583535	NON-EXPEDITED			US-ACCORD-063618		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Nightmare; Saliva Altered; Tongue Movement Disturbance	Escitalopram			S	Oral	Strength: 10 Mg		Not Reported	
	Benicar			C				Not Reported	
	Bystolic			C				Not Reported	
	Methyldopa			C				Not Reported	
	Amlodipine			C				Not Reported	
	Lovaza			C				Not Reported	
	Crestor			C				Not Reported	
	Ergocalciferol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583538	NON-EXPEDITED			US-ACCORD-069060			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Accord			S		Strength: 5 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583539	NON-EXPEDITED			US-ACCORD-068931		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Condition Aggravated;	Escitalopram Accord			S	Oral	Strength: 20 Mg		Not Reported	

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Decreased Interest; Drug
Ineffective; Fatigue;
Nightmare; Product
Physical Issue; Quality Of
Life Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583540	NON-EXPEDITED			US-ACCORD-071175			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Accord			S	Oral	Strength: 20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583541	EXPEDITED (15-DAY)		OT	US-ACCORD-070105			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash Pruritic	Escitalopram			S				Not Reported	
	Atorvastatin			C				Not Reported	
	Fluticasone			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Loratadine			C				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Nicotinamide/Pyridoxine			C				Not Reported	
	Hydrochloride/Riboflavin/Thiamine Hydrochloride							Not Reported	
	Ergocalciferol			C				Not Reported	
	Calcium Citrate			C				Not Reported	
	Walmart Miralax			C				Not Reported	
	Diphenhydramine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15584095	NON-EXPEDITED		HO	US-APOTEX-2018AP024016		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Treatment Noncompliance	Escitalopram			S	Unknown	5 Mg, Daily		Apotex	

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Escitalopram	S	Unknown	10 Unk, Daily	Apotex
Escitalopram	S	Unknown	10 Unk, Daily	Apotex
Escitalopram	S	Unknown	20 Unk, Unk	Apotex
Haloperidol	S	Unknown	1 Mg, Q.H.S.	Apotex
Haloperidol	S	Unknown	2 Mg, Q.H.S.	Apotex
Haloperidol	S	Unknown	2 Mg, Unk	Apotex
Haloperidol	S	Unknown	3 Mg, Unk	Apotex
Carvedilol	S	Unknown	Unk	Apotex
Glipizide	S	Unknown	Unk	Apotex
Pantoprazole	S	Unknown	Unk	Apotex
Potassium Chloride	S	Unknown	Unk	Apotex
Digoxin	S	Unknown	Unk	Not Reported
Furosemide	S	Unknown		Not Reported
Insulin Aspart	S	Unknown		Not Reported
Insulin Glargine	S	Unknown		Not Reported
Metolazone	S	Unknown		Not Reported
Rivaroxaban	S	Unknown		Not Reported
Spironolactone	S	Unknown		Not Reported
Trazodone	C	Unknown	25 Mg, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15584817	EXPEDITED (15-DAY)	HO		PHHY2018IT144773		49 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral	40 Mg, Total		Novartis
	Escitalopram Oxalate			S	Oral	14 Mg, Total		Not Reported
	Aripiprazole			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585160	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1851960US		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypernatraemia; Hypokalaemia; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Perindopril			S	Oral	4 Mg, Unk		Not Reported	
	Lepticur			S	Oral	20 Mg, Qd		Not Reported	
	Kardegic			C				Not Reported	
	Lansoyl			C				Not Reported	
	Vimpat			C				Not Reported	
	Mag 2			C				Not Reported	
	Tamsulosine			C				Not Reported	
	Pravastatine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585161	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1851918US		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis; Iron Deficiency Anaemia	Escitalopram Oxalate - Bp			S	Oral	5 Gtt, Qd		Allergan	
	Eliquis			S	Oral	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585184	EXPEDITED (15-DAY)		DE	FR-ALLERGAN-1851951US		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Kardegic			S	Oral	75 Mg, Qd		Not Reported	
	Xarelto			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585199	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1851961US		56 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Thrombosis	Escitalopram Oxalate - Bp			S	Oral	20 Mg Daily Per Oral		Allergan
	Risedronate Sodium - Bp			S	Oral	35 Mg A Week Per Oral		Allergan
	Cacit [Calcium Carbonate]			S	Oral	500 Mg Strength Tablet Daily Per Oral		Allergan
	Enbrel			S	Subcutaneous	50mg A Week Subcutaneously		Not Reported
	Speciafoldine			S	Oral	10 Mg A Week Per Oral		Not Reported
	Prednisone			S	Oral	4 Mg Daily Per Oral		Not Reported
	Valaciclovir			S	Oral	1000 Mg Daily Per Oral		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg A Week Subcutaneously		Not Reported
	Codeine			S	Oral	2 Dosage Forms Daily Per Oral		Not Reported
	Desloratadine			S	Oral	5 Mg Daily Per Oral		Not Reported
	Paracetamol			S	Oral	2 Dosage Forms Daily Per Oral		Not Reported
	Lisinopril Dihydrate			S	Oral	10 Mg Daily Per Oral		Not Reported
	Uvedose			S	Oral	Daily Dose Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15587897	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-07656		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Escitalopram			S	Unknown	5 Mg, Qd Every Morning		Lupin
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin
	Escitalopram			S	Unknown	10 Mg, Qd, In Morning		Lupin
	Escitalopram			S	Unknown	15 Mg, Qd Every Morning		Lupin
	Testosterone			S	Topical	Unk, Qd, 50 Mg/5 G Gel, Every Morning On The Right Upper Extremity		Not Reported

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Lamotrigine	S	Unknown	150 Mg, Qd	Not Reported
Lamotrigine	S	Unknown	100 Mg, Unk	Not Reported
Lorazepam	S	Unknown	0.5 Mg, Tid, As Necessary	Not Reported
Lorazepam	S	Unknown	1 Mg, Tid, As Necessary	Not Reported
Bupropion	S	Unknown	150 Mg, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	200 Mg, Qd, Every Morning	Not Reported
Bupropion	S	Unknown	300 Mg, Qd, Every Morning	Not Reported
Aripiprazole	S	Unknown	4 Mg, Qd, Every Bedtime	Not Reported
Aripiprazole	S	Unknown	2 Mg, Qd, Every Bedtime	Not Reported
Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Qd, Extended Release, Every Morning	Not Reported
Amfetamine W/Dexamfetamine	S	Unknown	10 Mg, Qd, Extended Release, Every Morning	Not Reported
Lurasidone	S	Unknown	40 Mg, Qd, After Dinner	Not Reported
Lithium	S	Unknown	600 Mg, Qd Every Bedtime	Not Reported
Buspirone	S	Unknown	15 Mg, Bid	Not Reported
Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Buspirone	S	Unknown	10 Mg, Qd	Not Reported
Buspirone	S	Unknown	17.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Buspirone	S	Unknown	15 Mg, Qd	Not Reported
Buspirone	S	Unknown	2.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	22.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Qd	Not Reported
Buspirone	S	Unknown	7.5 Mg, Bid	Not Reported

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	Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
	Buspirone	S	Unknown	20 Mg, Qd	Not Reported
	Benzotropine Mesylate	C	Unknown	0.5 Mg, Bid, As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15587908	NON-EXPEDITED			US-PFIZER INC-2018443311		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Metoprolol Tartrate			S		Unk		Unknown	
	Trazodone			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15588250	NON-EXPEDITED			US-JAZZ-2018-US-014379			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Fatigue; Nausea	Xyrem			S	Oral	3.75 G, Bid		Jazz	
	Nuvigil			S				Not Reported	
	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	12809565	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US18971			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Panic Attack; Sleep Disorder; Suicidal Ideation	Escitalopram			S	Unknown	10 Mg, Qd		Invagen	
	Escitalopram			S	Unknown	20 Mg, Qd		Invagen	
	Chantix			S	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	25 Mg, Bid As Needed, Been On It For 15 Years, Tablet		Not Reported	
	Metoprolol Tartrate			C	Unknown	25 Mg, Bid, Tablet		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	13297566	EXPEDITED (15-DAY)		HO, OT	ZA-CIPLA LTD.- 2017ZA02470			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression;	Escitalopram			S	Unknown	10 Mg, Unk		Invagen	
Hypokalaemia;	Amlodipine			C	Oral	Unk, Qd		Not Reported	
Hyponatraemia	Lisinopril			C	Oral	Unk, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	13896520	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2017US14053			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Febrile Neutropenia;	Risperidone			S	Oral	1 Mg, Bid		Cipla	
Leukopenia; Neutropenia;	Escitalopram			S	Unknown	20 Mg, Qd		Invagen	
Treatment Noncompliance									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14077531	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US18065			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Blood	Escitalopram			S	Unknown	Unk		Invagen	
Prolactin Increased; Blood	Risperidone			S	Unknown	0.5 Mg, Bid		Not Reported	
Testosterone Increased;	Paracetamol			S	Unknown	Unk		Not Reported	
Blunted Affect; Drug	Fluoxetine			S	Unknown	10 Mg, Unk		Not Reported	
Ineffective;	Aripiprazole			S	Unknown	2 Mg, Unk		Not Reported	
Gastrointestinal Disorder;	Lamotrigine			C	Unknown	25 Mg, Daily		Not Reported	
Overdose; Psychotic									
Disorder; Suicidal Ideation									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14229556	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2017US10618			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Pain Upper;	Escitalopram	S	Oral	10 Mg, Qd	Invagen
Asthenopia; Balance	Escitalopram	S	Oral	10 Mg, Qd	Invagen
Disorder; Constipation;	Aspirin /00002701/	C	Unknown	81 Mg, Qd	Not Reported
Depression; Diarrhoea;					
Dizziness; Fatigue;					
Headache; Heart Rate					
Increased; Hyperhidrosis;					
Insomnia; Nausea; White					
Blood Cells Urine Positive					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14662284	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2018GB11505			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bursitis;	Escitalopram			S	Oral	5 Mg, Unk		Invagen
Nasopharyngitis; Skin	Levonelle /00318901/			C	Unknown	Unk		Not Reported
Warm								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14707758	EXPEDITED (15-DAY)		HO	AU-CIPLA (EU) LIMITED-2018AU13055			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delusion;	Escitalopram			S	Unknown	10 Mg, Qd (Am)		Invagen
Eczema; Emotional	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
Distress; Eosinophil Count	Olanzapine			S	Unknown	5 Mg, Bid		Not Reported
Decreased; Feeling Cold;	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
Frustration Tolerance	Clozaril			S	Oral	Unk		Not Reported
Decreased; Haemoglobin	Clozaril			S	Oral	700 Mg, Qd (Pm)		Not Reported
Decreased; Hallucination,	Paliperidone			S	Unknown	100 Mg, Unk		Not Reported
Auditory; Hyperhidrosis;	Paliperidone			S	Unknown	15 Mg, Unk		Not Reported
Intentional Self-Injury;	Caltrate /00944201/			C	Unknown	Unk		Not Reported
Lymphocyte Count	Lorazepam			C	Unknown	Unk		Not Reported
Decreased; Mean Cell	Lurasidone			C	Unknown	Unk		Not Reported
Haemoglobin Decreased;								
Mental Impairment;								
Metamyelocyte Count								
Increased; Monocyte								
Count Decreased;								

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Myelocyte Count	Metformin	C	Unknown	Unk	Not Reported
Increased; Neutropenia;	Mirtazapine	C	Unknown	Unk	Not Reported
Platelet Count Increased;	Crestor	C	Unknown	Unk	Not Reported
Thermal Burn; Tinea	Zuclopenthixol	C	Unknown	Unk	Not Reported
Infection; Vitamin B12	Calcium Carbonate	C	Unknown	Unk	Not Reported
Deficiency; White Blood	Rosuvastatin	C	Unknown	Unk	Not Reported
Cell Count Decreased	Coloxyl /00061602/	C	Unknown	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
	Senna /00142201/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14817776	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US16673			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State	Sertraline			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	14971876	EXPEDITED (15-DAY)		DE, OT	US-CIPLA (EU) LIMITED-2018US18515			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Appetite Disorder;	Bupropion			S	Unknown	100 Mg, Unk		Invagen
Completed Suicide;	Bupropion			S	Unknown	300 Mg, Unk		Invagen
Depression; Hallucination,	Donepezil			S	Unknown	10 Mg, Unk		Cipla
Visual; Sleep Disorder;	Escitalopram			S	Unknown	Unk		Invagen
Treatment Noncompliance	Memantin			S	Unknown	28 Mg, Unk		Not Reported
	Baby Aspirin			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15034142	EXPEDITED (15-DAY)		DE, HO	GB-CIPLA LTD.- 2018GB19108			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral	20 Mg, Per Day		Invagen	
	Acetylsalicylic Acid			S	Oral	75 Mg, Per Day, Tablet		Not Reported	
	Dihydrocodeine			C	Oral	120 Mg, Per Day, Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15163654	EXPEDITED (15-DAY)		DS, HO, OT	GB-CIPLA LTD.- 2018GB20023			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15219924	EXPEDITED (15-DAY)		OT	DE-ALVOGEN-2018- ALVOGEN-096875		28 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Juvenile Myoclonic Epilepsy	Fluoxetine			S				Not Reported	
	Bupropion			S				Not Reported	
	Aripiprazole			S				Not Reported	
	Amisulpride			S				Not Reported	
	Olanzapine			S				Not Reported	
	Quetiapine			S				Not Reported	
	Duloxetine			S				Not Reported	
	Clozapine			S				Not Reported	
	Escitalopram			S				Not Reported	
	Venlafaxine			S				Not Reported	
	Risperidone			S				Not Reported	
	Biperiden Hydrochloride			S				Not Reported	
	Mirtazapine			S				Not Reported	
	Promethazine			S				Not Reported	
	Zopiclone			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15365231	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-071365		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Coma; Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Lorazepam Epinephrine			S S S		3 I Jctions		Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15365587	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2018GB21092			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral	25 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15515932	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US22586			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Muscle Twitching	Escitalopram Paxil /00500401/			S C	Oral Unknown	10 Mg, Unk Unk		Invagen Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15516214	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2018US21211			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Loss Of Weight; Back Pain; Night Sweats; Poor Quality Sleep	Escitalopram			S	Unknown	Unk		Invagen	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15516405	EXPEDITED (15-DAY)			US-CIPLA LTD.- 2017US20559			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	20 Mg, Qd		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15582745	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE- HET2018US01216		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Escitalopram			S	Unknown	5 Mg, Qd		Hetero	
	Escitalopram			S	Unknown	20 Mg, Qd		Hetero	
	Escitalopram			S	Unknown	10 Mg, Qd		Hetero	
	Escitalopram			S	Unknown	15 Mg, Qd		Hetero	
	Lithium			S	Unknown	600 Mg, Qd		Hetero	
	Aripiprazole			S	Unknown	4 Mg, Qd		Hetero	
	Aripiprazole			S	Unknown	2 Mg, Qd		Hetero	
	Amphetamine, Dextroamphetamine			S	Unknown	20 Mg Extended Release, Every Morning		Not Reported	
	Amphetamine, Dextroamphetamine			S	Unknown	10 Mg, Qd		Not Reported	
	Testosterone			S	Topical	Unk, Qd (50mg/5g)		Not Reported	
	Lurasidone			S	Unknown	40 Mg, Qd		Not Reported	
	Lamotrigine			S	Unknown	150 Milligram		Not Reported	
	Lamotrigine			S	Unknown	100 Milligram		Not Reported	
	Lorazepam			S	Unknown	0.5 Milligram As Necessary		Not Reported	
	Lorazepam			S	Unknown	1 Milligram As Necessary		Not Reported	
	Bupropion			S	Unknown	150 Milligram Every		Not Reported	

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Bupropion	S	Unknown	Morning 200 Milligram Every Morning	Not Reported
Bupropion	S	Unknown	300 Milligram Every Morning	Not Reported
Buspirone	S	Unknown	15 Milligram	Not Reported
Buspirone	S	Unknown	15 Milligram	Not Reported
Buspirone	S	Unknown	10 Milligram	Not Reported
Buspirone	S			Not Reported
Buspirone	S	Unknown	7.5 Milligram	Not Reported
Buspirone	S	Unknown	15 Milligram	Not Reported
Buspirone	S	Unknown	15 Milligram	Not Reported
Buspirone	S	Unknown	2.5 Milligram	Not Reported
Buspirone	S	Unknown	22.5 Milligram	Not Reported
Buspirone	S	Unknown	5 Milligram	Not Reported
Buspirone	S	Unknown	7.5 Milligram	Not Reported
Buspirone	S	Unknown	7.5 Milligram	Not Reported
Buspirone	S	Unknown	7.5 Milligram	Not Reported
Buspirone	S	Unknown	20 Milligram	Not Reported
Benzotropine Mesylate	C	Unknown	0.5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15584996	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851764US		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qam		Allergan
	Buspirone			S	Unknown	15 Mg, Tid		Not Reported

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Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
Buspirone	S	Unknown	15 Mg, Tid	Not Reported
Buspirone	S	Unknown	7.5 Mg, Tid	Not Reported
Lorazepam	C	Unknown	0.5 Mg, Bid (As Necessary)	Not Reported
Bupropion	C	Unknown	150 Mg, Qam	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15588932	EXPEDITED (15-DAY)	CA		DE-ACCORD-090687		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Escitalopram			S	Transplacental	7.5 Mg/D (Mutter) 0. - 40.3. Gestational Week		Not Reported
	Ebrantil			C	Unknown	Exposition: Paternal (Father route Of Admin. Oral)		Not Reported
	Simvastatin			C	Unknown	Probably Either Simvastatin Or Atozet Exposition: Paternal (Father route Of Admin. Oral)		Not Reported
	Valsartan			C	Unknown	160 Mg/D (Vater) Exposition: Paternal (Father route Of Admin. Oral)		Not Reported
	Folsan			C	Transplacental	0.4 Mg/D (Mutter)		Not Reported
	Ramilich			C	Unknown	10 Mg/D (Vater)		Not Reported
	Dekristol			C	Unknown	20000 Ie/D (Alle 2 Wochen) (Vater)		Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Bicanorm			C	Unknown	Exposition: Paternal (Father route Of Admin. Oral)		Not Reported
	Atozet			C	Unknown	40 Mg/D / 10 Mg/D (Vater)		Not Reported

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Ass 100	C	Unknown	/ Probably Either Atozet Or Simvastatin	Not Reported
Amlodipine	C	Unknown	100 Mg/D (Vater) 10 Mg/D (Vater) Exposition: Paternal (Father route Of Admin. Oral)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15589283	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-972690		30 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Impaired Quality Of Life; Treatment Noncompliance	Escitalopram			S	Unknown	10 Milligram Daily; Every Morning		Ivax	
	Gabapentin			S	Unknown	1000 Milligram Daily; Total Daily Dose		Ivax	
	Nortriptyline			S	Unknown	60 Milligram Daily; Every Bedtime		Teva	
	Alprazolam			S	Unknown	1 Milligram Daily; Extended Release; Total Daily Dose		Actavis	
	Alprazolam			S	Unknown	Total Daily Dose (1mg-0.5mg-1mg); Extended Release		Actavis	
	Lisdexamfetamine Dimesylate			S	Unknown	70 Milligram Daily; Every Morning		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15589746	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-190488		45 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Blood Prolactin Increased; Dizziness;	Escitalopram			S	Unknown	10 Mg, Daily		Not Reported	

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Drug Ineffective; Galactorrhoea; Hypertension; Nausea; Tachycardia; Therapy Partial Responder	Escitalopram	S	Unknown	20 Mg, Daily	Not Reported
	Sertraline	S	Unknown	50 Mg, Daily	Sun
	Sertraline	S	Unknown	200 Mg, Daily	Sun
	Sertraline	S	Unknown	250 Mg, Daily	Sun
	Sertraline	S		Dose Reduced 50 Mg/Day Each Week	Sun
	Paroxetine	S	Unknown	20 Mg, Daily	Sun
	Paroxetine	S	Unknown	30 Mg, Daily	Sun
	Citalopram	S	Unknown	20 Mg, Daily	Sun
	Citalopram	S	Unknown	60 Mg, Daily	Sun
	Risperidone	S	Unknown	1 Mg, Daily	Ranbaxy
	Venlafaxine	S	Unknown	75 Mg, Daily	Sun
	Venlafaxine	S	Unknown	150 Mg, Daily	Sun
	Venlafaxine	S	Unknown	225 Mg, Daily	Sun
	Valproic Acid	S	Unknown	1000 Mg, Daily	Sun
	Haloperidol	S	Unknown	1 Mg, Daily	Not Reported
	Venlafaxine	S	Unknown	37.5 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15590175	EXPEDITED (15-DAY)		HO, OT	FR- GLAXOSMITHKLINE- FR2018197442		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Speciafoldine			S	Oral	10 Mg, We		Glaxosmithkline	
	Valaciclovir			S	Oral	1000 Mg, Qd		Glaxosmithkline	
	Codeine			S	Oral	2 Df, Qd		Glaxosmithkline	
	Paracetamol			S	Oral	2 Df, Qd		Glaxosmithkline	
	Uvedose			S	Oral	1 Df, Unk		Glaxosmithkline	
	Escitalopram			S	Oral	20 Mg, Qd		Glaxosmithkline	
	Enbrel			S	Subcutaneous	50 Mg, We		Not Reported	

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	Prednisone	S	Oral	4 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, We	Not Reported
	Desloratadine	S	Oral	5 Mg, Qd	Not Reported
	Lisinopril Dihydrate	S	Oral	10 Mg, Qd	Not Reported
	Cacit (Calcium Carbonate) Effervescent Tablet, Unkmg	S	Oral	1 Df, Qd	Not Reported
	Risedronate Monosodium	S	Oral	35 Mg, We	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15590580	EXPEDITED (15-DAY)		OT	DE-009507513- 1810DEU013466			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Headache	Mirtazapine			S	Unknown	30 Mg, Unk		Merck	
	Levocarb			S	Unknown	0.5 Df, Unk		Not Reported	
	Escitalopram			S	Unknown	15 Mg, Qhs		Not Reported	
	Aspirin			C	Unknown	100 Mg, Qd		Not Reported	
	Atorvastatin			C	Unknown	300 Mg, Qhs		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15591757	DIRECT	Y	OT			50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram			S	Oral		2 WEEK	Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15592726	EXPEDITED (15-DAY)		OT	CH-ALLERGAN- 1852135US		37 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Mass; Gynaecomastia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15593927	EXPEDITED (15-DAY)		DE, HO, LT	US-MYLANLABS-2018M1083824		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Ineffective; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Not Reported	
	Lisinopril			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Trazodone			S	Oral			Not Reported	
	Norepinephrine			S	Unknown			Not Reported	
	Epinephrine			S	Unknown			Not Reported	
	Vasopressin			S	Unknown			Mylan	
	Dopamine			S	Unknown			Mylan	
	Dobutamine			S	Unknown			Mylan	
	Fat Emulsion			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15594562	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852125US		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Melaena; Microcytic Anaemia	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Plavix			S	Oral	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15595061	EXPEDITED (15-DAY)		HO	PHHY2018FR147576		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Paracetamol			S	Oral	2 Df, Qd		Not Reported	
	Prednisone			S	Oral	4 Mg, Qd		Novartis	

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Valaciclovir	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qd	Not Reported
Desloratadine	S	Oral	5 Mg, Qd	Not Reported
Lisinopril Dihydrate	S	Oral	10 Mg, Qd	Not Reported
Escitalopram	S	Oral	20 Mg, Qd	Not Reported
Codeine	S	Oral		Not Reported
Speciafoldine	S	Oral		Not Reported
Cacit [Calcium Carbonate]	S	Oral	1 Df, Qd	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Uvedose	S	Oral	1 Df, Qd	Not Reported
Risedronate	S	Oral	35 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	14257731	EXPEDITED (15-DAY)		HO, OT	SI-BIOGEN-2017BI00493562		48 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Sclerosis; Palpitations	Fampyra			S	Unknown			Biogen	
	Pregabalin			S	Unknown	150 Mg, Bid		Not Reported	
	Escitalopram			S	Unknown	1 Tablet In Morning		Not Reported	
	Tolterodine			S	Unknown	1 Tablet In Morning		Not Reported	
	Fty 720			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15298001	EXPEDITED (15-DAY)		DS, HO, LT	PT-ALLERGAN-1840382US		94 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	

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Hyperactivity; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15591239	EXPEDITED (15-DAY)		OT	GB- ELI_LILLY_AND_COMP ANY-GB201811001982		43 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Fluoxetine			S	Unknown	Unk Unk, Unknown		Not Reported	
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported	
	Dosulepin			S	Unknown	Unk, Unknown		Not Reported	
	Lofepamine			S	Unknown	Unk, Unknown		Not Reported	
	Quetiapine			C	Unknown	300 Mg, Daily		Not Reported	
	Citalopram			C	Unknown	20 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15593291	NON-EXPEDITED			US-OTSUKA- 2017_026184			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Ineffective; Gait Disturbance; Muscle Rigidity; Musculoskeletal Stiffness	Nuedexta			S	Unknown	Unk		Avanir	
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported	
	Namenda			S	Unknown	Unk		Not Reported	
	Prenatal Vitamins			C	Unknown	Unk		Not Reported	
	Nortriptyline			C	Unknown	2 Mg, Bid		Not Reported	
	Depakote			C	Unknown	500 Mg, Bid		Not Reported	
	Seroquel			C	Unknown	25 Mg, Bid		Not Reported	
	Baby Aspirin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15594350	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Intolerance		Lexapro		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15594805	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_035333		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Miosis; Orthostatic Hypotension; Product Use In Unapproved Indication; Somnolence	Aripiprazole			S	Oral	Unk		Otsuka	
	Escitalopram			S	Oral	Unk		Not Reported	
	Bromazepam			S	Oral	120 Mg, Unk		Not Reported	
	Zolpidem			S	Oral	Unk		Not Reported	
	Olanzapine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15596089	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181107344		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence; Prescription Form Tampering	Tramadol/Apap			S	Oral			Not Reported	
	Imovane			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Xanax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15178276	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-036405		31 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral	10 Milligram		Aurobindo	
	Escitalopram			S	Oral			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15221684	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-010701			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder;	Xyrem			S	Oral	2.25 G, Bid		Jazz
Anxiety; Decreased	Xyrem			S	Oral	3 G, Bid		Jazz
Appetite; Depression;	Xyrem			S	Oral	4 G, First Dose		Jazz
Fatigue; Insomnia; Mental	Xyrem			S	Oral	3.5 G, Second Dose		Jazz
Disorder; Nausea;	Xyrem			S	Oral	3 G, Bid		Jazz
Somnolence; Weight	Xyrem			S	Oral	Unk		Not Reported
Decreased	Ritalin			S				Not Reported
	Lexapro			S				Not Reported
	Lexapro			S				Not Reported
	Ibuprofen			C				Not Reported
	Loratadine			C				Not Reported
	Tylenol Extra Strength			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15579911	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851491US		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia;	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan
Cerebrovascular Accident;	Meloxicam			C	Oral	40 Mg, Qpm		Not Reported
Dysarthria; Feeling	Synthroid			C	Oral	75 Mg, Qam		Not Reported
Abnormal;	Simvastatin			C	Oral	40 Mg, Qd (At Lunch)		Not Reported
Hypersensitivity;	Mobic			C	Unknown	Unk		Not Reported
Hypoaesthesia; Swelling	Allegra			C	Oral	Unk		Not Reported
Face	Triamterene			C	Oral	37.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15598376	EXPEDITED (15-DAY)		HO	FR-SANIK-2018SA303414AA		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Melaena; Microcytic	Plavix			S	Oral	75 Mg, Qd		Sanofi
Anaemia	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15598444	EXPEDITED (15-DAY)		HO	ZA-MYLANLABS-2018M1073989			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Lumbar Vertebral Fracture	Mylan Pantoprazole 40 Mg			S		Unk		Mylan	
	Bilocor			S		Unk		Mylan	
	Co-Diovan			S		Unk		Mylan	
	Lexamil			S		Unk		Mylan	
	Amloc /00550802/			S		Unk		Mylan	
	Celebrex			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15599952	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-053957		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Prednisone			S	Oral	4 Milligram, Once A Day		Aurobindo	
	Valaciclovir			S	Oral	1000 Milligram, Once A Day		Aurobindo	
	Desloratadine			S	Oral	5 Milligram, Once A Day		Not Reported	
	Paracetamol			S	Oral	2 Dosage Form, Once A Day		Aurobindo	
	Lisinopril			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Risedronate			S	Oral	35 Milligram Weekly		Aurobindo	
	Enbrel			S	Subcutaneous	50 Milligram Weekly		Not Reported	
	Speciafoldine			S	Oral	10 Milligram Weekly		Not Reported	
	Methotrexate			S	Subcutaneous	20 Milligram Weekly		Not Reported	
	Codeine			S	Oral	2 Dosage Form, Once A Day		Not Reported	
	Uvedose			S	Oral	1 Dosage Form 1		Not Reported	

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Cacit /07357001/ S Oral Trimester
1 Dosage Form, Once A Day Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15599960	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-053959		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypernatraemia; Hypokalaemia; Urinary Retention	Perindopril			S	Oral	4 Milligram, Once A Day		Aurobindo
	Lepticur			S	Oral	20 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	10 Milligram, Once A Day		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Lansoyl			C	Unknown	Unk		Not Reported
	Vimpat			C	Unknown	Unk		Not Reported
	Mag 2 /00454301/			C	Unknown	Unk		Not Reported
	Tamsulosine /01280301/			C	Unknown	Unk		Not Reported
	Pravastatin /00880402/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	14915957	EXPEDITED (15-DAY)		OT	CA-ALLERGAN- 1826729US		89 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Aggregation Inhibition	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Heparin			S	Subcutaneous	5000 Units, Q12h		Not Reported
	Rivaroxaban			S	Oral	Unk		Not Reported
	Rivaroxaban			S	Oral	Unk		Not Reported
	Rivaroxaban			S	Oral	15 Mg, Qd		Not Reported
	Lidocaine 2%			C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 Mg/MI		Not Reported

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	Hydromorphone	C	Unknown	10 Mg/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion	Not Reported				
	Epinephrine	C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 Mg/MI	Not Reported				
	Bupivacaine	C	Unknown	1 Mg/MI, Infusion	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15599989	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-054080		56 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hyperhidrosis; Tachycardia; Toxicity To Various Agents; Tremor	Metoprolol			S	Oral	Unk		Aurobindo	
	Escitalopram Doc			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600200	EXPEDITED (15-DAY)		DS	IT-TEVA-2018-IT-973729		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral			Pliva	
	Rivotril			S	Oral	30 Gtt Daily;		Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600331	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2018-053935		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Kardegic			S	Oral	75 Milligram, Once A Day		Not Reported	
	Xarelto			S	Oral	20 Milligram, Once A Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600415	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-054431		82 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral	1 Week		Aurobindo	
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Acetylsalicylic Acid			S	Oral	75 Milligram, Once A Day		Not Reported	
	Felodipine			C	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Adcal D3			C	Unknown	Unk		Not Reported	
	Doxazosin			C	Unknown	Unk		Not Reported	
	Simvastatin			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
	Dymista			C	Unknown	Unk		Not Reported	
	Montelukast			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Ferrous Fumarate			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15601306	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2018159281		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen	
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported	
	Speciafoldine			S	Oral	10 Mg, Weekly		Not Reported	
	Prednisone			S	Oral	4 Mg, 1x/Day		Not Reported	
	Valaciclovir			S	Oral	1000 Mg, 1x/Day		Not Reported	

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Codeine	S	Oral	2 Df, 1x/Day	Not Reported
Desloratadine	S	Oral	5 Mg, 1x/Day	Not Reported
Paracetamol	S	Oral	2 Df, 1x/Day	Not Reported
Lisinopril Dihydrate	S	Oral	10 Mg, 1x/Day	Not Reported
Uvedose	S	Oral	1 Df, Every One Trimester (Oral Solution In Ampoule)	Not Reported
Escitalopram	S	Oral	20 Mg, 1x/Day	Not Reported
Cacit [Calcium Carbonate]	S	Oral	1 Df, 1x/Day	Not Reported
Risedronate Sodium	S	Oral	35 Mg, Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15601741	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1852664US		28 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Anxiety; Bruxism; Chills; Condition Aggravated; Depression; Gastroesophageal Reflux Disease; Hot Flush; Loss Of Libido; Migraine; Neuralgia; Palpitations; Paraesthesia; Suicidal Ideation; Weight Increased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Olanzapine			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15601742	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852401US		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	160 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15602065	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018457524		49 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Lorazepam			S	Oral	40 Mg, Total		Pfizer	
	Escitalopram Oxalate			S	Oral	14 Df, Total		Not Reported	
	Aripiprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15602991	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20181110885		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Haemorrhage; Drug Interaction; Prescription Drug Used Without A Prescription; Serotonin Syndrome	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15603345	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1843095US		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Suicide Attempt	Escitalopram Oxalate Unk			S	Oral	15 MI, In Total		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15603661	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1852699US		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Intentional Self-Injury; Nausea; Vomiting	Escitalopram Oxalate Unk			S	Oral	7.5 MI, In Total		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15603664	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1852721US		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram Oxalate - Bp	S	Oral	Unk	Allergan
	Aripiprazole	S	Oral	Unk	Not Reported
	Bromazepam	S	Oral	120 Mg, Unk	Not Reported
	Zolpidem	S	Oral	Unk	Not Reported
	Olanzapine	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	14901778	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2018192483		48 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Solanax 0.4mg			S	Oral	0.4 Mg, As Needed		Pfizer	
	Brotizolam			S	Oral	1 Df, 1x/Day		Not Reported	
	Lexapro			S	Oral	1 Df, 1x/Day		Not Reported	
	Calcitriol			C	Oral	1 Df, 2x/Day		Not Reported	
	Ternelin			C	Oral	1 Df, 3x/Day		Not Reported	
	Loxoprofen Na			C	Oral	1 Df, 3x/Day		Not Reported	
	Tsumura Hochuekkito			C	Oral	1 Df, 2x/Day		Not Reported	
	Divigel			C	Topical	1 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15274243	EXPEDITED (15-DAY)		DS, HO, LT	PT-AUROBINDO-AUR-APL-2018-041008		94 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor Hyperactivity; Vomiting	Escitalopram Film-Coated Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15605839	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS			Unknown	GBR

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PHARMACEUTICALS
US LTD-
MAC2018018555

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Escitalopram			S	Oral	20 Milligram, Qd		Macleods
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Alendronic Acid			S	Oral	70 Milligram, Q.W.		Not Reported
	L-Thyroxine Sodium			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Macleods
	Adcal-D3			C	Unknown	Unk		Not Reported
	Doxazosin			C	Unknown	Unk		Not Reported
	Dymista			C	Unknown	Unk		Not Reported
	Felodipine			C	Unknown	Unk		Not Reported
	Ferrous Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15605840	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018017715			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Foetal Exposure During Pregnancy; Pregnancy	Candesartan			S	Oral	16 Mg, Qd (0-4.4 Gestational Week)		Macleods
	Escitalopram			S	Oral	220 Mg, Qd (4.4-11.5 Gestational Week)		Macleods

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Escitalopram	S	Oral	20 Milligram, Qd	Macleods
Levetiracetam	S	Oral	1500 Mg, Qd	Not Reported
Nepresol (Dihydralazine Sulfate)	S	Oral	25 Mg, Qd	Not Reported
Paroxetine	S	Oral	30 Mg, Qd (0-4.4 Gestational Week)	Not Reported
Paroxetine	S	Oral	30 Mg, Qd (0-4.4 Gestational Week)	Not Reported
L-Thyroxine Sodium	C	Oral	Unk (0-11.5 Gestational Week)	Not Reported
Cytotec	C	Unknown	Unk (11-11.5 Gestational Week)	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15606125	EXPEDITED (15-DAY)		HO	GB-TORRENT-00019425		82 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Felodipine			C		Unknown		Unknown
	Levothyroxine			C				Unknown
	Adcal-D3			C				Unknown
	Doxazosin			C		Unknown		Unknown
	Alendronic Acid			S	Oral	Unknown		Unknown
	Simvastatin			C		Unknown		Unknown
	Salbutamol			C		Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Seretide			C		Unknown		Unknown
	Dymista			C		Unknown		Unknown
	Montelukast			C		Unknown		Unknown
	Gabapentin			C		Unknown		Unknown
	Ferrous Fumarate			C		Unknown		Unknown
	Zopiclone			C		Unknown		Unknown

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Acetylsalicylic Acid			S	Oral	Unknown			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15606730	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1852707US		44 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Seresta			S	Unknown	Unk		Not Reported	
	Lysanxia			S	Unknown	Unk		Not Reported	
	Xanax			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15607039	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX-2018AP024298		25 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hospitalisation; Lactation Disorder; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Apotex	
	Aripiprazole			S	Oral	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15608477	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMP ANY-FR201811000224		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Olanzapine			S	Oral	Unk Unk, Unknown		Eli Lilly And Co	
	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported	
	Bromazepam			S	Oral	120 Mg, Unknown		Not Reported	
	Aripiprazole			S	Oral	Unk Unk, Unknown		Not Reported	

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Zolpidem			S		Oral		Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Nov-2018	15609431	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2018M1084874		1 DAY	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 [Mg/D]/ Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D			Not Reported	
	Folio /07351001/			C	Transplacental	0.4 [Mg/D]			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Nov-2018	14779251	EXPEDITED (15-DAY)		HO, LT, OT	ES-APOTEX-2018AP010993		55 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Myocardial Ischaemia; Tachycardia; Torsade De Pointes	Escitalopram			S	Unknown	15 Mg, Daily			Apotex	
	Pantoprazole			S	Unknown	Unk			Apotex	
	Haloperidol			S	Unknown	2 Mg, Daily			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Nov-2018	15366177	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1066275		45 YR	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache; Therapeutic Product Effect	Escitalopram			S	Unknown	10 Mg, Qd			Not Reported	
	Escitalopram			S	Unknown	Unk			Not Reported	
	Amlodipin /00972401/			C	Unknown	10 Mg, Qd			Mylan	

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Incomplete

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15515899	EXPEDITED (15-DAY)		DS, OT	IT-AUROBINDO-AUR-APL-2018-050606		19 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autism Spectrum Disorder	Escitalopram			S	Oral	5 Gtt, Daily		Aurobindo
	Risperidone			S	Oral	1 Milligram, Daily		Aurobindo
	Depakin			C	Oral	100 Milligram, Daily		Not Reported
	Rivotril			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15558915	EXPEDITED (15-DAY)		CA, DE	DE-UCBSA-2018046834			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam			S	Transplacental	1500 Mg, Once Daily (Qd)		Ucb
	Nepresol (Dihydralazine Mesilate)			S	Transplacental	25 Mg, Once Daily (Qd)		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Once Daily (Qd)		Not Reported
	Candesartan			S	Transplacental	16 Mg, Once Daily (Qd)		Not Reported
	Paroxetine			S	Transplacental	30 Mg, Once Daily (Qd)		Not Reported
	L-Thyroxin			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Folic Acid			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15560088	EXPEDITED (15-DAY)		OT	DE-UCBSA-2018048184		38 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Off Label Use; Pregnancy	Levetiracetam			S	Oral	1500 Mg, Once Daily (Qd)		Ucb
	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Mg, Once Daily (Qd)		Not Reported

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Escitalopram	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Candesartan	S	Oral	16 Mg, Once Daily (Qd)	Not Reported
Paroxetine	S	Oral	30 Mg, Once Daily (Qd)	Not Reported
L-Thyroxine	C	Oral		Not Reported
Cytotec	C			Not Reported
Folic Acid	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15566253	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP020302			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Dizziness; Drug Ineffective; Fall; Headache; Insomnia; Pain In Extremity; Somnolence; Treatment Noncompliance	Tramadol/Acetaminophen			S	Unknown	1 Df, Tid		Apotex
	Paracetamol			S	Unknown	1 Df, Tid		Apotex
	Amlodipine			S	Unknown	1 Df, Qd		Apotex
	Omeprazole			S	Unknown	1 Dosage Forms Daily; 20 Mg		Apotex
	Simvastatin			S	Unknown	1 Dosage Forms Daily; 40 Mg		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Simvastatin			S	Unknown	20 Mg, Unk		Not Reported
	Enalapril /Hydrochlorothiazide			S	Unknown	1 Dosage Forms Daily; 1 Df = 20/12.5 Mg		Apotex
	Escitalopram			S	Unknown	1 Dosage Forms Daily; 10 Mg		Apotex
	Diazepam			S	Unknown	.5 Dosage Forms Daily; 5 Mg		Not Reported
	Topiramate			S	Unknown	0.5 Df, Qd		Apotex
	Topiramate			S	Unknown	1 Dosage Forms Daily; 50 Mg		Apotex
	Naproxen			S	Unknown	1 Df, Bid		Not Reported
	Amitriptyline			S	Unknown	Qd		Not Reported
	Amitriptyline			S	Unknown	12.5 Mg, Qd		Not Reported

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Amitriptyline	S	Unknown	25 Milligram Daily;	Not Reported
Amitriptyline	S	Unknown	25 Milligram Daily;	Not Reported
Glibenclamida	S	Unknown	2 Dosage Forms Daily;	Not Reported
Tepazepam	S	Unknown	Qd	Not Reported
Lormetazepam	S	Unknown	1 Df, Qd	Not Reported
Topiramato	S	Unknown	0.5 Df, Qd	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported
Metoclopramide	C	Unknown	1 Week Treatment	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15572709	EXPEDITED (15-DAY)			IT-ALLERGAN-1851569US		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Ineffective; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported
	Sertraline			S	Unknown	200 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Venlafaxin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15609991	EXPEDITED (15-DAY)		OT	DK-MACLEODS PHARMACEUTICALS US LTD- MAC2018018593			Unknown	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bile Acid Malabsorption	Venlafaxine			S	Unknown	225 Milligram, Qd		Macleods
	Escitalopram Oxalate			S	Unknown	40 Milligram, Qd		Macleods
	6-Mercaptopurine			C	Unknown	Unk		Not Reported
	Colesevelam			C	Unknown	625 Milligram, Tid		Not Reported

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Loperamide	C	Unknown	Unk, 2-8 Milligram Qd	Not Reported
Levetiracetam	C	Unknown	Unk	Not Reported
Lamotrigine	C	Unknown	400 Milligram, Qd	Not Reported
Infliximab	C	Unknown	Unk	Not Reported
Adalimumab	C			Not Reported
Natalizumab	C	Unknown	Unk	Not Reported
Vedolizumab	C	Unknown	Unk	Not Reported
Vancomycin	C	Unknown	125 Milligram Four Times Per Day	Not Reported
Spironolactone	C	Unknown	Unk	Not Reported
Octreotide	C	Unknown	Unk	Not Reported
Liraglutide	C	Unknown	Unk	Not Reported
Potassium	C	Unknown	100 Millimole	Not Reported
Sodium Chloride	C	Unknown	2000 MI Of 3% Sodium Chloride	Not Reported
Ibuprofen	C	Unknown	400 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15611369	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-190791		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	In Total		Not Reported	
	Lorazepam			S	Oral	In Total		Sun	
	Aripiprazole			C	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15611488	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029622		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole	S	Oral	Zydus Pharm
	Escitalopram	S	Oral	Zydus Pharm
	Olanzapine	S	Oral	Zydus Pharm
	Bromazepam	S	Oral	Not Reported
	Zolpidem	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15611530	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-054551		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo
	Bromazepam			S	Oral	Estimated Dose Of 20 Cp Bromazepam 6 Mg, Unk		Not Reported
	Escitalopram			S	Oral	Exact Dose At Unknown Imv ()		Aurobindo
	Olanzapine			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo
	Zolpidem			S	Oral	Exact Dose At Unknown Imv, Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15612092	EXPEDITED (15-DAY)		HO	GB-009507513- 1811GBR003175		82 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronate Sodium			S	Oral	70 Milligram, Qw		Merck
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Aspirin			S	Oral	75 Milligram, Qd		Not Reported
	Felodipine			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Adcal-D3			C				Not Reported
	Doxazosin			C				Not Reported
	Simvastatin			C				Not Reported

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Albuterol	C	Not Reported
Seretide	C	Not Reported
Dymista	C	Not Reported
Montelukast	C	Not Reported
Gabapentin	C	Not Reported
Ferrous Fumarate	C	Not Reported
Zopiclone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15612688	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181114285		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Loss Of Consciousness; Malaise; Orthostatic Hypotension	Tramadol/Paracetamol			S	Oral			Not Reported	
	Coaprovel			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Omeprazole			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15612735	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-974914		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	75 Milligram Daily;		Not Reported	
	Xarelto 20 Mg, Comprimé Pelliculé			S	Oral	20 Milligram Daily; 20 Mg/J		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613543	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1085907		31 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Impaired Gastric Emptying;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	

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Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613747	EXPEDITED (15-DAY)		DE	NO-PURDUE-GBR-2018-0061540		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Medication Error; Overdose	Tramadol Hydrochloride			S	Unknown	Unk		Purdue
	Oxynorm			S	Unknown	Unk		Purdue
	Vival			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Cipralex			S	Unknown	Unk		Not Reported
	Nozinan /00038601/			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown	Unk		Not Reported
	Catapresan /00171101/			S	Unknown	Unk		Not Reported
	Atarax /00058401/			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	Unk		Not Reported
	Nobligan			S	Unknown	Unk		Not Reported
	Pinex Forte			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Imovane			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613818	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC-2018464538		81 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Renal Failure	Methotrexate			S		2.5 Mg, Unk		Pfizer
	Premarin			S		0.625 Mg, Unk		Pfizer
	Puricos			S		300 Mg, Unk		Not Reported

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Nivaquine [Chloroquine]	S	200 Mg, Unk	Not Reported
Spiractin (Spironolactone)	S	25 Mg, Unk	Not Reported
Carloc	S	6.25 Mg, Unk	Not Reported
Be-Tabs Folic Acid	S	5 Mg, Unk	Not Reported
Puresis	S	40 Mg, Unk	Not Reported
Slow Mag [Magnesium Chloride]	S	535 Mg, Unk	Not Reported
Allecet [Cetirizine Hydrochloride]	S	10 Mg, Unk	Not Reported
Eltroxin	S	100 Ug, Unk	Not Reported
Nexomist	S	150 Ug, Unk	Not Reported
Citraz	S	20 Mg, Unk	Not Reported
Proben [Ketoprofen]	S	500 Mg, Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	S	80 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15632336	DIRECT					33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Increased Appetite; Insomnia; Irritability; Lack Of Satiety; Tremor; Weight Increased	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Zyrtec			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	12539614	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-119590		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose;	Escitalopram			S	Oral	840 Mg		Not Reported
	Venlafaxine			S	Oral	7875 Mg		Sun
	Bromazepam			S	Oral	180 Mg		Not Reported

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Nystagmus; Psychomotor Skills Impaired; Suicide Attempt; Toxicity To Various Agents; Toxicity To Various Agents	Lormetazepam	S	Oral	14 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	14246042	EXPEDITED (15-DAY)		DE	US-CIPLA (EU) LIMITED-2017US21762			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Invagen
	Estradiol			S	Oral	Unk		Not Reported
	Paracetamol + Difenhydramina			S	Oral	Unk		Not Reported
	Hasco Noc							
	Paracetamol/Codeine			S	Oral	Unk		Not Reported
	Oxycodone			S	Oral	Unk		Not Reported
	Levothyroxine			S	Oral	Unk		Not Reported
	Thiazide			S	Oral	Unk		Not Reported
Progestin			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15203919	EXPEDITED (15-DAY)		DS, HO, OT	GB-TEVA-2018-GB-931372		31 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15330467	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-APOTEX-2018AP019342		50 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Condition Aggravated;	Clarithromycin			S	Oral	Unk, Qd, Two 10 Day Courses		Apotex

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Depression; Drug Abuse;	Clarithromycin	S				Apotex
Drug Ineffective; Impaired	Escitalopram	S	Oral	10 Mg, Qd		Apotex
Work Ability; Insomnia;	Escitalopram	S				Apotex
Intentional Overdose;	Escitalopram	S				Apotex
Intentional Product	Escitalopram	S				Apotex
Misuse; Loss Of	Sertraline	S	Oral	50 Mg, Qd Am (In The Morning)		Apotex
Consciousness; Loss Of	Sertraline	S				Apotex
Personal Independence In	Perindopril	S	Oral	Unk		Apotex
Daily Activities; Overdose;	Perindopril	S				Apotex
Product Use In	Perindopril	S				Apotex
Unapproved Indication;	Atorvastatin	S	Oral	Unk, Qd (Bedtime)		Apotex
Suicide Attempt; Tinnitus	Zolpidem	S	Oral	10 Mg, Qd At Bedtime		Apotex
	Zolpidem	S				Apotex
	Meloxicam	S	Oral	Unk, Qd		Apotex
	Atoris	S	Unknown	Unk		Not Reported
	Tramadol	S	Oral	Unk, Qd		Not Reported
	Tramadol	S				Not Reported
	Concor	S	Unknown	Unk		Not Reported
	Polisen	S	Unknown	10 Mg At Bedtime		Not Reported
	Trosicam	S	Unknown	Unk		Not Reported
	Trosicam	S	Unknown	Unk		Not Reported
	Doxepin	S	Oral	25 Mg Qd At Bedtime		Not Reported
	Doxepin	S				Not Reported
	Doxepin	S				Not Reported
	Bisoprolol	S	Unknown	Unk		Not Reported
	Atorvastatin	C	Unknown	Unk		Not Reported
	Perindopril	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15591094	NON-EXPEDITED			US-PFIZER INC-2018447126			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchitis; Emotional Distress;	Chantix			S		Unk (Only Taken One Pill)		Pfizer	

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Hypertension	Xanax	S	Unk	Pfizer
	Lexapro	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15595765	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-972992		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Thrombosis	Escitalopram Oxalate - Bp			S	Oral	20 Milligram Daily;		Ivax
	Risedronate Sodium - Bp			S	Oral			Not Reported
	Prednisone			S	Oral	4 Daily;		Not Reported
	Valaciclovir			S	Oral	1000 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Cacit 500 Mg, Comprimé Effervescent			S	Oral	1 Dosage Forms Daily;		Not Reported
	Desloratadine			S	Oral	5 Milligram Daily;		Not Reported
	Paracetamol			S	Oral	2 Dosage Forms Daily;		Not Reported
	Lisinopril Dihydrate			S	Oral	10 Milligram Daily;		Ivax
	Codeine			S	Oral	2 Dosage Forms Daily;		Not Reported
	Speciafoldine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Uvedose 100 000 Ui, Solution Buvable En Ampoule			S	Oral	Daily Dose Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15614863	EXPEDITED (15-DAY)		OT	GB-TORRENT-00003877		43 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Restless Legs Syndrome	Quetiapine			S		Unknown		Unknown
	Citalopram			C		Unknown		Unknown
	Escitalopram			S		Unknown		Unknown
	Dosulepin			S		Unknown		Unknown

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	Fluoxetine		S			Unknown		Unknown	
	Lofepramine		S			Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15615020	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP024228		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Escitalopram			S	Unknown	15 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15615328	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2018-07799		27 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dystonia; Gait Disturbance; Pain	Escitalopram			S	Unknown	20 Mg, Unk		Lupin	
	Escitalopram			S				Lupin	
	Insulin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15615678	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-029720		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Zydus Pharm	
	Escitalopram			S	Oral			Zydus Pharm	
	Lisinopril			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Trazodone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15615955	EXPEDITED (15-DAY)		HO	FR-ALVOGEN-2018-ALVOGEN-097744		56 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Thrombosis	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Codeine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Risedronic Acid			S	Oral			Not Reported
	Desloratadine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Colecalciferol			S	Oral			Not Reported
	Calcium Carbonate/Citric Acid			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15618833	EXPEDITED (15-DAY)		HO	PHHY2018FR152894		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Zolpidem			S	Oral	Unk		Novartis
	Olanzapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Bromazepam			S	Oral	120 Mg, Unk		Not Reported
	Aripiprazole			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15448165	EXPEDITED (15-DAY)		HO, LT, OT	US-ALEMBIC PHARMACUETICALS LIMITED- 2018SCAL000697			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Respiratory Distress Syndrome; Agitation; Bundle Branch Block Left; Clonus; Electrocardiogram Qrs Complex Prolonged; Hyperreflexia; Hyporesponsive To Stimuli; Muscle Rigidity; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Lamotrigine	S	100 Mg Tablets	Alembic
	Escitalopram	S	20 Mg Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619679	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-07747		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin	
	Blisovi Fe 1/20			C	Unknown	Unk		Not Reported	
	Lamictal			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619757	EXPEDITED (15-DAY)		HO	FR-ACCORD-091946		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Methotrexate			S	Subcutaneous			Accord	
	Paracetamol			S	Oral			Accord	
	Lisinopril			S	Oral			Accord	
	Escitalopram			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Oral			Not Reported	

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	Prednisone	S	Oral	Not Reported
	Valaciclovir	S	Oral	Not Reported
	Codeine	S	Oral	Not Reported
	Desloratadine	S	Oral	Not Reported
	Colecalciferol	S	Oral	Not Reported
	Calcium Carbonate	S	Oral	Not Reported
	Risedronic Acid	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619846	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-975361		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax	
	Lorazepam			S	Oral			Actavis	
	Aripiprazole			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619935	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2018-US-975287		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Overdose; Toxicity To Various Agents	Atenolol			S	Oral			Not Reported	
	Lisinopril			S	Oral			Ivax	
	Escitalopram			S	Oral			Ivax	
	Clonazepam			S	Oral			Teva	
	Trazodone			S	Oral			Actavis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619985	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22563			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Treatment Failure	Sertraline	S	Unknown	Unk	Invagen
	Escitalopram	S	Unknown	Unk	Invagen
	Fluoxetine	S	Unknown	Unk	Not Reported
	Risperidone	S	Unknown	Unk	Not Reported
	Aripiprazole	S	Unknown	Unk	Not Reported
	Ziprasidone	S	Unknown	Unk	Not Reported
	Methylphenidate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15620588	NON-EXPEDITED			US-BAUSCH-BL-2017-029863		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective; Hypoaesthesia; Paraesthesia	Ativan			S	Oral	0.25mg At Noon And 0.25mg At 10pm		Not Reported	
	Ativan			S				Not Reported	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15621176	EXPEDITED (15-DAY)		OT	PHHY2018GR151230		86 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Inadequately Controlled	Exforge			S	Unknown			Novartis	
	Seropram (Escitalopram Oxalate)			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15621964	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1085993		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperleukocytosis; Pancreatitis; Renal Failure; Toxicity To	Escitalopram			S	Oral	140 Mg, Unk		Not Reported	
	Ibuprofen			S	Oral	6 G, Unk		Not Reported	

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Various Agents	Paracetamol	S		8.8 G, Unk	Not Reported
	Atarax /00058401/	S	Oral	750 Mg, Unk	Mylan
	Coltramyl	S	Oral	48 Mg, Unk	Mylan
	Cefuroxime	C	Oral	Unk	Mylan
	Brexin /00500404/	C	Oral	20 Mg, Unk	Mylan
	Alprazolam	C	Oral	5 Mg, Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15622038	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018462735		44 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence; Prescription Form Tampering	Xanax			S	Unknown	0.25 Mg, Unk		Pfizer	
	Seresta			S	Unknown	50 Mg, Unk		Not Reported	
	Lysanxia			S	Unknown	10 Mg, Unk		Not Reported	
	Seroplex			S	Unknown	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15622245	NON-EXPEDITED			US-TEVA-2018-US-973290			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Stiffness	Escitalopram			S	Unknown			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15623479	EXPEDITED (15-DAY)		OT	NO-ALLERGAN-1853499US		18 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Dyspepsia; Headache; Hypersensitivity; Insomnia; Muscle Spasms; Myalgia; Nausea; Palpitations;	Escitalopram Oxalate - Bp			S		20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

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Panic Attack; Tic;
Ventricular Extrasystoles

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	9536493	EXPEDITED (15-DAY)		DE, HO, OT	FR-ASTELLAS-2013US009607		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blister; Eschar; Graft Versus Host Disease In Gastrointestinal Tract; Haematuria; Hepatitis Fulminant; Mucosal Erosion; Multiple Organ Dysfunction Syndrome; Oedema; Skin Erosion; Skin Lesion; Toxic Epidermal Necrolysis	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Astellas	
	Fortum /00559702/			S	Unknown			Not Reported	
	Flagyl /00012501/			S	Oral			Not Reported	
	Gentamicine Panpharma			S	Intravenous (not otherwise specified)			Not Reported	
	Noxafil			S	Oral			Not Reported	
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported	
	Bactrim			S	Intravenous (not otherwise specified)			Not Reported	
	Folinic Acid			S	Intravenous (not otherwise specified)			Not Reported	
	Zelitrex			S	Intravenous (not otherwise specified)			Not Reported	
	Cymeavan			S	Intravenous (not otherwise specified)			Not Reported	
	Foscavir			S	Intravenous (not otherwise specified)			Not Reported	
	Clairyg			S	Intravenous (not otherwise specified)			Not Reported	
	Granocyte			S	Intravenous (not otherwise specified)			Not Reported	
	Heparin Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Inexium /01479302/			S	Intravenous (not otherwise specified)			Not Reported	

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Spasfon /00765801/	S	Intravenous (not otherwise specified)	Not Reported
Delursan	S	Oral	Not Reported
Defibrotide	S	Intravenous (not otherwise specified)	Not Reported
Largactil /00011901/	S	Intravenous (not otherwise specified)	Not Reported
Tranxene	S	Oral	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Not Reported
Exacyl	S	Intravenous (not otherwise specified)	Not Reported
Perfalgan	S	Intravenous (not otherwise specified)	Not Reported
Solumedrol	S	Intravenous (not otherwise specified)	Not Reported
Droleptan	S	Intravenous (not otherwise specified) 0.625 Mg, 4 Times Daily	Not Reported
Ultiva	S	Intravenous (not otherwise specified)	Not Reported
Atarax /00058401/	S	Oral	Not Reported
Lasilix /00032601/	S	Intravenous (not otherwise specified)	Not Reported
Noctamide	S	Unknown	Not Reported
Seroplex	S	Oral	Not Reported
Ceris	S	Oral	Not Reported
Colistine	C	Unknown	Not Reported
Vancomycine Mylan	C	Unknown	Not Reported
Ciflox /00697201/	C	Unknown	Not Reported
Triflucan	C	Unknown	Not Reported
Zovirax /00587301/	C	Unknown	Not Reported
Elvorine	C	Unknown	Not Reported

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Sandimmune	C	Unknown	Not Reported
Mopral /00661201/	C	Unknown	Not Reported
Ogastoro	C	Unknown	Not Reported
Gelox	C	Unknown	Not Reported
Smecta /00837601/	C	Unknown	Not Reported
Luteran	C	Unknown	Not Reported
Lexomil	C	Unknown	Not Reported
Zophren /00955301/	C	Unknown	Not Reported
Primperan	C	Unknown	Not Reported
Acupan	C	Unknown	Not Reported
Tiorfan	C	Unknown	Not Reported
Levocarnil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15623938	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-190777		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Thrombosis	Risedronate			S	Oral	35 Mg, Daily		Sun
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported
	Lisinopril			S	Oral	10 Mg, Daily		Sun
	Desloratadine			S	Oral	5 Mg, Daily		Sun
	Paracetamol			S	Oral	2 Df, Daily		Ohm Lab
	Valaciclovir			S	Oral	1000 Mg, Daily		Sun
	Enbrel			S	Subcutaneous			Not Reported
	Speciafoldine			S	Oral	10 Mg, 1/Week		Not Reported
	Prednisone			S	Oral	4 Mg, Daily		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Daily		Not Reported
	Codeine			S	Oral	2 Df, Daily		Not Reported

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Uvedose	S	Oral		Not Reported
Cacit [Calcium Carbonate]	S	Oral	1 Df, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15624688	NON-EXPEDITED			IN-ALKEM LABORATORIES LIMITED-IN-ALKEM- 2018-06357		33 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Sleep-Related Event; Aggression; Depressive Symptom; Derealisation; Drug Intolerance; Economic Problem; Inappropriate Affect; Psychomotor Hyperactivity; Sedation Complication	Escitalopram			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Alkem
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Lithium			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15625603	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2016GB00691			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Invagen
	Fluoxetine			S	Unknown	Unk		Not Reported
	Dosulepin			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	300 Mg, Per Day		Not Reported
	Lofepamine			S	Unknown	Unk		Not Reported
	Citalopram			C	Unknown	20 Mg, Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15626389	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1853352US		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Adrenal Insufficiency; Crying; Therapeutic Response Decreased	Lexapro			S	Oral		Unk		Allergan	
	Thyroid Medication Unspecified			C	Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15626456	EXPEDITED (15-DAY)		OT		PT-TEVA-2018-PT-977281		27 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Stiff Person Syndrome	Escitalopram				S	Unknown			Ivax	
	Insulin				C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15626809	EXPEDITED (15-DAY)		OT		TN-MYLANLABS-2018M1086399		38 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Hypersensitivity; Pruritus Generalised; Pyrexia	Carbamazepine				S	Unknown			Not Reported	
	Escitalopram				S	Unknown	Later, Re-Initiated In September 2017 At An Unknown Dose		Not Reported	
	Escitalopram				S	Unknown		Unk		Not Reported
	Amoxicillin				S	Unknown				Mylan
	Levomepromazine				C	Unknown			Mylan	
	Paracetamol				C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15627916	NON-EXPEDITED				US-MYLANLABS-2018M1084068			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dizziness; Hyperhidrosis; Incorrect Product Administration Duration; Malaise; Product Administered At	Fentanyl Transdermal System				S		100 Unk		Mylan	
	Venlafaxine				S		Unk		Mylan	
	Losartan Potassium				S		Unk		Mylan	

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Inappropriate Site; Tremor	Oxazepam	S	Unk	Mylan
	Hydrochlorothiazide	S	Unk	Mylan
	Escitalopram	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628506	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1086225		27 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Stiff Person Syndrome	Escitalopram			S	Unknown			Not Reported	
	Insulin			C	Unknown			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628524	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1853645US		45 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cortisol Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628542	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_036365		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Haematoma	Aripiprazole			S	Oral	5 Mg, Qd		Otsuka	
	Escitalopram			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported	
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported	
	Piroxicam			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628545	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1853812US		85 YR	Unknown	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage; Haematemesis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qam		Allergan	
	Clopidogrel			S	Oral	75 Mg, Qam		Not Reported	
	Fultium D3			C	Unknown	800 Iu, Unknown		Not Reported	
	Alverine			C	Unknown	60 Mg, Unknown		Not Reported	
	Co-Beneldopa			C	Unknown	25/100 Mg		Not Reported	
	Paracetamol			C	Unknown	1500 Mg, Unknown		Not Reported	
	Amlodipine			C	Unknown	5 Mg, Unknown		Not Reported	
	Co-Codamol			C	Unknown	8/500mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628551	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_036142		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Extrapyramidal Disorder; Hallucination; Product Use In Unapproved Indication; Tremor	Abilify			S	Oral	5 Mg, Qd		Otsuka	
	Lepticur			S	Oral	1 Df, Qd		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628706	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-974911		45 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Dizziness	Escitalopram			S	Oral			Ivax	
	Stilnoct			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15633162	DIRECT	Y				70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Electrocardiogram Qt Prolonged		Lexapro 10mg		S	Oral		6 DAY		Major
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2018	15583509	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-052989		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia; Toxicity To Various Agents	Aripiprazole			S	Unknown	4 Milligram, Daily,Every Bedtime		Aurobindo	
	Aripiprazole			S	Unknown	2 Milligram, Daily,Every Bedtime		Aurobindo	
	Dexamfetamine+Amfetamine			S	Unknown	20 Milligram, Daily,Extended Release, Every Morning		Aurobindo	
	Dexamfetamine+Amfetamine			S	Unknown	10 Milligram, Daily,Extended Release, Every Morning		Aurobindo	
	Escitalopram			S	Unknown	5 Milligram, Daily,Every Morning		Aurobindo	
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram, Daily,Every Morning		Aurobindo	
	Escitalopram			S	Unknown	15 Milligram, Daily,Every Morning		Aurobindo	
	Lamotrigine			S	Unknown	150 Milligram, Daily		Aurobindo	
	Lamotrigine			S	Unknown	100 Milligram, Daily		Aurobindo	
	Lorazepam			S	Unknown	0.5 Milligram,(8 Hours),As Necessary		Aurobindo	
	Lorazepam			S	Unknown	1 Milligram, (8 Hours),As Necessary		Aurobindo	
	Bupropion			S	Unknown	150 Milligram, Daily,Every Morning		Not Reported	
	Bupropion			S	Unknown	200 Milligram, Daily,Every Morning		Not Reported	

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Bupropion	S	Unknown	300 Milligram, Daily,Every Morning	Not Reported
Buspirone	S	Unknown	15 Milligram, Two Times A Day	Not Reported
Buspirone	S	Unknown	15 Milligram, (8hour)	Not Reported
Buspirone	S	Unknown	10 Milligram, Daily	Not Reported
Buspirone	S	Unknown	17.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	15 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	15 Milligram, Daily	Not Reported
Buspirone	S	Unknown	2.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	22.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Daily	Not Reported
Buspirone	S	Unknown	7.5 Milligram, Two Times A Day	Not Reported
Buspirone	S	Unknown	,7.5 Milligram, (8 Hour)	Not Reported
Buspirone	S	Unknown	20 Milligram, Daily	Not Reported
Testosterone	S	Topical	Daily, (50 Mg/5 G Every Morning On The Right Upper Extremity)	Not Reported
Lithium	S	Unknown	600 Milligram, Daily,Every Bedtime	Not Reported
Lurasidone	S	Unknown	40 Milligram, Daily,After Dinner	Not Reported
Benztropine Mesylate	C	Unknown	0.5 Milligram, Two Times A Day,As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	10216201	EXPEDITED (15-DAY)		HO	JP-FRI-1000067816		17 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Altered State Of Consciousness; Electrocardiogram Qt Prolonged; Nausea; Overdose; Product Use Issue; Somnolence; Suicide Attempt; Tetany; Toxicity To Various Agents; Tremor; Vomiting	Escitalopram Oxalate - Bp Ronlax	S C	Oral Oral	750 Mg, Qd; 75 Tablets 4 Df, Unk	Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	12247424	EXPEDITED (15-DAY)		HO	JP-FRI-1000083766		24 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Overdose	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Overdose: 10 MgX20tablets		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amoxan			S	Oral	10 Mg, Bid		Not Reported
	Amoxan			S	Oral	10 Mg, Overdose 10 Mg X32 Capsules		Not Reported
	Amoxan			S	Oral	10 Mg, Bid		Not Reported
	Abilify 1%			S	Oral	0.1 G, Bid		Not Reported
	Abilify 1%			S	Oral	0.1 G, Overdose: 0.1 Gram X 31 Packs		Not Reported
	Abilify 1%			S	Oral	0.1 G, Bid		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Bid		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Overdose: 0.3 Gram X 31 Packs		Not Reported
	Rivotril 0.1%			S	Oral	0.3 G, Bid		Not Reported
	Lendormin			C	Oral	.25 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15290706	EXPEDITED (15-DAY)		DS, HO, LT	PT-TEVA-2018-PT-943124		94 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Confusional State; Decreased Appetite; Hyponatraemia; Panic Attack; Psychomotor Hyperactivity; Vomiting	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15600548	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22407			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Insomnia; Panic Attack; Product Substitution Issue; Unevaluable Event	Escitalopram			S	Unknown	Unk, Generic Aurobindo For Years		Invagen	
	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15606729	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1852738US		79 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Donepezil Hydrochloride			C	Oral	5 Mg, Qam		Not Reported	
	Belsomra			C	Oral	15 Mg, Qhs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15630010	EXPEDITED (15-DAY)		HO, OT	US-SHIRE-US201843994		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Emotional Disorder; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Suicide Attempt; Weight Increased	Intuniv	S	Unknown	Unk	Shire
	Adderall Xr	S	Unknown	Unk	Shire
	Vyvanse	S	Unknown	Unk	Shire
	Lexapro	S	Unknown	Unk	Not Reported
	Risperidone	S	Oral	Unk	Not Reported
	Risperdal	S	Oral	4 Mg, Unk	Not Reported
	Risperdal	S	Oral	1 Mg, Unk	Not Reported
	Risperdal	S	Oral	2 Mg, Unk	Not Reported
	Risperdal	S	Unknown	Unk	Not Reported
	Sertraline	S	Unknown	Unk	Not Reported
	Strattera	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15630725	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2018ZA22788			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract	Escitalopram			S	Unknown	Unk		Invagen
	Aspavor			S	Unknown	Unk		Not Reported
	Ivedal			S	Unknown	Unk		Not Reported
	Pritor /01102601/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15631096	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR- APL-2018-055247		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Aurobindo
	Escitalopram			S		20 Milligram		Aurobindo
	Trazodone			C	Unknown	Dose Was Decreased From 300 Mg To 150 Mg Nightly.		Not Reported

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	Trazodone	C	Oral	Nightly At Bedtime	Not Reported
	Trazodone	C	Oral	Nightly	Not Reported
	Clonazepam	C	Unknown	0.5 Mg Two Times A Day	Not Reported
	Clonazepam	C		Given As Needed Doses Of Clonazepam	Not Reported
	Piperacillin, Tazobactam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15632298	EXPEDITED (15-DAY)		OT	SE-BAUSCH-BL-2018-031495		65 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Respiratory Tract Infection	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Brintellix			S	Oral			Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Ciprallex			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Mirtazapin			C	Unknown			Not Reported
	Stesolid			C	Unknown			Not Reported
	Stilnoct			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15632794	DIRECT		OT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Screen Positive	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15633187	EXPEDITED (15-DAY)		HO	GB-TEVA-2018-GB-975934		82 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral			Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			S	Oral	75 Milligram Daily;		Not Reported
	Felodipine			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Adcal-D3			C	Unknown			Not Reported
	Doxazosin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Dymista			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Ferrous Fumarate			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15633454	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-975720		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Melaena; Microcytic Anaemia	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Plavix 75 Mg, Comprimé			S	Oral	75 Milligram Daily;		Not Reported
	Pelliculé							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15634144	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-		73 YR	Male	FRA

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1853981US

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage; Drug Interaction; Off Label Use	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Kardegic			S	Oral	75 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15634300	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1853982US		42 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Coma; Intentional Overdose; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	9 Dosage Forms In The Context Of An Intentional Overdose		Allergan
	Diazepam			S	Oral	10 Df, Unk		Not Reported
	Tercian			S	Oral	5 Df, Unk		Not Reported
	Zopiclone			S	Oral	14 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	14522186	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2018-003448		74 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Lorazepam			S	Oral	In Total Once/Single		Not Reported
	Entact			S	Oral	20 Mg, Once/Single ; In Total		Not Reported
	Clozapine			S	Oral	In Total: 100 Mg Once/Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15547862	EXPEDITED (15-DAY)		OT	EE-ALLERGAN-1850343US		27 YR	Female	EST

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Agoraphobia; Akathisia; Anger; Anxiety; Autophobia; Cerebral Disorder; Derealisation; Fatigue; Fear Of Death; Impaired Quality Of Life; Insomnia; Nightmare; Palpitations; Panic Disorder; Restlessness; Suicidal Ideation; Visual Impairment; Vomiting; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Valdoxan			S	Oral	Unk Unk, Qd		Not Reported	
	Valdoxan			S	Unknown	12.5 Mg, Qd		Not Reported	
	Valdoxan			S	Unknown	25 Mg, Qd		Not Reported	
	Effexor			S	Unknown	37.5 Mg, Qd		Not Reported	
	Oxazepam			C		Unk		Not Reported	
	Diazepam			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15635187	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-976368		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Exact Dose At Unknown Imv		Ivax	
	Bromazepam			S	Oral	Intake Estimated At 20 Cp Of Bromazepam 6 Mg		Not Reported	
	Aripiprazole			S	Oral	Exact Dose At Unknown Imv		Teva	
	Zolpidem			S	Oral	Exact Dose At Unknown Imv		Teva	
	Olanzapine			S	Oral	Exact Dose At Unknown Imv		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15635612	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-976507		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional	Escitalopram Oxalate			S	Oral			Ivax	

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Self-Injury; Nausea;
Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15636464	EXPEDITED (15-DAY)		HO	GB-TORRENT-00019523		84 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Lansoprazole			C		Unknown		Unknown
	Paracetamol			C		Unknown		Unknown
	Co-Beneldopa			C		Unknown		Unknown
	Donepezil Hydrochloride			C		Unknown		Unknown
	Escitalopram			S	Oral	Unknown		Unknown
	Apixaban			C		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15636776	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2018208639		23 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Lamotrigine			S	Oral	1 Unk, Unk		Glaxosmithkline
	Tavor (Lorazepam)			S	Oral	In Total		Glaxosmithkline
	Escitalopram Oxalate			S	Oral	In Total		Glaxosmithkline
	Delorazepam			S	Oral	Unk		Not Reported
	Oki			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15638899	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181118975		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma	Imbruvica			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

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Kardegic			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15640320	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-976263			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease	Escitalopram Tablets			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15640563	NON-EXPEDITED			US-PFIZER INC-2018030170		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose;	Genotropin Pen 5			S		4 Mg, 1x/Day		Pfizer	
Anticonvulsant Drug Level Decreased; Device	Genotropin Pen 5			S		Unk		Pfizer	
Defective; Haematocrit Decreased; Haemoglobin Decreased; Intentional	Genotropin Pen 5			S		Unk		Pfizer	
Product Misuse; Red Cell Distribution Width Increased	Genotropin Pen 5			S		0.8 Mg, Daily		Pfizer	
	Lexapro			S		20 Mg, 1x/Day		Not Reported	
	Trazodone			S		50 Mg, 1x/Day At Night		Not Reported	
	Trazodone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	14066975	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1676914US		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hypoglycaemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported	
	Gliclazide			S	Unknown	Unk		Not Reported	
	Metformin			S	Unknown	1 G, Bid		Not Reported	
	Insulin			S	Unknown	Unk		Not Reported	
	L-Thyroxine			C	Unknown	Unk		Not Reported	

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Telmisartan	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

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21-Nov-2018	15285568	EXPEDITED (15-DAY)	HO		PHHY2018DE072864			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Clozapine			S	Unknown	75 Mg, Unk		Not Reported
	Quetiapine			S	Oral	Unk		Novartis
	Quetiapine			S				Novartis
	Olanzapine			S	Unknown	Unk		Not Reported
	Olanzapine			S				Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S				Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S				Not Reported
	Fluoxetine			S				Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Duloxetine			S				Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Bupropion			S				Not Reported
	Escitalopram			S	Unknown	20 Mg		Not Reported
	Escitalopram			S				Not Reported
	Aripiprazole			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown			Not Reported
	Zopiclone			S				Not Reported
	Oxazepam			S	Unknown			Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Amisulpride			S	Unknown			Not Reported
	Amisulpride			S				Not Reported
	Venlafaxine			S	Oral	Unk		Not Reported

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Venlafaxine	S			Not Reported
Promethazine	S	Unknown		Not Reported
Biperiden	S	Unknown	Unk	Not Reported
Oxazepam	C	Unknown	At Different Doses	Not Reported
Brivaracetam	C	Unknown	200-250mg, Received Over One Year	Not Reported
Oxcarbazepine	C	Unknown	Up To 2400mg, Received Over One Year	Not Reported
Zonisamide	C	Unknown	Up To 100mg	Not Reported
Carbamazepine	C	Unknown	Up To 900 Mg	Not Reported
Clobazam	C	Unknown	Up To 20mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15641637	EXPEDITED (15-DAY)		DS	PHHY2018IT157210		48 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Valproic Acid			S	Unknown	Unk		Novartis
	Quetiapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	200 Mg, Qd		Not Reported
	Sertraline			S	Unknown	50 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15641780	EXPEDITED (15-DAY)		OT	SE-AUROBINDO-AUR- APL-2018-055716		65 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Respiratory Tract Infection	Sertraline			S	Unknown	Unk		Aurobindo
	Sertraline			S	Unknown	Unk		Aurobindo

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Brintellix	S	Oral	15 Milligram, Daily	Not Reported
Brintellix	S	Oral	5 Milligram	Not Reported
Brintellix	S	Oral	10 Milligram, Daily	Not Reported
Cipramil /00582603/	S	Unknown	Unk	Not Reported
Cipralex /01588501/	S	Unknown	Unk	Not Reported
Venlafaxine Hydrochloride	S	Unknown	Unk	Not Reported
Mirtazapin	C	Unknown	Unk	Not Reported
Stesolid	C	Unknown	20 Milligram, Daily	Not Reported
Stilnoct	C	Unknown	10 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15641818	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-191149		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Not Reported	
	Aripiprazole			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Not Reported	
	Zolpidem			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Sun	
	Olanzapine			S	Oral	Dose Exacte Lors De L'Imv Inconnue ()		Sun	
	Bromazepam			S	Oral	Prise Estimee A 20 Cp De Bromazepam 6 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15641878	EXPEDITED (15-DAY)		OT	TN-LUPIN PHARMACEUTICALS INC.-2018-08015		38 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase	Escitalopram			S	Unknown	Unk		Lupin	

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Increased; Aspartate Aminotransferase	Escitalopram	S	Unknown	Unk	Lupin
Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema;	Carbamazepine	S	Unknown	Unk	Not Reported
Hypersensitivity; Pruritus Generalised; Pyrexia	Amoxicillin	S	Unknown	Unk	Not Reported
	Levomepromazine	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15643990	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018477761		85 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Aspavor			S		20 Mg, Unk		Pfizer	
	Zytomil			S		20 Mg, Unk		Not Reported	
	Adco-Zolpidem			S		10 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644041	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018474111		76 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumothorax	Xanor			S		0.25 Mg, Unk		Pfizer	
	Pearinda Plus			S		4/1.25 Mg, Unk		Not Reported	
	Lexamil			S		10 Mg, Unk		Not Reported	
	Adco-Simvastatin			S		20 Mg, Unk		Not Reported	
	Ecotrin			S		81 Mg, Unk		Not Reported	
	Vimovo			S		500/20 Mg, Unk		Not Reported	
	Trepiline [Amitriptyline]			S		25 Mg, Unk		Not Reported	
	Arcoxia			S		90 Mg, Unk		Not Reported	
	Azomid			S		250 Mg, Unk		Not Reported	
	Ipvent			S		40 Ug, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644064	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1854152US		23 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Intentional Self-Injury; Sopor	Escitalopram Oxalate Unk			S	Oral	50 Mg, Unknown		Allergan	
	Tavor (Lorazepam)			S	Oral	4 Dosage Forms; In Total		Not Reported	
	Delorazepam			S	Oral	Unk		Not Reported	
	Oki			S	Oral	800mg; In Total		Not Reported	
	Lamotrigine			S	Oral	4 Df, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644194	EXPEDITED (15-DAY)		DE	JP-JNJFOC-20180636493		86 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Labelled Drug-Drug Interaction Medication Error; Thalamus Haemorrhage	Xarelto			S	Oral			Not Reported	
	Xarelto			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Mirtazapine			C	Unknown			Not Reported	
	Heparin Sodium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15645791	EXPEDITED (15-DAY)		HO	PHHY2018FR160368		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd		Novartis	
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported	
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported	
	Piroxicam			C	Unknown	Unk		Not Reported	

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22-Nov-2018	15606020	EXPEDITED (15-DAY)		OT	SE-TAKEDA-2018TUS032321		65 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Respiratory Tract Infection	Brintellix			S	Oral	5 Mg, Unk		Takeda	
	Brintellix			S	Oral	10 Mg, Qd		Takeda	
	Brintellix			S	Oral	15 Mg, Qd		Takeda	
	Cipramil /00582602/			S	Unknown	Unk		Not Reported	
	Cipralex /01588501/			S	Unknown	Unk		Not Reported	
	Efexor			S	Unknown	Unk		Not Reported	
	Sertralin /01011401/			S	Unknown	Unk		Not Reported	
	Zoloft			S	Unknown	Unk		Not Reported	
	Mirtazapin			C	Unknown	Unk		Not Reported	
	Stesolid			C	Unknown	20 Mg, Qd		Not Reported	
	Stilnoct			C	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646769	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-056175		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Coumadin			S	Oral	5 Milligram, 1 As Necessary		Not Reported	
	Plavix			S	Oral	75 Milligram, Daily		Not Reported	
	Doxazosin			C	Unknown	Unk		Not Reported	
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
	Pregabalin			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646793	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-055937		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Coma; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral	10 Dosage Form, (In Total)		Not Reported	
	Escitalopram			S	Oral	9 Dosage Form, (In Total)		Aurobindo	
	Zopiclone			S	Oral	14 Dosage Form, (In Total)		Not Reported	
	Tercian /00759302/			S	Oral	5 Dosage Form, (In Total)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646802	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2018-056005		85 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel Film-Coated Tablets			S	Oral	75 Milligram, Daily, (Morning. Suspended During Admission)		Aurobindo	
	Escitalopram Tablets			S	Oral	5 Milligram, Daily, (Morning. Continued During Admission With Proton Pump Inhibitor Protection)		Aurobindo	
	Alverine			C	Unknown	60 Milligram		Not Reported	
	Amlodipine			C	Unknown	5 Milligram		Not Reported	
	Co-Codamol			C	Unknown	3 Dosage Form, Daily, (8mg/500mg)		Not Reported	
	Co-Beneldopa			C	Unknown	25mg/100mg		Not Reported	
	Fultium D3			C	Unknown	800 International Unit		Not Reported	
	Paracetamol			C	Unknown	1500 Milligram, Daily		Not Reported	

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22-Nov-2018	15647241	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-055307		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Haematoma	Prazepam Arrow 10 Mg Tablet			S	Oral	10 Milligram, Once A Day		Not Reported	
	Escitalopram			S	Oral	Unk		Aurobindo	
	Zolpidem			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Aripiprazole			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Piroxicam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647249	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-056433		23 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	50 Milligram, In Total		Aurobindo	
	Lamotrigine			S	Oral	4 Dosage Form, In Total		Aurobindo	
	Oki			S	Oral	800 Milligram, In Total		Not Reported	
	Tavor /00273201/			S	Oral	4 Dosage Form, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647287	NON-EXPEDITED			US-HETERO CORPORATE-HET2018US01408			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Somnolence	Escitalopram			S	Oral	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647288	EXPEDITED (15-DAY)		OT	PT-HETERO CORPORATE-HET2018PT01402		27 YR	Female	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stiff Person Syndrome	Escitalopram			S	Unknown	20 Mg		Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647426	EXPEDITED (15-DAY)		OT	TN-MACLEODS PHARMACEUTICALS US LTD- MAC2018018706			Unknown	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Hypersensitivity; Pruritus Generalised; Pyrexia	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Carbamazepine			S	Unknown	Unk		Not Reported	
	Levomepromazine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647832	EXPEDITED (15-DAY)		OT	SE-PFIZER INC- 2018475614		65 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Tract Infection	Sertraline Hcl			S		Unk		Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Brintellix			S	Oral	15 Mg, Daily		Not Reported	
	Brintellix			S	Oral	5 Mg, Unk		Not Reported	
	Brintellix			S	Oral	10 Mg, Daily		Not Reported	
	Cipramil [Citalopram Hydrochloride]			S		Unk		Not Reported	
	Cipralex [Escitalopram]			S		Unk		Not Reported	
	Mirtazapin			C		Unk		Not Reported	
	Stesolid			C		20 Mg, Daily		Not Reported	
	Stilnoct			C		10 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648469	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-032139		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Prednisolone			S	Oral			Not Reported	
	Hepatoum			S	Oral	Unspecified		Not Reported	
	Azithromycine Anhydre			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Arestal			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Inorial			S	Oral			Not Reported	
	Paracetamol			S	Oral			Not Reported	
	Augmentin			S	Oral			Not Reported	
	Cefpodoxime			S	Oral			Not Reported	
	Trimebutine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648625	NON-EXPEDITED			US-TEVA-2018-US-974229		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alopecia; Anger; Burning Sensation; Crying; Disorganised Speech; Dizziness; Feeling Abnormal; Influenza Like Illness; Irritability; Paraesthesia; Withdrawal Syndrome	Escitalopram			S				Ivax	
	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S				Ivax	
	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648685	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1854401US		16 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Suicidal Ideation; Therapy Change	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15653649	DIRECT		DS, HO			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alopecia; Anxiety; Arthralgia; Arthralgia; Arthritis; Back Pain; Bone Pain; Depression; Disability; Disturbance In Attention; Fibromyalgia; Gait Inability; Joint Noise; Myalgia; Neuralgia; Paralysis; Photophobia; Skin Disorder; Suicide Attempt; Tremor	Escitalopram			S				Not Reported	
	Beyaz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	12927787	NON-EXPEDITED		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2016-02479		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis	Metformin			S	Unknown	Unk Unk,Unk,Unknown		Lupin	
	Metformin			S	Unknown	1 G,Bid,		Lupin	
	Escitalopram			S	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Gliclazide Modified-Release			C	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Gliclazide Modified-Release			C	Unknown	Dose Reduced		Not Reported	
	Insulin			C	Unknown	Unk Unk,Unk,Unknown		Not Reported	

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	L-Thyroxine	C	Unknown	Unk Unk,Unk,Unknown	Not Reported
	Telmisartan	C	Unknown	Unk Unk,Unk,Unknown	Not Reported
	Trazodone	C	Unknown	Unk Unk,Unk,Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15588465	EXPEDITED (15-DAY)		OT	US-AMGEN- USASP2018154014		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tremor	Repatha			S	Unknown	140 Mg, Q2wk		Amgen	
	Lexapro			S	Unknown	Unk		Not Reported	
	Levothyroxine			S	Unknown	0.05 Unk, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15612288	EXPEDITED (15-DAY)		HO, LT, OT	US-GLENMARK PHARMACEUTICALS- 2018GMK038192		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Glenmark	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Trazodone			C	Oral	300 Mg, Hs		Not Reported	
	Trazodone			C	Oral	150 Mg, Hs		Not Reported	
	Clonazepam			C	Unknown	0.5 Mg, Bid (Given As Needed Doses Of Clonazepam)		Not Reported	
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported	
	Azithromycin			C	Unknown	Unk		Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15641556	EXPEDITED (15-DAY)		DS	IT-ASTRAZENECA- 2018SF50852		61 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Quetiapine	S	Oral	Zeneca
	Venlafaxine	S	Unknown	Not Reported
	Valproic Acid	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Mirtazapine	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Sertraline	S	Unknown	Not Reported
	Escitalopram	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650075	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP025515		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Apotex
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650345	EXPEDITED (15-DAY)		HO, LT, OT	US-APOTEX-2018AP025251		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Apotex
	Escitalopram			S	Unknown	20 Mg, Qd		Apotex
	Trazodone			S	Unknown	300 Mg, Q.H.S.		Apotex
	Trazodone			S	Unknown	150 Mg, Q.H.S.		Apotex
	Clonazepam			S	Unknown	0.5 Mg, Bid		Apotex
	Piperacillin / Tazobactam			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650397	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030616		63 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia	Escitalopram			S	Oral			Zyodus Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650566	EXPEDITED (15-DAY)		DS	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018018710			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Escitalopram			S	Unknown	Unk		Macleods
	Quetiapine			S	Unknown	Unk		Macleods
	Venlafaxine			S	Unknown	Unk		Macleods
	Valproic Acid			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	200 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650812	NON-EXPEDITED			US-TEVA-2018-US- 979227			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Product Substitution Issue	Escitalopram Teva			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650851	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018018715			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Wall	Escitalopram	S	Oral	10 Milligram, Qd	Macleods
Haematoma; Cerebral	Plavix	S	Oral	75 Milligram, Qd	Not Reported
Haemorrhage; Drug	Coumadin	S	Oral	5 Milligram, As Necessary	Not Reported
Interaction; Ecchymosis;	Esomeprazole	C	Unknown	Unk	Not Reported
Subdural Haematoma	Pregabalin	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Doxazosin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15651881	NON-EXPEDITED			US-009507513-1810USA011791		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anorgasmia; Ejaculation	Remeron			S	Oral	22.5 Milligram, Qhs		Merck
Failure; Erectile	Escitalopram			S		20 Milligram, Bid		Not Reported
Dysfunction; Loss Of	Alprazolam			S		1 Mg Tid, Prn		Not Reported
Libido; Sexual Dysfunction	Lamotrigine			S		100 Milligram, Tid		Not Reported
	Enalapril			S		20 Milligram, Qam		Not Reported
	Lansoprazole			S		30 Milligram, Qam		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2018	14964536	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-899034		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Prescribed	Esomeprazole			S	Oral			Teva
Underdose	Decapeptyl [Gonadorelin]			S	Intramuscular			Not Reported
	Innohep			S	Subcutaneous	1 Dosage Forms Daily;		Not Reported
	Amlor			S	Oral			Not Reported
	Novonorm			S	Oral			Not Reported
	Tramadol Base			S	Oral			Not Reported
	Xtandi			S	Oral	120 Milligram Daily;		Not Reported

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	Xtandi	S	Oral			Not Reported
	Lipanthyl	S	Oral	145 Milligram Daily;		Not Reported
	Seroplex	S	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2018	15653341	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00007213		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Interaction; Serotonin Syndrome; Toxicity To Various Agents	Clonazepam			S		Given As Needed Doses Of Clonazepam		Unknown	
	Escitalopram			S		Unknown		Unknown	
	Linezolid			S		Unknown		Unknown	
	Trazodone			S	Oral	Nightly At Bedtime		Unknown	
	Piperacillin, Tazobactam			C		Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2018	15653913	EXPEDITED (15-DAY)		OT	US-PRINSTON PHARMACEUTICAL INC.-2018PRN01597		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Interaction; Serotonin Syndrome	Clonazepam			S	Unknown			Prinston Pharmaceutical	
	Escitalopram			S	Unknown	20 Mg, 1x/Day		Prinston Pharmaceutical	
	Linezolid			S	Unknown			Not Reported	
	Trazodone			S	Unknown	300 Mg, 1x/Day		Not Reported	
	Trazodone			S	Unknown	150 Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2018	15654102	DIRECT					17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Alopecia; Pruritus	Lexapro 5 Mg & 10 Mg	S	Oral	Quantity:30 Tablet(S);	Forest
	Periactin	C			Not Reported
	Albuterol	C			Not Reported
	Flonase	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2018	15654324	EXPEDITED (15-DAY)		HO, LT, OT	US-CIPLA LTD.- 2018US22804			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg, Qd		Invagen
	Linezolid			S	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	300 Mg, Nightly (Per Day)		Not Reported
	Trazodone			C	Oral	150 Mg, Nightly At Bedtime (Per Day)		Not Reported
	Clonazepam			C	Unknown	0.5 Mg, (Given As Needed Doses Of Clonazepam)		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2018	15655615	DIRECT		OT			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Drug Ineffective; Product Substitution Issue	Escitalopram Tab 20 Mg			S	Oral	Quantity:90 Tablet(S);		Aurobindo
	Ropenerol			C				Not Reported
	Pravastatin			C				Not Reported
	Metamucil			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	14188939	EXPEDITED (15-DAY)		HO, OT	CZ-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-154673		45 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Escitalopram			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15607438	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2018457177		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer	
	Escitalopram			S		20 Mg, Daily		Not Reported	
	Trazodone			S		300 Mg, Daily (Nightly, High-Dose)		Not Reported	
	Trazodone			S	Oral	150 Mg, Daily (Nightly,At Bedtime, Dose Was Decreased, After 3 Days Of Linezolid Therapy)		Not Reported	
	Clonazepam			S		0.5 Mg, 2x/Day (Scheduled Doses)		Not Reported	
	Clonazepam			S		Unk, As Needed(As Needed Doses)		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Azithromycin			C		Unk		Not Reported	
	Vancomycin			C		Unk		Not Reported	
	Cefepime			C		Unk		Not Reported	
	Metronidazole			C		Unk		Not Reported	
	Piperacillin / Tazobactam			C		Unk		Not Reported	
	Piperacillin / Tazobactam			C				Not Reported	

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Amikacin	C	Unk, Single	Not Reported
Amikacin	C		Not Reported
Levothyroxine	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15623218	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1853514US		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram Oxalate Unk			S	Oral	140 Mg, 1 Day		Allergan
	Arestal			S	Oral	30 Mg, Total		Not Reported
	Seresta			S	Oral	310 Mg, Total		Not Reported
	Prednisolone			S	Oral	200 Mg, Total		Not Reported
	Inorial			S	Oral	120 Mg, Total		Not Reported
	Paracetamol			S	Oral	79 G, Total		Not Reported
	Augmentin			S	Oral	6 G, 1 Day		Not Reported
	Cefpodoxime			S	Oral	2000 Mg, Total		Not Reported
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Hepatoum			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15629656	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-092592		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hypotension; Pleural Effusion; Pneumonia; Serotonin Syndrome; Staphylococcal Infection	Escitalopram			S		20 Mg Daily		Not Reported
	Trazodone/Trazodone Hydrochloride			S		300 Mg Nightly, Decreased To 150 Mg Nightly.		Not Reported
	Clonazepam			S		0.5 Mg Two Times A Day.		Not Reported
	Linezolid			S				Not Reported
	Ceftriaxone			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	C	Not Reported
Vancomycin/Vancomycin	C	Not Reported
Hydrochloride		
Cefepime	C	Not Reported
Metronidazole	C	Not Reported
Piperacillin Sodium/Tazobactam	C	Not Reported
Sodium		
Amikacin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15647511	EXPEDITED (15-DAY)		HO, OT	JP-ASTRAZENECA-2018SF44731		72 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumothorax; Product Dose Omission; Respiratory Failure	Symbicort Turbuhaler			S	Respiratory (inhalation)			Astrazeneca
	Zacras			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Flunitrazepam			S	Oral			Not Reported
	Desyrel			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15654683	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP025661		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Zopiclone			S	Oral	Maximum Possible Ingestion 187.5 Mg		Not Reported
	Diazepam			S	Unknown	Unk		Apotex
	Lorazepam			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex
	Escitalopram Amneal			S	Unknown	10 Mg, Paer Day		Not Reported
	Escitalopram Amneal			S	Unknown	Maximum Possible Ingestion 140 Mg		Not Reported
	Morphine			S	Unknown	Maximum Possible		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine	S	Unknown	Ingestion: 9500 Mg	Not Reported
Morphine	S	Unknown	30 Mg, Per Day	Not Reported
Morphine	S	Unknown	Maximum Possible Ingestion 2640 Mg	Not Reported
Morphine	S	Unknown	420 Mg, Unk	Not Reported
Acetaminophen W/Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	60 Unk, Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15654746	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.- 2018GB22890			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Haemorrhage; Haematemesis	Escitalopram			S	Oral	5 Mg Tablet Per Day, Morning, Continued During Admission With Proton Pump Inhibitor Protection		Invagen
	Clopidogrel			S	Oral	75 Mg Tablet Per Day, Morning, Suspended During Admission		Not Reported
	Fultium D3			C	Unknown	800 Iu, Capsule, Unk		Not Reported
	Alverine			C	Unknown	60 Mg, Capsule, Unk		Not Reported
	Co-Beneldopa			C	Unknown	Unk, 25 Mg/100 Mg Capsule		Not Reported
	Paracetamol			C	Unknown	1500 Mg Capsule Per Day		Not Reported
	Amlodipine			C	Unknown	5 Mg Tablet, Unk		Not Reported
	Co-Codamol			C	Unknown	3 Df, Capsule, Per Day, 8 Mg/500 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15656906	EXPEDITED (15-DAY)		HO	IT-SANIK- 2018SA316773AA		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Wall	Plavix	S	Oral	75 Mg, Qd	Sanofi
Haematoma; Cerebral	Escitalopram Oxalate	S	Oral		Not Reported
Haemorrhage; Drug	Warfarin Sodium	S	Oral	5 Mg, Prn	Not Reported
Interaction; Ecchymosis;	Pregabalin	C		Unk, Unk	Not Reported
Subdural Haematoma	Furosemide	C		Unk, Unk	Not Reported
	Esomeprazole Sodium	C		Unk, Unk	Not Reported
	Doxazosin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	14830178	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1822944US		45 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Disorder; Discomfort;	Amlodipin			C	Unknown	10 Mg, Qd		Not Reported
Feeling Abnormal;								
Malaise; Nervousness;								
Psychomotor								
Hyperactivity; Stress;								
Tension Headache								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15659087	EXPEDITED (15-DAY)		HO	FR-SA-2018SA316781		72 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Fall;	Zolpidem Tartrate			S	Oral	10 Mg, Qd		Sanofi
Haematoma	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	Unk		Not Reported
	Prazepam Arrow			S	Oral	10 Mg, Qd		Not Reported
	Piroxicam			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15659722	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030668		72 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Fall; Haematoma	Escitalopram			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Aripiprazole			S	Oral			Zydus Pharm
	Prazepam			S	Oral			Not Reported
	Piroxicam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660916	NON-EXPEDITED			US-APOTEX- 2018AP022835		21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Depression; Drug Ineffective; Fatigue; Sedation; Therapeutic Product Effect Incomplete; Weight Increased	Mirtazapine			S	Unknown	7.5 To 15 Mg		Apotex
	Fluvoxamine			S	Unknown	250 Mg, Unk		Apotex
	Fluvoxamine			S	Unknown	200 Mg, Unk		Apotex
	Sertraline			S	Unknown	Up To 300 Mg Daily		Apotex
	Sertraline			S				Apotex
	Sertraline			S				Apotex
	Bupropion			S	Unknown	150 Mg, Unk		Apotex
	Clonazepam			S	Unknown			Apotex
	Citalopram			S	Unknown	40 Mg, Unk		Apotex
	Escitalopram			S	Unknown			Apotex
	Lamotrigine			C	Unknown	100 Mg, Daily		Not Reported
	Fluoxetine			C	Unknown	60 Mg, Daily		Not Reported
	Junel Fe 1/20			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660932	EXPEDITED (15-DAY)		OT	US-OXFORD PHARMACEUTICALS, LLC-2018OXF00142		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Serotonin Syndrome	Trazodone	S	Unknown	300 Mg, 1x/Day	Oxford Pharmaceuticals Oxford Pharmaceuticals Not Reported Not Reported Not Reported
	Trazodone	S	Unknown	150 Unk	
	Clonazepam	S	Unknown		
	Escitalopram	S	Unknown	20 Mg, 1x/Day	
	Linezolid	S	Unknown		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661090	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2018483626		79 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Loss Of Consciousness; Sopor	Xanax			S	Oral	20 Df, Total		Pfizer	
	Levopraid [Levosulpiride]			S	Oral	19 Df, Total		Not Reported	
	Cipralex [Escitalopram Oxalate]			S	Oral	28 Df, Total		Not Reported	
	Rabeprazole Sodium			C				Not Reported	
	Olanzapine			C				Not Reported	
	Alprazolam			C				Not Reported	
	Sucrafate			C				Not Reported	
	Gabapentin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661517	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1854794US		27 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Emotional Poverty; Libido Decreased; Memory Impairment	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661938	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2018480018		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bradyphrenia; Disturbance In Attention;	Xanax	S	Oral	49 Df, Single	Pfizer
Hypoglycaemia; Hypotension;	Cetirizine	S	Oral	50 Mg, Single	Not Reported
Somnolence; Suicide Attempt; Toxicity To Various Agents	Mag 2 [Magnesium Carbonate]	S	Oral	7 Df, Single	Not Reported
	Zopiclone	S	Oral	30 Mg, Single	Not Reported
	Escitalopram	S	Oral	140 Mg, Single	Not Reported
	Doliprane	S	Oral	3 G, Single	Not Reported
	Flagyl [Metronidazole Benzoate]	S	Oral	9 Df, Single	Not Reported
	Naproxene [Naproxen Sodium]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15662107	NON-EXPEDITED			US-PFIZER INC-2018475915		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Lyrica			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15662428	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1087633		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Renal Failure; Speech Disorder; Tooth Loss	Escitalopram Mylan 5 Mg			S		Unk		Mylan	
	Teralithe			C		Adapted Posology: 2.5 Tablets Daily (Lithium 0.84 Mmol/L).		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	14683984	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2018US014277		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Prescribed Underdose	Xtandi			S	Oral			Astellas	
	Decapeptyl /00975902/			S	Intramuscular	1 Df, 1 Cyclical		Not Reported	

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Innohep	S	Subcutaneous		Not Reported
Amlor	S	Oral	Unk, Unknown Freq.	Not Reported
Novonorm	S	Oral	Unk, Unknown Freq.	Not Reported
Novonorm	S	Oral	Not Reported	Not Reported
Tramadol	S	Oral	Unk, Unknown Freq.	Not Reported
Esomeprazole Magnesium	S	Oral	Unk, Unknown Freq.	Not Reported
Lipanthyl	S	Oral		Not Reported
Seroplex	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15664147	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2018-032825			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Epclusa			S	Unknown			Not Reported
	Flurazepam			S	Unknown			Not Reported
	Chlorpromazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15666231	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1855097US			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Treatment Failure	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Risperidone			S	Unknown			Not Reported
	Epclusa			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lorazepam	S	Unknown	Not Reported
Flurazepam	S	Unknown	Not Reported
Chlorpromazine	S	Unknown	Not Reported
Diazepam	S	Unknown	Not Reported
Acetylsalicylic Acid	S	Unknown	Not Reported
Lamotrigine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15705578	DIRECT	Y	HO				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Infection	Humira 40mg/0.8ml Pen			S	Subcutaneous			Abbvie
	Lorazepam			C				Not Reported
	Warferin			C				Not Reported
	Meloxicam			C				Not Reported
	Folic Acid			C				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15665378	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018485360		23 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Tavor (Lorazepam)			S	Oral	4 Df, Total		Pfizer
	Delorazepam			S	Oral	Unk		Not Reported
	Oki			S	Oral	800 Mg, Total		Not Reported
	Escitalopram Oxalate			S	Oral	50 Mg, Total		Not Reported
	Lamotrigine			S	Oral	4 Df, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15668296	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2018-GB-979065		85 YR	Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel	S	Oral	75 Milligram Daily; Morning. Suspended During Admission	Teva
	Escitalopram	S	Oral	5 Milligram Daily; Morning. Continued During Admission With Proton Pump Inhibitor Protection	Ivax
	Fultium-D3	C	Unknown		Not Reported
	Alverine	C	Unknown		Not Reported
	Co-Beneldopa	C	Unknown	25mg/100mg	Not Reported
	Paracetamol	C	Unknown	1500 Milligram Daily;	Not Reported
	Amlodipine	C	Unknown		Not Reported
	Co-Codamol	C	Unknown	3 Dosage Forms Daily; 8mg/500mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15668616	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-979664		42 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Coma; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Zopiclone			S	Oral			Not Reported
	Tercian			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15673376	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1855298US		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Rectal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Previscan (Fluindione)			S	Oral	20 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15673462	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1855301US		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Arthralgia;	Escitalopram Oxalate - Bp			S	Unknown	20 (Units Unspecified)		Allergan	
Back Pain; Chills;	Tramadol			C	Unknown			Not Reported	
Confusional State;	Royal Jelly			C	Unknown			Not Reported	
Dehydration; Dementia	Risperdal			C	Unknown			Not Reported	
Alzheimer'S Type; Eating	Exelon			C	Unknown			Not Reported	
Disorder; Gait	Seresta			C	Unknown			Not Reported	
Disturbance; Hallucination;	Mianserin			C	Unknown			Not Reported	
Headache; Malaise;									
Myalgia; Speech Disorder;									
Urinary Tract Infection									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15673600	EXPEDITED (15-DAY)		HO	CN-MYLANLABS-2018M1087931		60 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Dysarthria;	Risperidone			S	Unknown			Not Reported	
Insomnia; Irritability;	Escitalopram			S	Unknown	10mg At Night		Not Reported	
Sluggishness									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	13958848	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1750584US		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Drug Ineffective;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Unk		Allergan	
Ejaculation Disorder;	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
Epilepsy; Heart Rate	Depakine			C		500 Mg, Bid		Not Reported	
Increased; Reaction To									
Excipient; Somnolence;									
Suicidal Ideation; Tongue									
Biting; Tremor									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15622005	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1853460US			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Lithium Carbonate			C	Unknown	250 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15628174	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2018M1084789		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Dislocation; Device Malfunction; Drug Ineffective	Mydan-Nitro Sublingual Spray			S	Oral	Unk		Mydan	
	Mydan-Nitro Sublingual Spray			S	Oral	Unk (Administer 1 Spray Under The Tongue If Chest Pain; Repeat After 5 Min If The Pain Persists. I)		Mydan	
	Stieprox			S		Unk (2-3 Times Per Week As Directed By Your Doctor)		Mydan	
	Emocort			S	Topical	Unk, Qd (Use Locally On The Lesions In Thin Layer 2 Times Per Day)		Mydan	
	Amlodipine Sandoz /00972402/			S		1.5 Df, Hs (Take One Tablet Once Daily At The Same Time Each Day)		Mydan	
	Apo Rosuvastatin			S		1 Df, Qd (One Tablet Once Daily At The Same Time Each Day)		Mydan	
	Dexilant			S		1 Df, Qd (Take One Capsule Once Daily At The Same Time Each Day)		Mydan	
	Synthroid			S		1 Df, Qd (Take One Tablet		Mydan	

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Ratio-Zopiclone	S		Once Daily 07:00)	Mylan
Apo-Trazodone	S		1 Df, Prn (Take 1 Tablet One Time At Bedtime If Needed)	Mylan
Cipralex /01588501/	S		1 Df, Hs (One Tablet Once Daily At Bedtime)	Mylan
Apo Escitalopram	S		1 Df, Am (1 Tablet Once Daily In The Morning)	Mylan
Escitalopram /01588502/	S		Unk	Mylan
Jamp Asa	S		Unk	Mylan
Tevabisoprol	S		1 Df, Am (Take 1 Tablet Once Daily With Breakfast (Blood Circulation) 07:00)	Mylan
Nitro-Dur	S		1 Df, Qd (1 Tablet Once Daily At The Same Time Each Day)	Mylan
Brilinta	S		1 Df, Am (The Patch On A Dry Hairless Surface At 8:00 In The Morning And Remove At 20:00 In The Eve)	Mylan
Apo Tamsulosin	S		1 Df, Bid	Mylan
Clonazepam	S		1 Df, Hs	Mylan
Triatec /00116401/	S		1 Df, Tid	Mylan
Metonia	S		1 Df, Qid	Mylan
Nasonex	S	Nasal	1 Df, Tid	Mylan
Delatestryl	S		2 Sprays In Each Nostril, Qd	Mylan
Diltiazem	S		0.5 MI, Q2w	Mylan
			1 Dosage Form, Qd(Morning)	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15644003	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-		40 YR	Female	DEU

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1000084338

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram Oxalate - Bp			S	Unknown	Drops		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd (Started With 1 Drop Daily)		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Tablets		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15662097	EXPEDITED (15-DAY)		OT	JP-ALLERGAN- 1854830US		42 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15674627	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT- 980505		23 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Ivax
	Tavor (Lorazepam)			S	Oral			Not Reported
	Oki 80 Mg Granulato Per Soluzione Orale			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15674628	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 980490		72 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Dizziness; Fall; Haematoma	Escitalopram	S	Oral		Not Reported
	Zolpidem	S	Oral	10 Milligram Daily;	Teva
	Aripiprazole	S	Oral	5 Milligram Daily;	Teva
	Prazepam Arrow 10 Mg, Comprimé	S	Oral	10 Milligram Daily;	Not Reported
	Piroxicam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676567	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US- 2018LAN001361		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Bundle Branch Block Left; Electrocardiogram Qrs Complex Prolonged; Overdose; Pneumonia Aspiration; Rhabdomyolysis; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	20 Mg, Unk		Lannett
	Lamotrigine			S	Oral	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676717	EXPEDITED (15-DAY)		DE, HO, OT	US-JNJFOC- 20181140769			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Drug Interaction	Fentanyl			S	Unknown			Not Reported
	Hydromorphone Hcl			S	Unknown			Not Reported
	Cocaine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported

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Clonazepam	S	Unknown	Not Reported
Cyclobenzaprine	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Apo-Escitalopram	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Ethanol	S	Unknown	Not Reported
Diphenhydramine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15677261	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1855459US		19 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pharyngeal Haemorrhage	Citalopram Hydrobromide - Bp			S	Oral	Unk		Allergan	
	Citalopram Hydrobromide - Bp			S				Allergan	
	Citalopram Hydrobromide - Bp			S				Allergan	
	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15677942	EXPEDITED (15-DAY)		HO, LT	CN-ALLERGAN-1855586US		64 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Back Pain; Inappropriate Schedule Of Product Administration; Product Physical Issue; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	0.2 Df, Prn Every 2 To 3 Days		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2018	15730883	DIRECT		OT			42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Diarrhoea; Migraine	Escitalopram			S				Not Reported	
	Vyvanse			C				Not Reported	
	Adderall			C				Not Reported	
	Multi Vit			C				Not Reported	
	Vit B			C				Not Reported	
	Vit D			C				Not Reported	
	Cq 10			C				Not Reported	
	Fish Oil			C				Not Reported	
	Hydroxiline			C				Not Reported	
	Strontium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15665746	EXPEDITED (15-DAY)		HO	PHHY2018FR166791		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Cefpodoxime			S	Oral	2000 Mg, Unk (Total)		Not Reported	
	Escitalopram			S	Oral	140 Mg, Unk (One Day)		Not Reported	
	Paracetamol			S	Oral	79 G, Unk (Total)		Not Reported	
	Trimebutine			S	Oral	14000 Mg, Unk (Total)		Not Reported	
	Prednisolon			S	Oral	200 Mg, Unk (Total)		Novartis	
	Hepatoum			S	Oral	Unk		Not Reported	
	Azithromycin Anhydrous			S	Oral	1500 Mg, Unk (Total)		Not Reported	
	Arestal			S	Oral	30 Mg, Unk (Total)		Not Reported	
	Seresta			S	Oral	310 Mg, Unk (Total)		Not Reported	
	Inorial			S	Oral	120 Mg, Unk (Total)		Not Reported	
	Augmentin			S	Oral	6 G, Unk (One Day)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15679490	NON-EXPEDITED			US-TEVA-2018-US-976922			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Product Substitution Issue	Escitalopram Teva			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15679524	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-057968		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo	
	Cipralex /01588501/			S	Unknown	Unk		Not Reported	
	Cipralex /01588501/			S	Unknown	20 Milligram, Daily (Started With 1 Drop Daily)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15681352	EXPEDITED (15-DAY)		HO, LT, OT	US-GLAXOSMITHKLINE-US2018217135		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15681763	EXPEDITED (15-DAY)		OT	PHHY2018IT169644			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Treatment Failure	Diazepam			S	Unknown	Unk		Not Reported	

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Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
Lamotrigine	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown		Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Lorazepam	S	Unknown	Unk	Not Reported
Epclusa	S	Unknown	Unk	Not Reported
Flurazepam	S	Unknown	Unk	Not Reported
Chlorpromazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15682958	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192387		72 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	()		Not Reported
	Zolpidem			S	Oral	10 Milligram, Daily		Sun
	Aripiprazole			S	Oral	5 Milligram, Daily		Not Reported
	Prazepam Arrow 10 Mg, Comprime			S	Oral	10 Milligram, Daily		Not Reported
	Piroxicam			C	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	14528629	EXPEDITED (15-DAY)		OT	IT-ACCORD-063481		54 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vaginal Haemorrhage	Escitalopram			S				Not Reported
	Cardioaspirin			S				Not Reported
	Pritor (Telmisartan)			C				Not Reported
	Bisoprolol			C				Not Reported
	Sertraline			C				Not Reported
	Ranexa			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683063	EXPEDITED (15-DAY)		OT	IE-ACCORD-094405		40 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Discomfort; Insomnia; Motor Dysfunction; Pain In Extremity; Paraesthesia	Escitalopram			S		10mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683468	EXPEDITED (15-DAY)		HO	US-APOTEX-2018AP025931		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Depression; Joint Stiffness; Orthostatic Hypotension	Escitalopram			S	Unknown	Unk		Apotex	
	Risperidone			S	Unknown	Unk		Apotex	
	Topiramate			S	Unknown	Unk		Apotex	
	Lorazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683841	EXPEDITED (15-DAY)		DS	GB-AUROBINDO-AUR-APL-2018-058412			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dysgraphia; Dyskinesia; Off Label Use; Therapeutic Product Effect Decreased; Tremor	Escitalopram			S	Unknown	Unk		Aurobindo	
	Venlafaxine			S	Unknown	Unk		Aurobindo	
	Mirtazapine			S	Unknown	Unk		Aurobindo	
	Quetiapine			S	Unknown	Unk		Aurobindo	
	Sertraline			S	Unknown	50 Milligram, Once A Day		Aurobindo	
	Sertraline			S	Unknown	200 Milligram, Once A Day		Aurobindo	
	Valproic Acid			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15684206	NON-EXPEDITED			US-TEVA-2018-US-984278			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15684356	EXPEDITED (15-DAY)		OT	DE-TORRENT-00012578		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown	Unknown		Unknown	
	Cipralex Oral Drops			S	Unknown	Started With 1 Drop Daily		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15684812	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-058406			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Treatment Failure	Diazepam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Aurobindo	
	Lamotrigine			S	Unknown	Unk		Aurobindo	
	Lorazepam			S	Unknown	Unk		Aurobindo	
	Risperidone			S	Unknown	Unk		Aurobindo	
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported	
	Epclusa			S	Unknown	Unk		Not Reported	
	Flurazepam			S	Unknown	Unk		Not Reported	
	Chlorpromazine			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15685703	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-981558		75 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram Oxalate			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15686563	EXPEDITED (15-DAY)		DE, OT	NO-JNJFOC-20181201230		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Medication Error; Overdose	Tramadol Hydrochloride			S	Unknown			Not Reported
	Nobligan			S	Unknown			Not Reported
	Vival			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported
	Ciprallex			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Remeron			S	Unknown			Not Reported
	Catapresan			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Orfiril			S	Unknown			Not Reported
	Pinex Forte			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Oxynorm			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15687205	EXPEDITED (15-DAY)		DE, OT	FR-BRISTOL-MYERS		64 YR	Female	FRA

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SQUIBB COMPANY-
BMS-2018-113313

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Interstitial Lung Disease	Hydrea			S	Oral	500 Mg, (500-500-1000mg)		Bristol Myers Squibb
	Seroplex			S	Oral	5 Mg, 1 Day		Not Reported
	Xagrid			S	Oral	Unk		Not Reported
	Bromazepam			C	Unknown	Unk		Not Reported
	Rovamycine /00074401/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	9745337	EXPEDITED (15-DAY)		DE, LT, OT	NO-JNJFOC-20131204536		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Intentional Self-Injury; Medication Error; Sedation; Unevaluable Event	Nobligan			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Catapressan (Clonidine)			S	Unknown			Not Reported
	Cipramil [Citalopram Hydrobromide]			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Sobril			S	Unknown			Not Reported
	Cipralext			S	Unknown			Not Reported
	Imovane			S	Oral			Not Reported
	Orfiril			S	Unknown			Not Reported
	Oxynorm			S	Unknown	Dose 5 To 10 Mg		Not Reported
	Oxynorm			S	Unknown	Dose 5 To 10 Mg		Not Reported
	Remeron			S	Unknown			Not Reported
	Atarax			S	Unknown			Not Reported

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Truxal	S	Unknown	600 To 1200 Mg	Not Reported
Pinex Forte	S	Unknown	Dose: 300/30 Mg	Not Reported
Vival	S	Unknown		Not Reported
Lamictal	S	Unknown		Not Reported
Sarotex	S	Unknown		Not Reported
Seroquel	S	Unknown		Not Reported
Codeine Phosphate	C	Unknown		Not Reported
Cyanocobalamin	C	Unknown		Not Reported
Diamorphine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15585185	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1851952US		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Medrol			C	Unknown			Not Reported	
	Plavix			C	Unknown			Not Reported	
	Omeprazen			C	Unknown			Not Reported	
	Desloratadine			C	Unknown			Not Reported	
	Pregabalin			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687281	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE-HET2018DE01488		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown	Unk		Not Reported	
	CipraleX /01588501/			S	Oral	20 Mg, Qd		Not Reported	
	CipraleX /01588501/			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687324	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-057897		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral	79 G, Total		Aurobindo	
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported	
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Aurobindo	
	Prednisolone			S	Oral	200 Mg, Total		Aurobindo	
	Cefpodoxime			S	Oral	2000 Mg, Total		Aurobindo	
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported	
	Oxazepam			S	Oral	310 Mg, Total		Not Reported	
	Amoxicillin Sodium And Clavulanate Potassium			S	Oral	6 G, 1 Day		Not Reported	
	Loperamide Oxide			S	Oral	30 Mg, Total		Not Reported	
	Bilastine			S	Oral	120 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687623	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2018US23216			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Cipla	
	Escitalopram			S	Unknown	Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687974	EXPEDITED (15-DAY)		OT	IT-ROCHE-2221297			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported	
	Acetylsalicylic Acid			S	Unknown			Not Reported	

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	Lamotrigine	S	Unknown					Not Reported
	Escitalopram	S	Unknown					Not Reported
	Risperidone	S	Unknown					Not Reported
	Epclusa	S	Unknown	Unk				Not Reported
	Lorazepam	S	Unknown					Not Reported
	Flurazepam	S	Unknown					Not Reported
	Chlorpromazine	S	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15688334	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP026058		23 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Loss Of Consciousness	Escitalopram			S	Oral	15 Mg, Qd		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15691946	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1856267US		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Lercan			C	Oral			Not Reported
	Lormetazepam			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15692027	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1856511US		52 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Tenelia			S	Oral	20 Mg, Qd		Not Reported
	Glimepiride			S	Oral	2 Mg, Qd		Not Reported
	Doral			S	Oral	15 Mg, Qd		Not Reported

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Belsomra			S	Oral	20 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	8774271	EXPEDITED (15-DAY)		OT	FR-FRI-1000038416		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus; Skin Oedema	Escitalopram Oxalate Unk			S	Oral	15 Mg, Unk		Allergan	
	Surgam			S	Oral	200 Mg, Unk		Not Reported	
	Crestor			C	Unknown	Unk		Not Reported	
	Levothyrox			C	Unknown	Unk		Not Reported	
	Daflon			C	Unknown	Unk		Not Reported	
	Bromazepam			C	Unknown	Unk		Not Reported	
	Tanakan			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15058774	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1042987			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus; Myoclonus	Zopiclone			S	Unknown			Not Reported	
	Zopiclone			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Aripiprazole			S	Unknown			Not Reported	
	Aripiprazole			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Oral	Unk		Not Reported	
	Quetiapine			S	Oral	Unk		Not Reported	
	Duloxetine			S	Unknown			Not Reported	

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Duloxetine	S	Unknown	Unk	Not Reported
Clozapine	S	Unknown	75 Mg, Unk	Not Reported
Clozapine	S	Unknown	75 Mg, Unk	Not Reported
Clozapine	S			Not Reported
Escitalopram	S	Unknown	20 Mg	Not Reported
Escitalopram	S	Unknown	20 Mg	Not Reported
Escitalopram	S			Not Reported
Venlafaxine	S	Oral		Not Reported
Venlafaxine	S	Oral	Unk	Not Reported
Mirtazapine	S	Unknown		Not Reported
Mirtazapine	S	Oral	Unk	Not Reported
Risperidone	S	Unknown		Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Amisulpride	S	Unknown		Not Reported
Amisulpride	S	Unknown		Not Reported
Bupropion	S	Unknown		Not Reported
Bupropion	S	Unknown	Unk	Not Reported
Promethazine	S	Unknown		Not Reported
Promethazine	S	Unknown		Not Reported
Biperiden	S	Unknown		Mylan
Biperiden	S	Unknown		Mylan
Oxcarbazepine	C	Unknown	Up To 2400mg; Received Over One Year	Mylan
Oxcarbazepine	C			Mylan
Brivaracetam	C	Unknown	200-250mg; Received Over One Year	Mylan
Brivaracetam	C			Mylan
Carbamazepine	C	Unknown	Up To 900 Mg	Mylan
Carbamazepine	C			Mylan
Oxazepam	C	Unknown	At Different Doses	Not Reported
Oxazepam	C			Not Reported
Oxazepam	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zonisamide	C	Unknown	Up To 100mg	Mylan
Zonisamide	C			Mylan
Clobazam	C	Unknown	Up To 20mg	Mylan
Clobazam	C			Mylan
Oxazepam	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15600117	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-053841		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral	Unk		Aurobindo	
	Desloratadine			C	Unknown	Unk		Not Reported	
	Medrol /00049601/			C	Unknown	Unk		Not Reported	
	Omeprazen /00661201/			C	Unknown	Unk		Not Reported	
	Plavix			C	Unknown	Unk		Not Reported	
	Pregabalin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15692966	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-058208		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral	Unk		Aurobindo	
	Lercan			C	Oral	Unk		Not Reported	
	Lormetazepam			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15694167	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018019019			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram	S	Oral	Unk, Film Coated Tablet	Macleods
	Cipralex	S	Oral	Unk, Oral Drops	Not Reported
	Cipralex	S	Oral	20 Milligram, Bid, Oral Drops, Started With 1 Drop Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15694301	EXPEDITED (15-DAY)		HO, LT, OT	ES-APOTEX- 2018AP026069		18 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hypocoagulable State	Ibuprofen			S	Oral	2800 Mg, In Total (400 Mg X 7 Cps)		Apotex
	Paracetamol			S	Oral	12 G, In Total		Apotex
	Escitalopram			S	Oral	Unk Unk, Qd		Apotex
	Exforge			S	Oral	5 Df, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15695622	EXPEDITED (15-DAY)		HO	FR-PROVELL PHARMACEUTICALS- 2059777		61 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Euthyrox			S	Oral			Provell Pharmaceuticals
	Navelbine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15696532	EXPEDITED (15-DAY)		DE	FR-ALLERGAN- 1856503US		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Interstitial Lung Disease; Multiple Organ	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Hydrea			S	Oral	500-1000 Mg		Not Reported

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Dysfunction Syndrome	Xagrid	S	Oral	1 Mg, Qd	Not Reported
	Bromazepam	C	Unknown	Unk, Unknown	Not Reported
	Rovamycine	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15697017	EXPEDITED (15-DAY)		HO	US-PRINSTON PHARMACEUTICAL INC.-2018PRN01643		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Prinston Pharmaceutical
	Lamotrigine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15645148	EXPEDITED (15-DAY)		OT	JP-ALLERGAN- 1854396US			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Cancer	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Mirtazapine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15645662	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1854188US		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Lasilix			S	Oral	20 Mg, Qd		Not Reported
	Ramipril			S	Oral	2.5 Mg, Qd		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Aspirine Protect			S	Oral	100 Mg, Qd		Not Reported

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	Bisoce	S	Oral	1.25 Mg, Qd	Not Reported
	Exemestane	S	Oral	25 Mg, Qd	Not Reported
	Gabapentine	S	Oral	200 Mg, Qd	Not Reported
	Fluidabak	C	Ophthalmic	3 Gtt, Unknown	Not Reported
	Transipeg (Macrogol 3350)	C	Oral	11.8 G, Unknown	Not Reported
	Gluconate De Potassium	C	Oral	1 Df, Unknown	Not Reported
	Levothyroxine Sodique	C	Oral	30 Gtt, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15697937	EXPEDITED (15-DAY)		HO, LT, OT	US-TORRENT-00007268		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S		Unknown		Unknown	
	Escitalopram			S		Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15698817	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP026426		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15698938	EXPEDITED (15-DAY)		HO, LT, OT	NL-APOTEX-2018AP026308		69 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug	Hydrochlorothiazide			S	Unknown			Apotex	
	Escitalopram			S	Unknown	10 Mg, Qd (1 X Per Day 1		Not Reported	

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Interaction; Hyponatraemia Piece)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15699389	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018019059			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety Disorder; Discomfort; Feeling Abnormal; Malaise; Nervousness; Psychomotor Hyperactivity; Stress; Tension Headache; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	10 Milligram, Qd		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Amlodipine Besylate			C	Unknown	10 Milligram, Qd		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15699747	EXPEDITED (15-DAY)		HO	CA-PFIZER INC- 2018501372			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer
	Cipralext [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, 3x/Day		Not Reported
	Domperidone			S	Unknown	10 Mg, 2x/Day		Not Reported
	Ferrous Sulphate [Ferrous Sulfate]			S	Unknown	300 Mg, 3x/Day		Not Reported
	Temazepam			S	Oral	30 Mg, 1x/Day		Not Reported
	Tylenol With Codeine No.3			S	Oral	2 Df, 3x/Day		Not Reported
	Vitalux [Ascorbic Acid;Betacarotene;Copper;Ribofl avin;Selenium;Tocofer			S	Oral	Unk, 2x/Day		Not Reported

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Wellbutrin XL

S

Oral

150 Mg, 2x/Day

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15700115	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2018480078		60 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Spinal Compression Fracture	Lyrice			S		150 Mg, Unk		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Trisequens [Estradiol;Norethisterone Acetate]			S		Unk		Not Reported
	Lexamil			S		20 Mg, Unk		Not Reported
	Peploc [Ranitidine Hydrochloride]			S		40 Mg, Unk		Not Reported
	Be-Tabs Folic Acid			S		5 Mg, Unk		Not Reported
	Rheumalef			S		20 Mg, Unk		Not Reported
	Pexola			S		0375 Mg, Unk (Er)		Not Reported
	Pramex			S		0.25 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15701376	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-983383		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Azithromycine Anhydre			S	Oral			Not Reported
	Escitalopram			S	Oral	140 Milligram Daily;		Ivax
	Prednisolone			S	Oral			Actavis
	Paracetamol			S	Oral			Not Reported
	Cefpodoxime			S	Oral			Not Reported
	Trimebutine			S	Oral			Not Reported
	Hepatoum, Solution Buvable			S	Oral	Not Informed		Not Reported

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Arestal 1 Mg, Comprimé	S	Oral	Not Reported
Seresta 10 Mg, Comprimé	S	Oral	Not Reported
Inorial 20 Mg, Comprimé	S	Oral	Not Reported
Augmentin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2018	14160254	EXPEDITED (15-DAY)	HO		CH-ROCHE-2014835		74 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Confusional State; Drug Withdrawal Syndrome	Seresta			S	Oral			Not Reported
	Valium			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Tramal			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Quetiapin			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Clexane			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported
	Atorvastatine			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Zanidip			C	Unknown			Not Reported
	Coversum			C	Unknown			Not Reported
	Inderal			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Enalapril			C	Unknown			Not Reported

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Anxiolit	C	Oral	Not Reported
Vit D3	C	Unknown	Not Reported
Prontalgine	C	Unknown	Not Reported
Nacl	C	Unknown	Not Reported
Torasemide	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Dafalgan	C	Unknown	Not Reported
Motilium	C	Unknown	Not Reported
Benerva	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2018	15703439	DIRECT		DS			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anorgasmia; Chills; Cold Sweat; Headache; Hyperhidrosis; Hypoaesthesia; Nausea; Paraesthesia; Sexual Dysfunction; Skin Burning Sensation; Tremor; Withdrawal Syndrome	Escitalopram 5 Mg Substitute For Lexapro 5. Mg Tablet			S	Oral	Quantity:1 Tablet(S);		Cipla

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	13828244	EXPEDITED (15-DAY)		DE, OT	JP-ASTRAZENECA- 2017SE78445		77 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Dyspnoea; Interstitial Lung Disease; Off Label Use	Seroquel			S	Oral			Zeneca
	Escitalopram			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15618244	EXPEDITED (15-DAY)		HO	FR-ARBOR PHARMACEUTICALS, LLC-FR- 2018ARB001145		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Prescribed Underdose	Triptodur			S	Intramuscular	1 Df, Cyclical		Arbor	
	Lipanthyl			S	Oral	145 Mg, 1 D		Not Reported	
	Esomeprazole			S	Oral	Unk		Not Reported	
	Xtandi			S	Oral	120 Mg, 1 D		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	10 Mg, 1 D		Not Reported	
	Amlor			S	Oral	Unk		Not Reported	
	Novonorm			S	Oral	Unk		Not Reported	
	Innohep			S	Subcutaneous	1 Dosage Forms, 1 D		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15659820	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-056616		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, Once A Day (Overdose: 140 Mg, 1 Day)		Aurobindo	
	Prednisolone			S	Oral	200 Milligram, In Total		Aurobindo	
	Prednisolone			S	Oral	20 Milligram In Total (200 Mg, Total)		Aurobindo	
	Paracetamol			S	Oral	79 Gram, In Total		Aurobindo	
	Cefpodoxime			S	Oral	2000 Milligram, In Total		Aurobindo	
	Cefpodoxime			S	Oral	100 Milligram In Total		Aurobindo	
	Trimebutine			S	Oral	14000 Milligram, In Total		Not Reported	

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Trimebutine	S	Oral	200 Milligram In Total (14000 Mg, Total)	Not Reported
Azithromycin	S	Oral	1500 Milligram, Total	Aurobindo
Azithromycin	S	Oral	250 Milligram Total (1500 Mg, Total)	Aurobindo
Hepatoum	S	Oral	Unk	Not Reported
Seresta	S	Oral	310 Milligram, Total	Not Reported
Seresta	S	Oral	10 Milligram Total (310 Mg, Total)	Not Reported
Arestal	S	Oral	30 Milligram, Total	Not Reported
Arestal	S	Oral	1 Milligram Total (30 Mg, Total)	Not Reported
Inorial	S	Oral	120 Milligram, Total	Not Reported
Inorial	S	Oral	20 Milligram, Total (120 Mg, Total)	Not Reported
Augmentin /00756801/	S	Oral	6 Gram, Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15660054	NON-EXPEDITED			US-BIOGEN- 2018BI00661716			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Tecfidera			S	Unknown	Starter Dose		Biogen
Abdominal Pain; Balance	Tecfidera			S	Unknown	Maintenance Dose		Biogen
Disorder; Depression;	Tecfidera			S	Unknown			Biogen
Feeling Abnormal; Feeling	Lexapro			S	Unknown			Not Reported
Hot; Insomnia; Myalgia;	Ampyra			C	Oral			Not Reported
Nausea; Pruritus								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15661262	EXPEDITED (15-DAY)			IT-PFIZER INC- 2018483377		48 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Anxiety; Drug Ineffective	Venlafaxine Hcl	S	Unknown	Unk	Pfizer
	Valproic Acid	S	Unknown		Not Reported
	Quetiapine	S	Unknown	Unk	Not Reported
	Escitalopram	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15701507	EXPEDITED (15-DAY)		HO, LT, OT	US-HETERO CORPORATE- HET2018US01504		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	Unk		Hetero	
	Lamotrigine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15702477	EXPEDITED (15-DAY)		HO, LT, OT	ES-ACCORD-095252		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral			Not Reported	
	Enoxaparin/Enoxaparin Sodium			S	Subcutaneous			Not Reported	
	Sintrom			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15702486	EXPEDITED (15-DAY)		HO	FR-ACCORD-095347		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; General Physical Health Deterioration; Orthostatic Hypotension	Furosemide			S	Oral			Accord	
	Seroplex			S	Oral	10 Mg Film-Coated Tablets		Not Reported	
	Xarelto			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15702537	EXPEDITED (15-DAY)		OT	PL-APOTEX-2018AP025950			Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Learning Disorder; Mental Impairment; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	37.5 Mg, Qd		Apotex	
	Tianeptine			C	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15702817	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-983545		39 YR	Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Suicide Attempt	Escitalopram Teva			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15703541	DIRECT		LT, OT			31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Weight Decreased	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15704077	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018501689			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer	
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer	
	Acetaminophen And Codeine Phosphate			S	Oral	2 Df, 3x/Day		Not Reported	
	Cipralext [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, 3x/Day		Not Reported	

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Co Temazepam	S	Oral	30 Mg, 1x/Day	Not Reported
Domperidone	S	Unknown	10 Mg, 2x/Day	Not Reported
Ferrous Sulfate	S	Unknown	300 Mg, 3x/Day	Not Reported
Wellbutrin XL	S	Oral	150 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15705229	EXPEDITED (15-DAY)		HO	US-JUBILANT CADISTA PHARMACEUTICALS- 2018JUB00493		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	Unk		Jubilant
	Lamotrigine			S	Unknown			Jubilant

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15706657	EXPEDITED (15-DAY)		LT	FR-ALLERGAN- 1856980US		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Overdose; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15707027	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS- 2018M1092051		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Duoplavin			S	Oral	75 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	10153841	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2014121792		30 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Intentional Product Misuse; Lung Infection; Melanocytic Naevus; Rheumatoid Factor Increased; Stillbirth	Tecta			S	Unknown	30 Mg, Qd		Pfizer	
	Ciprallex			S	Unknown	10 Mg, Unk		Not Reported	
	Imodium			S	Unknown	As Required, Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 In 8 Weeks		Not Reported	
	Tylenol With Codeine No.3			S	Unknown	Unk		Not Reported	
	Ventolin			S	Unknown	Unk		Not Reported	
	Loperamide Hydrochloride			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	14144705	EXPEDITED (15-DAY)		HO	CH-UCBSA-2017042706		74 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Confusional State; Drug Withdrawal Syndrome	Keppra			S	Oral	250 Mg, 2x/Day (Bid)		Ucb	
	Seresta			S	Oral	Unk		Not Reported	
	Valium			S	Oral	5 Mg, 6x/Day (3-4 Caps/Day)		Not Reported	
	Risperdal			S	Oral	0.25 Mg, 2x/Day (Bid)		Not Reported	
	Quetiapin			S	Oral	50 Mg, Once Daily (Qd)		Not Reported	
	Haldol			S	Oral	4 Mg Daily		Not Reported	
	Escitalopram			S	Oral	10 Mg, Once Daily (Qd)		Not Reported	
	Fluoxetine			S	Oral	20 Mg, Once Daily (Qd)		Not Reported	
	Tramal			S	Oral	12.5 Mg, 2x/Day (Bid)		Not Reported	
	Clexane			C		Unk		Not Reported	
	Aspirin Cardio			C				Not Reported	
	Atorvastatine			C				Not Reported	
	Crestor			C				Not Reported	
	Tenormin			C				Not Reported	
	Concor			C				Not Reported	
	Zanidip			C				Not Reported	
	Coversum			C				Not Reported	

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Inderal	C	Not Reported
Atarax	C	Not Reported
Enalapril	C	Not Reported
Anxiolit	C	Not Reported
Vit D3	C	Not Reported
Caffeine W/Codeine	C	Not Reported
Phosphate/Paracetamol		
Nacl	C	Not Reported
Potassium	C	Not Reported
Laxoberon	C	Not Reported
Dafalgan	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	14831664	EXPEDITED (15-DAY)		OT	BE-ACCORD-066259		39 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Insomnia; Lacrimation Increased; Tachypnea; Vertigo	Escitalopram Alprazolam			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15706659	EXPEDITED (15-DAY)		HO, LT, OT	US-ALLERGAN-1856821US		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram Oxalate Unk Lamotrigine			S S	Unknown Unknown	Unk Unk		Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15708066	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-095253		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms;	Escitalopram Lamotrigine			S S				Not Reported Not Reported

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Hepatic Failure; Toxic
Epidermal Necrolysis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15708875	EXPEDITED (15-DAY)		HO	SE-COLLEGIUM PHARMACEUTICAL, INC.-SE- 2018COL014620			Unknown	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Tapentadol			S		Unk		Collegium Pharmaceutical
	Fentanyl			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Glytrin /00003201/			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Zopiklon			C		Unk		Not Reported
	Behepan /00056201/			C		Unk		Not Reported
	Panodil			C		Unk		Not Reported
	Trombyl			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15709361	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS- 2018M1089986		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Not Reported
	Norepinephrine			S	Unknown			Not Reported
	Phenylephrine			C	Unknown			Mylan
	Valsartan			C	Unknown			Mylan
	Metoprolol			C	Unknown			Mylan
	Nimodipine			C	Oral			Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15709859	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1856984US		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Off Label Use; Sensory Disturbance	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Lamictal			C	Oral			Not Reported	
	Rivotril			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15709946	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1856969US		56 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Metoprolol			S	Oral	Unk		Not Reported	
	Xarelto			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15710339	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1856983US		22 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	270 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15711078	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-984923		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Hypermetropia; Migraine; Optic Nerve Injury; Visual Field Defect	Escitalopram			S	Unknown			Ivax	
	Cipralext Oral Drops			S	Unknown	Started With 1 Drop Daily		Not Reported	
	Cipralext Oral Drops			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15711351	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1823788US		44 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition Aggravated; Drug Ineffective; Dysphemia; Libido Increased; Movement Disorder; Musculoskeletal Stiffness; Off Label Use; Palpitations; Prescribed Overdose; Product Use Issue; Reduced Facial Expression; Suicidal Ideation	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Unknown		Allergan	
	Citalopram Hydrobromide - Bp			S	Oral	20 Mg, Tid (1 Tablet In The Morning And 2 Tablets In The Afternoon)		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Bid		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Bid		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Bid		Allergan	
	Quetiapine			C	Unknown	1 Tablet, Bid (One In The Morning And One In The Evening)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15351976	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2018355913		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Disorder; Pulmonary Fibrosis	Pantoprazole			S	Oral	20 Mg, Qd		Pfizer	
	Paracetamol			S	Oral	1500 Mg, Qd		Unknown	
	Atorvastatine Pfizer			S	Oral	10 Mg, Qd		Pfizer	
	Ramipril			S	Oral	5 Mg, Qd		Pfizer	
	Lorazepam			S	Oral	1 Mg, Qd		Pfizer	
	Amiodarone Hcl			S	Oral	200 Mg, Qd		Pfizer	
	Levothyrox			S	Oral	1 Unk, Qd		Not Reported	
	Kardegic			S	Oral	1 Df, 1x/Day		Not Reported	
	Caltrate Vitamine D3			S	Oral	Unk (600mg/400ui)		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15711584	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030940		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral			Not Reported	
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported	
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported	
	Cefpodoxime/Cefpodoxime			S	Oral			Not Reported	
	Proxetil								
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Zydus Pharm	
	Inorial			S	Oral			Not Reported	
	Chloroform/Glycerol/Herbal Extract Nos/Isoamyl Acetate/Menthol [Hepatoum]			S	Oral			Not Reported	
	Loperamide			S	Oral			Not Reported	
	Oxazepam			S	Oral	310 Mg, Total		Not Reported	
	Amoxicillin Sodium/Clavulanate			S	Oral	6 G, 1 Day		Not Reported	
	Potassium								
	Prednisolone			S	Oral	200 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15711952	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-030986		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hemiparesis; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown			Zydus Pharm	
	Metoprolol			C	Unknown			Not Reported	
	Valsartan			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15712309	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2018-08617		17 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15712407	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2018-058490		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15713685	EXPEDITED (15-DAY)		OT	SE-TEVA-2018-SE-985433		19 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngeal Haemorrhage	Escitalopram			S	Oral			Ivax	
	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	
	Citalopram			S	Oral			Actavis	
	Citalopram			S				Actavis	
	Citalopram			S				Actavis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15714747	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-984996		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral			Ivax	
	Lercan 20 Mg, Comprimé			C	Oral			Not Reported	

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Pelliculé
Lormetazepam

C

Oral

Not Reported

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12-Dec-2018	15715119	EXPEDITED (15-DAY)		OT	PHHY2018CA183344			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Voltaren			S	Topical	Unk Unk, Qd		Novartis
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naprelan			S	Unknown	1000 Mg, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Tylenol			S	Topical	Unk Unk, Prn		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	700 Mg, Every 6 Weeks		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	600 Mg,/ Q 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
Inflectra			C	Intravenous (not otherwise specified)	Unk		Not Reported	
Diclofenac			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15486053	EXPEDITED (15-DAY)		HO	ZA-CIPLA (EU) LIMITED-2018ZA21652			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Lumbar Vertebral Fracture	Escitalopram			S	Unknown	Unk		Invagen
	Amloc /00550802/			S	Unknown	Unk		Not Reported
	Bilocor			S	Unknown	Unk		Not Reported
	Co-Diovan			S	Unknown	Unk		Not Reported

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Mylan Pantoprazole	S	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported

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13-Dec-2018	15687591	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192631		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram		Not Reported
	Cefpodoxime			S	Oral	In Total		Sun
	Prednisolone			S	Oral	In Total		Taro
	Trimebutine			S	Oral	In Total		Not Reported
	Paracetamol		Y	S	Oral	In Total		Ohm Lab
	Azithromycine			S	Oral	In Total		Sun
	Hepatoum, Solution Buvable			S	Oral	Non Renseigneur ()		Not Reported
	Arestal 1 Mg, Comprime			S	Oral	In Total		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	In Total		Not Reported
	Inorial 20 Mg, Comprime			S	Oral	In Total		Not Reported
Augmentin			S	Oral	6 Gram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15716308	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2018US23492			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Orthostatic Hypotension	Topiramate			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15716746	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2018-059595		67 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Escitalopram			S	Oral	40 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15718620	EXPEDITED (15-DAY)		HO, LT, OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2018019184			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram Oxalate			S	Unknown	Unk, 2.5 Weeks		Macleods	
	Lamotrigine			S	Unknown	Unk, 2.5 Weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15718711	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX- 2018AP026915		67 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac Sodium			S	Unknown	Unk, Unknown		Apotex	
	Escitalopram			S	Unknown	Unk, Unknown		Apotex	
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15718980	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 18-088		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown	()		Hikma	
	Lamotrigine			S	Unknown	()		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15720322	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-986500		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome; Thunderclap Headache	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S				Ivax	
	Norepinephrine			S	Unknown			Teva	
	Phenylephrine			S	Unknown			Not Reported	
	Valsartan			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Nimodipine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	9767492	EXPEDITED (15-DAY)		DE, LT, OT	NO-NAPPMUNDI-GBR-2013-0016523		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Tramadol Hydrochloride			S	Unknown	50, 200mg		Purdue	
	Oxynorm			S	Unknown	10 Mg, Unk		Purdue	
	Oxynorm			S	Unknown	5 To 10mg		Purdue	
	Rivotril			S	Unknown	Unk		Not Reported	
	Rivotril			S	Unknown	Unk		Not Reported	
	Rivotril			S	Unknown			Not Reported	
	Vival			S	Unknown	Unk		Not Reported	
	Catapresan /00171101/			S	Unknown	Strength 25 Mg, 50 Mg, Unk		Not Reported	
	Cipralext			S	Unknown			Not Reported	
	Nobligan			S	Unknown	200 Mg, Unk, Strength: 50 Mg-200 Mg		Not Reported	
	Atarax /00058401/			S	Unknown	Unk		Not Reported	
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported	

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Orfiril	S	Unknown	Strength: 600 Mg-1200 Mg	Not Reported
Nozinan /00038601/	S	Unknown	Unk	Not Reported
Sobril	S	Unknown	Unk	Not Reported
Sobril	S			Not Reported
Remeron	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Cipramil /00582603/	S	Unknown	Unk	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	Strength: 500/30 Mg And Pandeine	Not Reported
Pinex Forte	S	Unknown	300/30 Mg And Pandeine	Not Reported
Imovane	S	Oral	Unk	Not Reported
Truxal /00012102/	S	Unknown	600 To 1200mg	Not Reported
Sarotex	S	Unknown	Unk	Not Reported
Sarotex	S	Unknown	Unk	Not Reported
Lamictal	S	Unknown	100 Mg, Unk	Not Reported
Lamictal	S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg	Not Reported
Diazepam	S	Unknown	Unk	Not Reported
Diamorphine	C		Unk	Not Reported
Diamorphine	C	Unknown	Unk	Not Reported
Nozinan /00038601/	C		Unk	Not Reported
Cyanocobalamin	C	Unknown		Not Reported
Cyanocobalamin	C		Unk	Not Reported
Codeine Phosphate Tablet	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	14165657	EXPEDITED (15-DAY)	HO		CH-JNJFOC-20171105275		74 YR	Female	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Confusional State; Drug Interaction; Drug Withdrawal Syndrome; Fall; Hypotension	Tramal			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Haldol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Keppra			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Quetiapin			S	Oral			Not Reported
	Valium			S	Oral	Strength Of Each Capsule: 5 Mg; Dose: 3-6 Capsules		Not Reported
	Fluoxetine			S	Oral			Not Reported
	Sodium Chloride			C	Unknown	0.9 Percent Injectable Perfusion		Not Reported
	Motilium			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Zanidip			C	Unknown			Not Reported
	Coversum			C	Unknown			Not Reported
	Prontalgine			C	Unknown			Not Reported
	Dafalgan			C	Unknown			Not Reported
	Clexane			C	Unknown			Not Reported
	Benerva			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Concor			C	Unknown			Not Reported
	Atarax			C	Unknown			Not Reported
	Enalapril			C	Unknown			Not Reported
	Anxiolit			C	Unknown			Not Reported
	Anxiolit			C	Unknown			Not Reported

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Vitamin D3	C	Unknown	Not Reported
Potassium	C	Unknown	Not Reported
Torsemide	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Becozyme C	C	Unknown	Not Reported
Inderal	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15351152	EXPEDITED (15-DAY)		DE, HO, OT	FR-BAUSCH-BL-2018-024361		87 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder; Pulmonary Fibrosis	Lorazepam			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Levothyrox			S	Oral	1 (Unspecified)		Not Reported
	Atorvastatine			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Caltrate Vitamine D3			S	Oral	600 Mg / 400 Iu; Divisible Coated Tablet		Not Reported
	Amiodarone Hydrochloride			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Escitalopram Oxalate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15668963	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192275		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Gabapentine			S	Oral	200 Milligram, Qd		Ranbaxy
	Ramipril			S	Oral	2.5 Milligram, Qd		Ranbaxy

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Exemestane	S	Oral	25 Milligram, Qd	Not Reported
Seroplex 5 Mg, Comprime Pellicule	S	Oral	5 Milligram, Qd	Not Reported
Bisoce 1,25 Mg, Comprime Pellicule	S	Oral	1.25 Milligram, Qd	Not Reported
Lasilix 10 Mg/MI, Solution Buvable	S	Oral	20 Milligram, Qd	Not Reported
Aspirine Protect 100 Mg, Comprime Gastro Resistant	S	Oral	100 Milligram, Qd	Not Reported
Lamotrigine	S	Oral	100 Milligram, Qd	Not Reported
Fluidabak 1,5 %, Collyre En Solution	C	Ophthalmic	3 Gtt, Qd	Not Reported
Transipeg 5,9 G, Poudre Pour Solution Buvable En Sachet	C	Oral	11.8 Gram, Qd	Not Reported
Gluconate De Potassium	C	Oral	(1 Cs Par Jour)	Not Reported
Levothyroxine Sodique	C	Oral	30 Gtt, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15699736	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018501418		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, 2x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Ciprallex [Escitalopram]			S	Oral	20 Mg, Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, 3x/Day		Not Reported
	Domperidone			S	Oral	10 Mg, 2x/Day		Not Reported
	Ferrous Sulfate			S	Oral	300 Mg, 3x/Day		Not Reported
	Temazepam			S	Oral	30 Mg, 1x/Day		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, 3x/Day		Not Reported
	Wellbutrin XI			S	Oral	150 Mg, 2x/Day		Not Reported
	Vitalux [Ascorbic Acid;Betacarotene;Copper;Riboflavin;Selenium;Tocofer			S	Oral	Unk Unk, 2x/Day		Not Reported

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14-Dec-2018	15720982	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018019187			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Macleods	
	Metoprolol			S	Oral	Unk		Not Reported	
	Xarelto			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15721172	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE- HET2018US01521		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Hetero	
	Phenylephrine			S	Unknown	Unk		Not Reported	
	Norepinephrine			S	Unknown	Unk		Not Reported	
	Metoprolol			C	Unknown	Unk		Not Reported	
	Valsartan			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15722200	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2018-060061		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo	
	Lamictal			C	Oral	200 Milligram		Not Reported	
	Rivotril			C	Oral	0.5 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15722207	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-059942		56 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Aurobindo	
	Metoprolol			S	Oral	Unk		Aurobindo	
	Xarelto			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15722988	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2018M1093315		64 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Mania	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported	
	Amitriptyline			S	Unknown	25 Milligram, Qd		Not Reported	
	Tramadol			S	Unknown			Not Reported	
	Levofloxacin			C	Unknown			Mylan	
	Acetaminophen			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15725037	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN-1000070451		19 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	18 Tablets Of 5 Mg In Total, Overdose 90 Mg		Allergan	
	Cerazette [Desogestrel]			S	Oral	6 Tablets Of 75 Mcg In Total		Not Reported	
	Alvedon			S	Oral	8 Or 9 Tables, In Total		Not Reported	
	Atarax			S	Oral	6 Tablets Of 10 Mg In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2018	15629007	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-975073		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram	S	Oral	Ivax
	Medrol	C	Unknown	Not Reported
	Plavix	C	Unknown	Not Reported
	Omeprazen	C	Unknown	Not Reported
	Desloratadine	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2018	15725565	EXPEDITED (15-DAY)		CA, OT	NL-ACCORD-096287			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Oral Malformation; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 1		Not Reported	
	Foliumzuur			C				Not Reported	
	Retinol			C				Not Reported	
	Cyklokapron			C				Not Reported	
	Colecalciferol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	13516802	EXPEDITED (15-DAY)		HO	IT-ACCORD-051030		51 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Crying; Drug Abuse; Intentional Self- Injury	Escitalopram			S	Oral	Strength: 10 Mg		Accord	
	Xanax			S	Oral	Strength: 0.25 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	14294111	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS- 2017M1078502		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradypnoea; Bundle Branch Block Right; Electrocardiogram Qrs Complex Prolonged;	Bisoprolol			S	Oral	5.75 Mg, Qd (3.25 Mg In Morning And 2.5 Mg In Evening)		Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	

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Haematuria;	Ramipril	S				Not Reported
Hyperkalaemia; Intentional	Lactibiane (Probiotic)	S				Mylan
Overdose; Sinus	Diffu-K	S	Oral	Unk		Mylan
Bradycardia; Somnolence	Triatec [Ramipril]	S	Oral	5 Mg (2.5 Mg, Bid)		Mylan
	Triatec [Ramipril]	S	Oral	2.5 Milligram, Bid		Mylan
	Brilique	S	Oral	180 Mg (90 Mg, Bid)		Mylan
	Brilique	S	Oral	Unk		Mylan
	Seroplex	S	Oral	5 Mg, Qd		Mylan
	Seroplex	S	Oral	Unk		Mylan
	Tahor	S	Oral	Unk		Mylan
	Tahor	S	Oral	40 Milligram, Qd		Mylan
	Inexium /01479302/	C		20 Mg, Unk		Mylan
	Kardegic	C		75 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15701253	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2018501330		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose;	Inorial			S	Oral	120 Mg, Single		Not Reported
Malaise; Mydriasis;	Bilastine			S	Oral	120 Mg, Unk		Not Reported
Product Use In	Azithromycine			S	Oral	1500 Mg, Single		Pfizer
Unapproved Indication;	Trimebutine Maleate			S	Oral	14000 Mg, Single		Not Reported
Somnolence; Suicide	Hepatoum			S	Oral	Unk		Not Reported
Attempt; Toxicity To	Escitalopram			S	Oral	140 Mg, 1x/Day		Not Reported
Various Agents; Vomiting	Arestal			S	Oral	30 Mg, Single		Not Reported
	Seresta			S	Oral	310 Mg, Single		Not Reported
	Prednisolone			S	Oral	200 Mg, Single		Not Reported
	Paracetamol			S	Oral	79 G, Single		Not Reported
	Augmentin [Amoxicillin			S	Oral	6 G, 1x/Day		Not Reported
	Sodium;Clavulanate Potassium]							
	Cefpodoxime			S	Oral	2000 Mg, Single		Not Reported

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17-Dec-2018	15726789	EXPEDITED (15-DAY)		HO	DK-ACCORD-095916		82 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Atrial Fibrillation; Muscle Spasms; Muscle Twitching; Somnolence	Escitalopram Verapamil			S S		As Extended Release Tablets 240 Mg		Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15726878	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR- 986937		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Escitalopram			S	Oral	40 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15727458	EXPEDITED (15-DAY)		LT	FI-ASTRAZENECA- 2018SF62795			Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hyporesponsive To Stimuli; Jaundice Neonatal; Maternal Condition Affecting Foetus; Neonatal Respiratory Distress; Sepsis Neonatal	Ketipinor Escitalopram Albetol Thyroxin			S S C C	Transplacental Transplacental Transplacental Transplacental			Zeneca Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15727495	EXPEDITED (15-DAY)		HO, OT	BE-APOTEX- 2018AP026913		70 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram			S	Unknown	Unk, Unknown		Apotex	

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Gastrointestinal Haemorrhage	Rivaroxaban	S	Oral	15 Mg, Qd	Not Reported
	Rivaroxaban	S			Not Reported
	Clarithromycin	S	Unknown	Unk, Unknown	Not Reported
	Diltiazem	S	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15730184	EXPEDITED (15-DAY)		HO, OT	AU-SA-2018SA336954		73 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Asthenia; Blood Creatinine Increased; Hypomagnesaemia; Lethargy; Malaise; Myalgia; Nausea; Vomiting	Irbesartan			S		Unk Unk, Unk		Sanofi
	Metformin Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Ondansetron			S		Unk Unk, Unk		Not Reported
	Escitalopram Oxalate			S		Unk Unk, Unk		Not Reported
	Ranitidine			S	Unknown	Unk Unk, Unk		Sanofi
	Amphotericin B			S		Unk Unk, Unk		Not Reported
	Posaconazole			S		Unk Unk, Unk		Not Reported
	Isavuconazole			S	Unknown	Unk Unk, Unk		Not Reported
	Amlodipine			C	Unknown	Unk Unk, Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk Unk, Unk		Not Reported
	Tapentadol			C		Unk		Not Reported
	Gliclazide			C		Unk Unk, Unk		Not Reported
	Metoclopramide			C		Unk Unk, Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk Unk, Unk		Not Reported
	Oxycodone			C	Unknown	Unk Unk, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15731630	EXPEDITED (15-DAY)		HO	PHHY2018FR184365		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Escitalopram			S	Oral	10 Mg, Unk		Not Reported

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Hyponatraemia	Hydrochlorothiazide	S	Oral	Unk	Novartis				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15732154	EXPEDITED (15-DAY)		DE, HO, LT	DK-MYLANLABS-2018M1093886		82 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Atrial Fibrillation; Bradycardia; Bundle Branch Block Left; Cardiotoxicity; Completed Suicide; Hypercapnia; Intentional Overdose; Muscle Spasms; Muscle Twitching; Somnolence; Toxicity To Various Agents	Verapamil			S	Oral	Formulation: Extended Release		Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	13389662	EXPEDITED (15-DAY)		HO	IT-ACCORD-049648		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor; Toxicity To Various Agents	Escitalopram			S	Oral			Accord	
	Quetiapine			S	Oral			Accord	
	Carbolithium Teva			S	Oral	Strength: 300 Mg, Capsule Rigid		Not Reported	
	Etiltox			S	Oral	Strength: 200 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15614007	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1085608		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Feeling Abnormal; Panic Attack	Escitalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S		15 Milligram, Qd		Not Reported	
	Ciprallex /01588501/			S		Unk		Mylan	

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Cipralex /01588501/			S		Unknown		15 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Dec-2018	15700047	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1856620US		66 YR	Male	GRC	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Dyspnoea Exertional; Pleural Effusion; Pleuritic Pain; Pulmonary Embolism	Escitalopram Oxalate - Bp			S	Unknown			Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Dec-2018	15734508	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC-2018SUN00617		17 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Taro		
	Escitalopram			S	Unknown	Unk		Taro		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Dec-2018	15735605	EXPEDITED (15-DAY)		HO	BE-MYLANLABS-2018M1093872		70 YR	Female	BEL	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Interaction; Gastrointestinal Haemorrhage	Diltiazem			S	Unknown			Not Reported		
	Clarithromycin			S	Unknown			Not Reported		
	Escitalopram			S	Unknown			Not Reported		
	Rivaroxaban			S	Oral			Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Dec-2018	15736137	EXPEDITED (15-DAY)		HO	SE-TEVA-2018-SE-988719		22 YR	Female	SWE	

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Intentional Overdose; Toxicity To Various Agents	Escitalopram			S	Unknown	270 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15736700	EXPEDITED (15-DAY)		HO, OT	BE-BAUSCH-BL-2018-035292		67 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown			Bausch And Lomb	
	Rivaroxaban			S	Oral	Duration More Than 1 Year		Not Reported	
	Rivaroxaban			S				Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15736955	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1091965		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Not Reported	
	Lamotrigine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	13960570	EXPEDITED (15-DAY)		DS	US-ALLERGAN-1681370US		41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Ejaculation Delayed; Hypoaesthesia	Lexapro			S	Unknown	Unk		Allergan	
	Lorazepam			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	14461504	NON-EXPEDITED			US-ALLERGAN-1774042US			Female	USA

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Dry Mouth; Lip Dry; Nervousness; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan	
	Inderal			C	Oral	Unk		Not Reported	
	Spiroinolactone			C	Oral	Unk Unk, Prn		Not Reported	
	Zocor			C	Oral	20 Mg, Qd		Not Reported	
	Linzess			C	Oral	145 Mg, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15118007	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR- APL-2018-034563		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Fear-Related Avoidance Of Activities; Learning Disorder; Mental Impairment; Overdose; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	37.5 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Tianeptine			C	Unknown	10 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15665794	EXPEDITED (15-DAY)		HO	GR-MYLANLABS- 2018M1088424		66 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism	Mylan-Escitalopram			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739238	EXPEDITED (15-DAY)		OT	GB-TORRENT- 00019749		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Feeling Cold; Incorrect Dose Administered; Nausea	Escitalopram			S	Oral	Prescribed 10 Mg		Unknown	

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19-Dec-2018	15739268	NON-EXPEDITED			US-ALLERGAN-1769657US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739274	NON-EXPEDITED			US-ALLERGAN-1805436US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739277	NON-EXPEDITED			US-ALLERGAN-1812188US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739279	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1800825US		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Distractibility; Feeling	Lexapro			S	Oral	10 Mg, Qd		Allergan	
Abnormal; Memory	Lexapro			S	Oral	5 Mg, Qd		Allergan	
Impairment; Off Label	Latuda			C	Unknown	20 Mg, Qd		Not Reported	
Use; Pulmonary Embolism	Haldol			C	Unknown	1 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739280	NON-EXPEDITED			US-ALLERGAN-1827505US		21 YR	Female	USA

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Asthenia	Lexapro			S	Oral	2.5 Mg, Unk		Allergan	
	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Ativan			C	Oral	Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739282	NON-EXPEDITED			US-ALLERGAN-1803991US		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739283	NON-EXPEDITED			US-ALLERGAN-1834895US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Lexapro			S	Unknown	Unk		Allergan	
	Votrient			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739284	NON-EXPEDITED			US-ALLERGAN-1803998US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Cold; Feeling Hot; Nasopharyngitis; Paraesthesia	Lexapro			S	Unknown			Allergan	
	Robitussin /00048001/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739285	NON-EXPEDITED			US-ALLERGAN-1838837US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Lexapro			S	Oral	20 Mg, Qd		Allergan	

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Feeling Jittery; Intentional
Dose Omission; Lethargy;
Seizure; Serum Serotonin
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739286	NON-EXPEDITED			US-ALLERGAN-1803505US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Libido; Sexual Dysfunction	Lexapro			S	Oral			Allergan	
	Latuda			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739287	NON-EXPEDITED			US-ALLERGAN-1816775US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nervousness	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
	Effexor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739288	NON-EXPEDITED			US-ALLERGAN-1809644US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Lorazepam			C	Oral	0.5 Mg, Prn		Not Reported	
	Garlic			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739290	NON-EXPEDITED			US-ALLERGAN-1811555US		80 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739291	EXPEDITED (15-DAY)		OT		US-ALLERGAN-1837915US		Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Amnesia; Cognitive Disorder; Confusional State; Depression; Impaired Driving Ability; Malaise; Off Label Use; Withdrawal Syndrome	Lexapro			S	Oral	Unk Unk, Qd		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
	Xanax			C	Oral	Unk Unk, Unknown		Not Reported	
	Xanax			C				Not Reported	
	Xanax			C				Not Reported	
	Prozac			C	Oral	Unk Unk, Unknown		Not Reported	
Prozac				C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739292	NON-EXPEDITED				US-ALLERGAN-1832357US		Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Skin Exfoliation	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739293	NON-EXPEDITED				US-ALLERGAN-1801818US		Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alopecia; Anxiety; Depression	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15739294	NON-EXPEDITED				US-ALLERGAN-1833815US	22 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Seroquel			C	Oral	50 Mg, Qd		Not Reported	
	Inderal			C	Oral	120 Mg, Qd		Not Reported	
	Klonopin			C	Oral	1 Mg, Qhs		Not Reported	
	Xanax			C	Oral	1 Mg, Bed Time		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739295	NON-EXPEDITED			US-ALLERGAN-1800908US		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hyperacusis; Tinnitus	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Lexapro			S				Allergan	
	Prilosec			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15739296	NON-EXPEDITED			US-ALLERGAN-1815769US		16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15740758	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-987757		56 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Escitalopram			S	Oral			Ivax	
	Metoprolol			S	Oral			Not Reported	
	Xarelto 10 Mg Film-Coated Tablets			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15742031	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1858146US		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Psychomotor Retardation	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Depalgos			S	Oral	3 Df, Qd		Not Reported	
	Aprovel			C	Unknown			Not Reported	
	Sinemet			C	Unknown			Not Reported	
	Moduretic			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15742219	NON-EXPEDITED			US-TEVA-2018-US-984671			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Nausea	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15742337	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1094357		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Alprazolam			S	Oral	1 Dosage Form, Total		Not Reported	
	Seroplex			S	Oral	1 Dosage Form, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15210113	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1055418		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Tramadol			S	Oral	Unk (Posologie Inconnue)		Not Reported	
	Seroplex			S	Oral	20 Mg, Unk		Mylan	

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Bilaska	S	Oral	Unk (Posologie Inconnue)	Mylan
Seresta	S	Oral	Unk (Posologie Inconnue)	Mylan
Nocertone	S	Oral	Unk	Mylan
Simponi	S	Subcutaneous	50 Mg, Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15715532	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1857142US			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Disorder	Escitalopram Oxalate - Bp			S	Oral			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15738577	NON-EXPEDITED			US-PFIZER INC-2018520725		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Zoloft			S				Pfizer
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Cymbalta			S		Unk		Not Reported
	Cymbalta			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15739590	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP027291		83 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Product Substitution Error	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Idaptan			S	Oral	20 Mg, Bid		Not Reported
	Nifedipino			C	Oral	20 Mg, Bid		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15743829	EXPEDITED (15-DAY)		HO	FR-ACCORD-096656		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised	Escitalopram			S				Not Reported	
Exanthematous Pustulosis	Ceftriaxone			S				Not Reported	
	Risperidone			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15744209	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20180211067		93 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness; Fall;	Imodium		Y	S	Unknown			Not Reported	
Hyponatraemia;	Imodium			S	Unknown			Not Reported	
Hypotension;	Metoprolol			S	Unknown			Not Reported	
Hypovitaminosis	Metoprolol			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Tamsulosin			S	Unknown			Not Reported	
	Telmisartan			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15744765	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1857933US		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Feeling Cold; Intentional Product Misuse; Nausea; Wrong	Escitalopram Oxalate - Bp			S	Oral	Actual: 5 Mg		Allergan	

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Technique In Product
Usage Process

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15745557	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1858332US		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Paraesthesia; Swollen Tongue	Lexapro			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15745746	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-989206		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram			S	Unknown			Ivax	
	Lamotrigine			S	Unknown			Teva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15747071	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1858321US		52 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Blood Pressure Fluctuation; Dysstasia; Erythema; Feeling Abnormal; Headache; Heart Rate Abnormal; Heart Rate Increased; Hot Flush; Hyperhidrosis; Hypertension; Hypotension; Insomnia; Malaise; Migraine; Pallor; Sleep Disorder; Syncope; Vertigo	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Laroxyl			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	11987849	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-06543		43 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Interaction; Dyskinesia; Muscle Twitching; Restless Legs Syndrome; Sleep Disorder	Citalopram 20mg			S	Unknown	20 Mg, Unk		Aurobindo	
	Escitalopram			S	Unknown	Unk		Aurobindo	
	Quetiapine 300mg			S	Unknown	300 Mg, Once A Day		Aurobindo	
	Fluoxetine			S	Unknown	Unk		Aurobindo	
	Lofepramine			S	Unknown	Unk		Not Reported	
	Dosulepin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	14820665	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1822796US		32 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Product Use In Unapproved Indication; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Saroten Retard			S	Oral	25 Mg, Qd		Not Reported	
	Saroten Retard			S	Oral	50 Mg, Qd		Not Reported	
	Diazepam			S	Oral	9 Mg, Qd		Not Reported	
	Diazepam			S				Not Reported	
	Alprazolam			C	Unknown	Delayed-Release Alprazolam 2mg/D + Alprazolam 0.5 Mg As Needed		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	14928152	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-067222		14 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abnormal Behaviour;	Aripiprazole	S	Oral	Not Reported
Accidental Overdose;	Cipralex	S	Oral	Not Reported
Disinhibition; Drug Interaction; Mental Disorder	Calcium/Ergocalciferol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15624968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018018620			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Macleods	
	Quetiapine 300 Mg			S	Unknown	300 Milligram, Qd		Macleods	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Dosulepin			S	Unknown	Unk		Not Reported	
	Lofepamine			S	Unknown	Unk		Not Reported	
	Citalopram			S	Unknown	20 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15633930	EXPEDITED (15-DAY)		OT	PHHY2018GB155213		43 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Escitalopram			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Unknown	300 Mg, Unk		Novartis	
	Dosulepin			S	Unknown	Unk		Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Lofepamine			S	Unknown	Unk		Not Reported	
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15692995	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-983314		51 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Aggression; Aggression; Drug Ineffective; Extrapramidal Disorder	Olanzapine			S	Unknown	20 Milligram Daily; Once At Night		Teva
	Aripiprazole			S	Unknown			Teva
	Quetiapine			S	Unknown			Teva
	Lithium			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Escitalopram			S	Unknown	20 Milligram Daily; Once In The Morning		Not Reported
	Trazodone			S	Unknown	200 Milligram Daily; Once At Night		Not Reported
	Dextromethorphan/Quinidine			S		Dextromethorphan 20mg And Quinidine 10mg Daily		Not Reported
	Dextromethorphan/Quinidine			S		Dextromethorphan 20mg And Quinidine 10mg Twice Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15747721	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE185954		70 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Gastrointestinal Haemorrhage	Rivaroxaban			S	Unknown	15 Mg, Qd		Not Reported
	Diltiazem			S	Unknown	Unk		Novartis
	Clarithromycin			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15748105	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-031575		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort; Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Failure; Lymph Node Pain; Lymphadenopathy; Lymphocytosis; Pyrexia; Rash Erythematous; Rash Pruritic; Toxic Epidermal Necrolysis	Escitalopram Lamotrigine	S S	Unknown Unknown	Zydus Pharm Zydus Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15749027	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-194275		54 YR	Male	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Therapeutic Product Effect Incomplete	Quetiapine			S	Unknown	300 Milligram, Daily		Sun
	Quetiapine			S	Unknown	800 Milligram, Daily		Sun
	Escitalopram			S	Unknown	10 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Ranbaxy
	Olanzapine			S	Unknown	15 Milligram, Daily		Sun
	Duloxetine			S	Unknown	60 Milligram, Daily		Sun
	Doxepin			S	Unknown	100 Milligram, Daily		Sun
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15749097	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018019271			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10mg.		Macleods

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15749519	EXPEDITED (15-DAY)		DE, OT	FR-ACCORD-096615		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Not Reported	
	Benzoic Acid/Sodium Benzoate			S	Unknown	Unk		Not Reported	
	Indapamide			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15749779	EXPEDITED (15-DAY)		HO	PHHY2018HR190284			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance	Amyzol			S	Unknown	Unk		Novartis	
	Ketonal			S	Unknown	Unk		Not Reported	
	Propranolol			S	Unknown	180 Mg, Unk		Not Reported	
	Propranolol			S	Unknown	120 Mg, Unk		Not Reported	
	Imigran			S	Unknown	Unk		Not Reported	
	Plivadon (Caffeine\Phenacetin\Propyphenazone)			S	Unknown			Not Reported	
	Knavon			S	Unknown			Not Reported	
	Cipralext			S	Unknown			Not Reported	
	Helex			S	Unknown	Unk		Not Reported	
	Elicea			S	Unknown	Unk		Not Reported	
	Botox			S	Unknown	Unk		Not Reported	
	Topiramate			S	Unknown	Unk		Not Reported	
	Normabel			S	Unknown	Unk		Not Reported	
	Erenumab			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15750000	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2018GB23779			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	5 Mg, Tablet, Prescribed 10mg		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15750191	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1858299US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Medication Error; Overdose	Escitalopram Oxalate - Bp			S	Oral	Overdose: 30 Mg, Total		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15751912	EXPEDITED (15-DAY)		HO	GB-ANIPHARMA-2018- UK-000170		83 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Candesartan			S	Oral	16 Mg Unk		Ani	
	Omexel			S	Oral	1 Df Daily		Not Reported	
	Imovane			S	Oral	1 Df Daily		Not Reported	
	Seebri Breezhaler			C	Unknown	Unk		Not Reported	
	Tenordate			S	Oral	1 Df Daily		Not Reported	
	Kardegic			C	Unknown	Unk		Not Reported	
	Avodart			C	Unknown	Unk		Not Reported	
	Lovenox			C	Unknown	Unk		Not Reported	
	Escitalopram			S	Oral	5 Mg Daily		Not Reported	
	Lasilix			S	Oral	4 Df Daily / Dose Text: Reduced Dose		Not Reported	
	Seresta			S	Oral	1 Df Daily		Not Reported	

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Spironolactone			S		Oral	25 Mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15752223	EXPEDITED (15-DAY)		HO, OT	AT-JNJFOC-20181212522			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation;	Risperdal			S	Unknown			Not Reported	
Alcoholism; Apraxia;	Risperidone			S	Unknown			Not Reported	
Behaviour Disorder;	Risperidone			S	Unknown			Not Reported	
Cognitive Disorder;	Risperidone			S	Unknown			Not Reported	
Dementia; Dementia With	Risperidone			S	Unknown			Not Reported	
Lewy Bodies; Depression;	Quetiapine Fumarate			S	Oral			Not Reported	
Drug Ineffective;	Quetiapine Fumarate			S	Oral			Not Reported	
Dysphoria; Hallucination;	Quetiapine Fumarate			S	Oral	Low Dose		Not Reported	
Hallucination, Visual;	Valproic Acid			S	Unknown			Not Reported	
Insomnia; Korsakoff'S	Naltrexone			S	Unknown			Not Reported	
Syndrome; Mania; Muscle	Lorazepam			S	Unknown			Not Reported	
Rigidity; Parkinsonism;	Escitalopram			S	Unknown			Not Reported	
Restlessness; Sleep	Escitalopram			S	Unknown			Not Reported	
Disorder; Tremor; Urinary	Escitalopram			S	Unknown			Not Reported	
Incontinence	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Pregabalin			S	Oral			Not Reported	

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	Pregabalin		S	Oral				Not Reported	
	Oxazepam		S	Unknown				Not Reported	
	Piracetam		S	Unknown				Not Reported	
	Cerebrolysin		S	Unknown				Not Reported	
	Mirtazapine		S	Unknown				Not Reported	
	Rivastigmine		S	Transdermal				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15752529	EXPEDITED (15-DAY)		OT	PT-LANNETT COMPANY, INC.-PT- 2018LAN004632		27 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stiff Person Syndrome	Escitalopram Oxalate			S	Unknown		20 Mg, Unk		Lannett
	Escitalopram Oxalate			S					Lannett
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15752672	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US- 2018LAN004631		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram Oxalate			S	Unknown		Unk		Lannett
	Norepinephrine			S			Unk		Not Reported
	Phenylephrine			S			Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15752924	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1859040US		27 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Headache; Muscle Spasms; Product Use In Unapproved Indication; Tinnitus; Tremor	Escitalopram Oxalate - Bp			S	Oral		Unk		Allergan
	Terbinafina			C	Unknown		Un Mes 1comprimido Al Dia		Not Reported

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22-Dec-2018	15720983	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018019188			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Qd, CipraleX		Macleods	
	Lamictal			C	Oral	200 Milligram		Not Reported	
	Rivotril			C	Oral	0.5 Milligram, Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2018	15753232	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB- 989608		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10mg.		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2018	15753663	EXPEDITED (15-DAY)		OT	FR-ACCORD-096618		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
	Furosemide			S	Unknown	Unk		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2018	15753681	EXPEDITED (15-DAY)		OT	GB-ACCORD-096645		25 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bursitis; Nasopharyngitis; Skin Warm	Escitalopram			S	Oral			Not Reported	
	Levonelle			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2018	15753774	EXPEDITED (15-DAY)		OT	DE-ACCORD-096927		30 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthenia; Decreased Appetite; Dizziness; Fatigue; Galactorrhoea; Headache; Nightmare; Orgasm Abnormal; Sexual Dysfunction; Sleep Disorder; Suicidal Ideation; Tremor; Wound	Escitalopram			S	Oral	Daily Dose: 15 Mg Milligram(S) Every Day		Not Reported	
	Escitalopram			S	Oral	Daily Dose: 20 Mg Milligram(S) Every Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2018	15659335	NON-EXPEDITED			US-TEVA-2018-US- 973070		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Wrong Technique In Product Usage Process	Escitalopram Teva			S	Unknown			Not Reported	
	Escitalopram Teva			S	Unknown	(1 Quarter Of 20mg Pill + 10mg Pill)		Not Reported	
	Escitalopram Teva			S	Unknown	(1 Remaining Half Of 20 Mg Pill + 1 Remaining Quarter Of 20 Mg Pill)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	14102003	EXPEDITED (15-DAY)		OT	PK-ALLERGAN- 1759174US		68 YR	Male	PAK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Arthropathy; Asthenia; Balance Disorder; Blood Pressure Increased; Cough; Deafness; Drug Ineffective; Energy	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan	

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Increased; Fall; Fatigue; Gastric Disorder; Heart Rate Increased; Hypoacusis; Insomnia; Laziness; Muscle Atrophy; Nasopharyngitis; Overdose; Product Dose Omission; Prostatic Disorder; Salivary Hypersecretion; Sensory Disturbance; Urine Output Increased; Withdrawal Syndrome	Escitalopram Oxalate - Bp	S	Unknown	20mg After Breakfast And 20mg At About 3 Pm Overdose	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	40 Mg, Unk	Allergan
	Brintellix	S	Unknown	30 Mg, Unk	Not Reported
	Brintellix	S	Unknown	20 Mg, Unk	Not Reported
	Brintellix	S	Unknown	40 Mg, Unk	Not Reported
	Trioptal	C	Unknown	600 + 300 Mg, Unk	Not Reported
	Losec	C	Unknown	20 Mg, Unk	Not Reported
	Lipiget	C	Unknown	5 Mg, Qd	Not Reported
	Vitamin D3	C	Other	1 Df, Q Month	Not Reported
	Ca C 1000	C	Unknown	Unk	Not Reported
	Concor	C	Unknown	2.5 Mg, Unk	Not Reported
	Concor	C	Unknown	5 Mg, Unk	Not Reported
	Tranxene	C	Unknown	30 Mg, Unk	Not Reported
	Lexotanil	C	Unknown	9 Mg, Unk	Not Reported
	Lexotanil	C	Unknown	7.5 Mg, Qd	Not Reported
	Lyrica	C	Unknown	75 Mg, Unk	Not Reported
	Lyrica	C	Unknown	300 Mg, Unk	Not Reported
	Qusel	C	Unknown		Not Reported
	Qusel Xr	C	Unknown		Not Reported
	Zyprexa	C	Unknown	Unk	Not Reported
	Dehydroepiandrosterone	C	Unknown	Unk	Not Reported
	Vitamin B 6	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Tamsolin	C	Unknown	0.5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	14728558	EXPEDITED (15-DAY)		HO	JP-ALLERGAN- 1817122US		53 YR	Female	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Microscopic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Wypax			C	Oral	0.5 Mg, Q8hr		Not Reported
	Depakene-R			C	Oral	400 Mg, Qd		Not Reported
	Myslee			C	Oral	5 Mg, Qd		Not Reported
	Rivotril			C	Oral	0.5 Mg, Qd		Not Reported
	Silece			C	Oral	2 Mg, Qd		Not Reported
	Depas (Etizolam)			C	Oral	0.5 Mg, Qd		Not Reported
	Ternelin			C	Oral	1 Mg, Qd		Not Reported
	Daikenchuto			C	Oral	2.5 G, Q8hr		Not Reported
	Magnesium Oxide			C	Oral	250 Mg, Q8hr		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	14817394	EXPEDITED (15-DAY)		OT	PL-TAKEDA-2018TUS012677		34 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Depression; Dizziness; Mental Impairment	Vortioxetine			S	Unknown	10 Mg, Qd		Takeda
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15587379	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1851981US			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Agitation; Anxiety; Crying; Exposure Via Breast Milk; Irritability; Myoclonus; Seizure; Sleep Disorder	Escitalopram Oxalate - Bp			S	Transmammary			Allergan
	Bupropion			S	Transmammary			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15743874	EXPEDITED (15-DAY)		HO, OT	PT-LUPIN PHARMACEUTICALS		64 YR	Female	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mania	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Tramadol			S	Unknown	225 Mg, Qd		Lupin
	Amitriptyline			S	Unknown	25 Mg, Qd		Not Reported
	Paracetamol			C	Unknown	3000 Mg, Qd		Not Reported
	Levofloxacin			C	Unknown	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15755095	EXPEDITED (15-DAY)		HO	FR-ACCORD-097136		40 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Coma; Sinus Bradycardia; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Plavix			S	Oral	75 Mg Strength		Not Reported
	Coveram			S	Oral	10 Mg/10 Mg Strength		Not Reported
	Seresta			S	Oral	50 Mg Strength, Scored Tablet		Not Reported
	Bisoce			S	Oral	10 Mg Strength		Not Reported
	Zopiclone			S	Oral			Not Reported
	Aldactazine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15755341	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-060945		63 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Feeling Cold; Nausea	Escitalopram Tablets			S	Oral	5 Milligram (Prescribed 10mg)		Aurobindo

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15756079	EXPEDITED (15-DAY)		HO	FR-ZYDUS-031871		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram			S	Oral			Not Reported	
	Acetylsalicylic Acid			S	Oral	75 Mg Powder For Oral Solution In Sachet-Dose		Not Reported	
	Tamsulosin			C		0.4 Mg Prolonged-Release Film-Coated Tablet		Not Reported	
	Candesartan/Candesartan			C				Not Reported	
	Cilexetil								
	Dutasteride			C		0.5 Mg Soft Capsule		Not Reported	
	Oxazepam			C		10 Mg Tablet		Not Reported	
	Atenolol/Nifedipine			C				Not Reported	
	Zopiclone			C		7.5 Mg Film-Coated Tablets		Not Reported	
	Spironolactone			C				Not Reported	
	Furosemide			C		40 Mg, Scored Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15756597	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1858423US		1 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Vomiting	Lexapro			S	Transplacental			Allergan	
	Suboxone			S	Transplacental	8 Mg, Bid		Not Reported	
	Remeron			S	Transplacental			Not Reported	
	Nicotine			S	Transplacental			Not Reported	
	Buprenorphine			S	Transplacental	Unk		Not Reported	
	Buprenorphine			S	Transmammary	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	14822663	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1822782US		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Depression; Dizziness; Mental Impairment	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Brintellix			S	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15757678	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-060337		28 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Ecchymosis; Thrombocytopenia	Escitalopram			S	Oral	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15758170	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-060489		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arteriosclerosis; Bradycardia; Hemiplegia; Reversible Cerebral Vasoconstriction Syndrome; Thunderclap Headache; Vasospasm	Escitalopram			S	Unknown	Unk		Aurobindo	
	Norepinephrine			S	Unknown	Unk		Not Reported	
	Phenylephrine			S	Unknown	Unk		Not Reported	
	Metoprolol			C	Unknown	Unk		Not Reported	
	Valsartan			C	Unknown	Unk		Not Reported	
	Nimodipine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15758650	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1859242US		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebral Haemorrhage; Incorrect Dose Administered	Escitalopram Oxalate - Bp	S	Oral	10 Df, Qd	Allergan
	Kardegic	S	Oral	1 Df, Qd	Not Reported
	Omexel	C	Unknown		Not Reported
	Candesartan Cilexetil	C	Unknown		Not Reported
	Seebri Breezhaler	C	Unknown		Not Reported
	Avodart	C	Unknown		Not Reported
	Seresta	C	Unknown		Not Reported
	Tenordate	C	Unknown		Not Reported
	Imovane	C	Unknown		Not Reported
	Spironolactone	C	Unknown		Not Reported
	Lasilix	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	11970104	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-110432			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	300 Milligram, Qd		Sun	
	Escitalopram			S	Unknown			Not Reported	
	Dosulepin			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Sun	
	Lofepamine			S	Unknown			Not Reported	
	Citalopram			C	Unknown	20 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	12417884	EXPEDITED (15-DAY)		DS	IT-AUROBINDO-AUR- APL-2016-06373		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dysgraphia; Dyskinesia; Therapeutic	Mirtazapine			S	Unknown	Unk		Aurobindo	
	Mirtazapine			S				Aurobindo	

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Product Effect Decreased; Tremor	Sertraline	S	Unknown	200 Mg Daily	Aurobindo
	Sertraline	S	Unknown	50 Milligram, Once A Day	Aurobindo
	Sertraline	S			Aurobindo
	Quetiapine Film-Coated Tablet	S	Oral	Unk	Aurobindo
	Quetiapine Film-Coated Tablet	S			Aurobindo
	Venlafaxine	S	Unknown	Unk	Aurobindo
	Venlafaxine	S			Aurobindo
	Escitalopram	S	Unknown	Unk	Aurobindo
	Escitalopram	S			Aurobindo
	Valproic Acid	S	Unknown	Unk	Not Reported
	Valproic Acid	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	14408904	EXPEDITED (15-DAY)		HO	FR-ACCORD-062847		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Raynaud'S Phenomenon	Quetiapine			S	Oral			Accord
	Laroxyl			S				Not Reported
	Methylphenidate			S	Oral	80 Mg In The Morning And 20 Mg At 4pm		Not Reported
	Lexapro			S	Oral			Not Reported
	Xeroquel			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Ritaline			S	Oral			Not Reported
	Lepticur			S				Not Reported
	Abilify			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15576747	EXPEDITED (15-DAY)		OT	PK-TAKEDA- 2018TUS031574		68 YR	Male	PAK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Asthenia; Balance	Brintellix			S	Unknown	30 Mg, Unk		Takeda



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Disorder; Blood Pressure Increased; Cough; Deafness; Drug Ineffective; Drug Ineffective; Energy Increased; Fall; Fatigue; Fatigue; Gastric Disorder; Heart Rate Increased; Hypoacusis; Insomnia; Laziness; Muscle Atrophy; Nasopharyngitis; Overdose; Prescribed Overdose; Prostatic Disorder; Salivary Hypersecretion; Sensory Disturbance; Urine Output Increased; Withdrawal Syndrome	Brintellix	S	Unknown	20 Mg, Unk	Takeda
	Brintellix	S	Unknown	30 Mg	Takeda
	Brintellix	S	Unknown	20 Mg, Unk	Takeda
	Brintellix	S	Unknown	40 Mg, Unk	Takeda
	Ciprallex /01588501/	S	Unknown	5 Mg, Unk	Not Reported
	Ciprallex /01588501/	S	Unknown	10 Mg, Unk	Not Reported
	Ciprallex /01588501/	S	Unknown	20 Mg, Unk	Not Reported
	Ciprallex /01588501/	S	Unknown	30 Mg, Unk	Not Reported
	Ciprallex /01588501/	S	Unknown	20 Mg, Bid	Not Reported
	Ciprallex /01588501/	S	Unknown	40 Mg, Unk	Not Reported
	Trioptal	C	Unknown	600/300 Mg, Unk	Not Reported
	Losec /00661201/	C	Unknown	Unk	Not Reported
	Lipigetez	C	Unknown	5 Mg, Qd	Not Reported
	Vitamin D /00318501/	C	Unknown	Unk, Qd	Not Reported
	Cac	C	Unknown	Unk	Not Reported
	Concor	C	Unknown	2.5 Mg, Unk	Not Reported
	Concor	C	Unknown	5 Mg, Unk	Not Reported
	Tranxene	C	Unknown	Unk	Not Reported
	Tranxene	C	Unknown		Not Reported
	Lexotanil	C	Unknown	Unk	Not Reported
	Lexotanil	C	Unknown	7.5 Mg, Qd	Not Reported
	Lyrica	C	Unknown	75 Mg, Unk	Not Reported
	Lyrica	C	Unknown	300 Mg, Unk	Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Qusel	C	Unknown	Unk	Not Reported
	Qusel	C	Unknown		Not Reported

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Zyprexa	C	Unknown	Unk	Not Reported
Zyprexa	C	Unknown		Not Reported
Dehydroepiandrosterone	C	Unknown		Not Reported
Dehydroepiandrosterone	C	Unknown		Not Reported
Tamsolin	C	Unknown	0.5 Mg, Unk	Not Reported
Tamsolin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15759020	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2018-09001		66 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Euphoric Mood; Flight Of Ideas; Insomnia; Irritability; Mania; Pressure Of Speech; Psychomotor Hyperactivity	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15759292	NON-EXPEDITED			US- ELI_LILLY_AND_COMP ANY-US201812008034			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder	Zyprexa			S	Oral	40 Mg, 30mg At Bedtime And 10mg Daily		Eli Lilly And Co	
	Latuda			S	Unknown	Unk, Unknown		Not Reported	
	Latuda			S	Unknown	120 Mg, Unknown		Not Reported	
	Fanapt			S	Unknown	Unk, Unknown		Not Reported	
	Lexapro			S	Unknown	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760005	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-062410		84 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Dosage Form, Daily		Aurobindo
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported
	Omexel			C	Unknown			Not Reported
	Tenordate			C	Unknown			Not Reported
	Lasilix /00032601/			C	Unknown			Not Reported
	Candesartan Cilexetil			C	Unknown			Not Reported
	Avodart			C	Unknown			Not Reported
	Seresta			C	Unknown			Not Reported
	Seebri Breezhaler			C				Not Reported
	Imovane			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760061	EXPEDITED (15-DAY)		CA	DE-TORRENT-00012763			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Kidney Duplex	Magnetrans			C	Transplacental	Unknown		Unknown
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Unknown
	Cetirizine			C	Transplacental	Unknown		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Unknown
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Unknown
	Cytotec			C	Transplacental	Unknown		Unknown
	Olynth			C	Transplacental	If Required		Unknown
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760140	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2018-061079		54 YR	Unknown	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness	Escitalopram			S	Unknown	10 Milligram		Aurobindo
Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Treatment Noncompliance; Weight Decreased	Duloxetine			S	Unknown	60 Milligram, Daily		Aurobindo
	Olanzapine			S	Unknown	15 Milligram, Daily		Aurobindo
	Mirtazapine			S	Unknown	30 Milligram, Daily		Aurobindo
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported
	Quetiapine			S	Unknown	800 Milligram, Daily		Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported
	Doxepine			S	Unknown	100 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760974	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Expiration Date Issue; Product Lot Number Issue	Escitalopram Oxalate			S	Oral			Bluepoint Laboratories

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15761322	EXPEDITED (15-DAY)		HO	PHHY2018IT194748		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Sluggishness	Escitalopram Oxalate			S	Oral	30 MI, Once/Single (Total)		Not Reported	
	Alprazolam			S	Oral	20 MI, Once/Single (Total)		Not Reported	
	Omeprazole			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15761636	EXPEDITED (15-DAY)		OT	FI-GLAXOSMITHKLINE- FI2018GSK231885		46 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Metoclopramide Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
Acute Sinusitis;	Amoxicillin Trihydrate			S	Oral	Unk Tablet		Glaxosmithkline	
Adjustment Disorder With	Amoxicillin Trihydrate			S				Glaxosmithkline	
Mixed Anxiety And	Amoxin			S	Oral	Unk		Glaxosmithkline	
Depressed Mood; Adrenal	Nicorette			S	Unknown	2 Mg, Unk Gum		Glaxosmithkline	
Insufficiency; Aggression;	Nicorette			S	Unknown	Unk Patch		Glaxosmithkline	
Agitation; Akathisia;	Sertraline			S	Unknown	0.5 Df, Qd		Glaxosmithkline	
Anxiety; Blood Cholesterol	Ciprallex			S	Unknown	Unk		Not Reported	
Increased; Blood Glucose	Champix			S	Oral	0.5 Mg, Qd		Not Reported	
Increased;	Champix			S	Oral	Unk 0.5		Not Reported	
Cerebrovascular Accident;	Champix			S	Unknown	1 Mg, Bid		Not Reported	
Confusional State;	Rinexin			S	Oral	50 Mg, Unk		Not Reported	
Craniocerebral Injury;	Azithromycin			C		Unk		Glaxosmithkline	
Depression; Dizziness;	Havrix			C				Glaxosmithkline	
Drug Dependence; Drug	Klacid			C		Unk		Not Reported	
Interaction; Dyskinesia;	Toclase			C		Unk		Not Reported	
Dyspnoea; Erectile	Doximycin			C		Unk		Not Reported	
Dysfunction; Erythema;									
Euphoric Mood; Fatigue;									
Fear; Feeling Abnormal;									
Feeling Cold; Gastric									
Disorder; General Physical									
Health Deterioration;									
Hallucination; Hepatic									

Steatosis; Hyperhidrosis;
Hypersensitivity;
Hypopituitarism;
Hyposmia;
Hypothyroidism; Increased
Appetite; Infection;
Influenza; Irritability; Loss
Of Libido; Loss Of
Personal Independence In
Daily Activities; Lower
Respiratory Tract
Infection; Medication
Error; Memory
Impairment; Mood Swings;
Musculoskeletal
Discomfort; Nausea;
Neurotoxicity; Nightmare;
Obesity; Olfacto Genital
Dysplasia; Overweight;
Palpitations; Panic
Reaction; Parkinson'S
Disease; Personality
Change; Restlessness;
Secondary
Hypogonadism; Sense Of
Oppression; Sleep
Disorder; Snoring;
Swelling; Tinnitus; Tremor;
Upper Respiratory Tract
Infection; Vasodilatation;
Vertigo; Weight Increased;
Withdrawal Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15762637	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1095751		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported	

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26-Dec-2018	15762686	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1095772		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Medication Error	Escitalopram			S	Oral	35 Gtt Drops, Once		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15763032	NON-EXPEDITED			US-AMGEN-USASP2018184248			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Aimovig			S	Unknown	70 Mg, Unk		Amgen	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15763205	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-062408		83 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Candesartan			S	Oral	16 Milligram, Daily		Not Reported	
	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo	
	Spironolactone			S	Oral	25 Milligram, Daily		Aurobindo	
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported	
	Imovane			S	Oral	1 Dosage Form, Daily		Not Reported	
	Lasilix /00032601/			S	Oral	4 Dosage Form, Daily		Not Reported	
	Omexel			S	Oral	1 Dosage Form, Daily		Not Reported	
	Tenordate			S	Oral	1 Dosage Form, Daily		Not Reported	
	Seebri Breezhaler			C	Unknown	Unk		Not Reported	
	Lovenox			C	Unknown	Unk		Not Reported	
	Kardegic			C	Unknown	Unk		Not Reported	

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Avodart			C		Unknown	Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	14313413	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2017M1079666		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose; Labelled Drug-Drug Interaction Medication Error	Quetiapine			S	Oral	19 G, Total		Not Reported	
	Escitalopram			S	Oral	30 Mg, Total		Not Reported	
	Abilify			S	Oral	30 Mg, Qd		Mylan	
	Valproato			S	Oral	3.6 Mg, Total		Mylan	
	Antabus			S	Oral	250 Mg, Qd		Mylan	
	Clonazepam			S	Oral	22.5 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15764573	EXPEDITED (15-DAY)		HO	FR-ZYDUS-031797		83 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral			Zydus Pharm	
	Imovane			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Lasilix			S	Oral			Not Reported	
	Omexel			S	Oral			Not Reported	
	Candesartan Cilexetil			S	Oral			Zydus Pharm	
	Spirolonolactone			S	Oral			Zydus Pharm	
	Tenordate			S	Oral			Not Reported	
	Seebri Breezhaler			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Acetylsalicylate			C				Not Reported	
	Lysine/Acetylsalicylic Acid								
	Dutasteride			C				Not Reported	

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27-Dec-2018	15765310	EXPEDITED (15-DAY)		OT	FI-SA-2018SA390556		46 YR	Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Metoclopramide Hydrochloride			S		Unk		Not Reported
Acute Sinusitis;	Klacid [Clarithromycin]			C	Oral	Ten Days Course		Not Reported
Adjustment Disorder With	Azithromycin			C	Oral	3		Not Reported
Mixed Anxiety And	Amoxicillin Trihydrate			S	Oral	Tablet		Not Reported
Depressed Mood; Adrenal	Amoxicillin Trihydrate			S				Not Reported
Insufficiency; Aggression;	Ciprallex [Escitalopram]			S		Unk		Not Reported
Agitation; Akathisia;	Havrix			C	Intramuscular	Unk		Not Reported
Anxiety; Blood Cholesterol	Toclase [Pentoxifyverine Citrate]			C		Unk		Not Reported
Increased; Blood Glucose	Amoxin			S	Oral	Unk		Not Reported
Increased;	Doximycin			C	Oral	Unk		Not Reported
Cerebrovascular Accident;	Nicorette			S		2 Mg, Unk Gum		Sanofi
Confusional State;	Nicorette			S		Patch		Sanofi
Confusional State;	Champix			S	Oral	0.5 Mg, 1x/Day, Film		Not Reported
Craniocerebral Injury;	Champix			S		Coated Tablet		Not Reported
Depression; Depression;	Champix			S	Oral	0.5 Unk, Film-Coated		Not Reported
Dizziness; Drug	Sertraline			S		Tablet		Not Reported
Dependence; Drug	Rinexin			S	Oral	0.5 Df, Qd		Not Reported
Interaction; Dyskinesia;						50 Mg, Unk		Not Reported
Dyspnoea; Erectile								
Dysfunction; Erythema;								
Euphoric Mood; Fatigue;								
Fear; Feeling Abnormal;								
Feeling Cold; Gastric								
Disorder; General Physical								
Health Deterioration;								
Hallucination; Hepatic								
Steatosis; Hyperhidrosis;								
Hypersensitivity;								
Hypopituitarism;								
Hyposmia;								
Hypothyroidism;								
Hypothyroidism; Increased								
Appetite; Infection;								
Influenza; Irritability; Loss								
Of Libido; Loss Of								
Personal Independence In								

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Daily Activities; Lower
Respiratory Tract
Infection; Medication
Error; Memory
Impairment; Mood Swings;
Musculoskeletal
Discomfort; Nausea;
Neurotoxicity; Nightmare;
Obesity; Olfacto Genital
Dysplasia; Overweight;
Palpitations; Panic
Reaction; Parkinson'S
Disease; Personality
Change; Restlessness;
Secondary
Hypogonadism; Sense Of
Oppression; Sleep
Disorder; Snoring;
Swelling; Tinnitus; Tremor;
Upper Respiratory Tract
Infection; Vasodilatation;
Vertigo; Weight Increased;
Withdrawal Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15767263	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1859370US		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Microcytic Anaemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Xarelto			S	Oral	15 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15767525	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20181225291		91 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Trismus	Haldol			S	Oral			Not Reported	
	Haldol			S	Oral	Max 3 Times A Day		Not Reported	

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Haldol	S	Oral	Max 3 Times A Day	Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Quetiapine	S	Oral		Not Reported
Ondansetron	S	Subcutaneous		Not Reported
Ondansetron	S	Subcutaneous		Not Reported
Ciprallex	S	Oral		Not Reported
Ciprallex	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Ondansetron	S	Oral		Not Reported
Calciparine	C	Unknown		Not Reported
Clomethiazole Edisilate	C	Unknown		Not Reported
Temesta [Lorazepam]	C	Unknown		Not Reported
Xanax	C	Unknown		Not Reported
Aprovel	C	Unknown		Not Reported
Physiotens	C	Unknown		Not Reported
Zanidip	C	Unknown		Not Reported
Euthyrox	C	Unknown		Not Reported
Mycostatine	C	Unknown		Not Reported
Laxoberon	C	Unknown		Not Reported

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Laxoberon	C	Unknown	Not Reported
Aldactone	C	Unknown	Not Reported
Dafalgan	C	Unknown	Not Reported
Phosphoric Acid Sodium	C	Unknown	Not Reported
Midazolam Hydrochloride	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15767827	EXPEDITED (15-DAY)		HO, OT	CH-OTSUKA-2015_014491		93 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Confusional State; Encephalopathy; Enterococcus Test Positive; Extrapyrimalidal Disorder; Loss Of Consciousness; Malaise; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Abilify			S	Oral	Unk		Otsuka
	Ciprallex			S	Oral	20 Mg, Qd		Not Reported
	Ciprallex			S	Oral	10 Mg, Qd		Not Reported
	Keppra			S	Oral	250 Mg, Bid		Not Reported
	Keppra			S	Oral	250 Mg, Qd		Not Reported
	Amoxicillin Sodium			S	Oral	500 Mg, Bid		Not Reported
	Valdoxan			C	Oral	25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.25 Mg, Qd		Not Reported
	Xanax			C	Oral	0.125 Mg, Qd		Not Reported
	Temesta [Lorazepam]			C	Oral	0.5 Mg, Qd		Not Reported
	Aspirin Cardio			C	Unknown	100 Mg, Unk		Not Reported
	Nexium			C	Oral	20 Mg, Qd		Not Reported
	Anxiolit			C	Oral	15 Mg, Qid		Not Reported
	Anxiolit			C	Oral	15 Mg, Qid		Not Reported
	Anxiolit			C	Oral	7.5 Mg, Qid		Not Reported
	Prednisone			C	Oral	2.5 Mg, Qd		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported
	Valtrex			C	Oral	500 Mg, Qd		Not Reported
	Vitamine B6			C	Oral	40 Mg, Qd		Not Reported

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	Metoject		C	Subcutaneous	15 Mg, Qwk			Not Reported	
	Laxoberon		C	Oral	5 Mg, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15768092	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2018M1097097		45 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypomania	Venlafaxine			S	Unknown	37.5 Milligram, Qd		Not Reported	
	Venlafaxine			S	Unknown	187.5 Milligram, Qd		Not Reported	
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported	
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported	
	Prednisolone			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15769889	DIRECT	Y	OT			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Palpitations; Ventricular Extrasystoles	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	14302902	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2017-ES-835842		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Intentional Overdose; Labelled Drug-Drug Interaction Medication Error	Escitalopram			S	Oral	30 Mg, In Total		Not Reported	
	Quetiapine			S	Oral	19 Gram In Total		Not Reported	
	Clonazepam (635a)			S	Oral	22.5 Mg, In Total		Not Reported	
	Valproato Sodio (3194so)			S	Oral	3.6 Mg, In Total		Not Reported	
	Antabus 250 Mg Comprimidos , 40 Comprimidos			S	Oral			Not Reported	
	Abilify 15 Mg Comprimidos, 28 Comprimidos			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	14574141	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2018M1012872		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral	Unk			Not Reported
	Enoxaparina Sodica			S	Subcutaneous	Unk			Mylan
	Sintrom			S	Oral	Unk			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	14987926	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bundle Branch Block Left; Clonus; Hyperreflexia; Hypotension; Loss Of Consciousness; Muscle Rigidity; Overdose; Rhabdomyolysis; Sinus Tachycardia; Tachycardia	Escitalopram			S	Oral				Hikma
	Lamotrigine			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15702482	EXPEDITED (15-DAY)		HO, LT	GR-ACCORD-095165		67 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Clonus; Confusional State; Delayed Recovery From Anaesthesia; Disorientation; Drug Interaction; Fear; Hyperpyrexia; Hyperreflexia; Mental	Escitalopram			S	Unknown				Not Reported
	Methylthioninium			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk			Not Reported

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Status Changes; Muscle
Rigidity; Mydriasis;
Psychomotor
Hyperactivity; Serotonin
Syndrome

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28-Dec-2018	15738152	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-987689		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Sensory Disturbance	Ciprallex			S	Oral			Not Reported	
	Lamictal			C	Oral			Not Reported	
	Rivotril 0,5 Mg Comprese			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15768701	EXPEDITED (15-DAY)		OT	ES-ZYDUS-032127			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Medication Error	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15768833	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061898		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral			Aurobindo	
	Gabapentin			S	Oral			Aurobindo	
	Ibuprofen			S	Oral			Aurobindo	
	Ethanol			S	Oral			Not Reported	
	Amitriptyline			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769171	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-992506		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Dosage Forms Daily;		Ivax	
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Omexel L.P. 0,4 Mg, Comprimé Pelliculé À Libération Prolongée			C	Unknown			Not Reported	
	Candesartan Cilexetil			C				Not Reported	
	Seebri Breezhaler			C				Not Reported	
	Avodart 0,5 Mg, Capsule Molle			C				Not Reported	
	Seresta 10 Mg, Comprimé			C				Not Reported	
	Tenordate			C				Not Reported	
	Imovane 7,5 Mg, Comprimé Pelliculé Sécable			C				Not Reported	
	Spiroonolactone			C				Not Reported	
	Lasilix 40 Mg, Comprimé Sécable			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769211	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-AUROBINDO-AUR-APL-2018-062672		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Abuse; Respiratory Arrest	Escitalopram			S	Unknown			Aurobindo	
	Alprazolam			S				Aurobindo	
	Cocaine			S	Unknown			Not Reported	
	Bupropion			S	Unknown			Not Reported	
	Ethanol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769245	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-AUROBINDO-AUR-APL-2018-062757		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram	S	Unknown	Aurobindo
	Diphenhydramine	S	Unknown	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769358	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-062792		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Unknown			Aurobindo	
	Lamotrigine			S	Unknown			Aurobindo	
	Mirtazapine			S	Oral			Aurobindo	
	Cyclobenzaprine			S	Oral			Aurobindo	
	Buspirone Hydrochloride			S	Oral			Aurobindo	
	Clonazepam			S				Not Reported	
	Activated Charcoal			S	Oral			Not Reported	
	Propranolol			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769512	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-060653		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral			Aurobindo	
	Loratadine			S	Oral			Aurobindo	
	Ethylene Glycol			S	Oral			Not Reported	
	Furosemide			S	Oral			Not Reported	
	Levothyroxine			S	Oral			Not Reported	
	Folic Acid			S	Oral			Not Reported	
	Vitamin B1 /00056101/			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769567	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-060703		43 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral			Aurobindo	
	Lorazepam			S	Oral			Aurobindo	
	Lithium			S	Oral			Not Reported	
	Amitriptyline			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769586	EXPEDITED (15-DAY)		OT	NL-ACCORD-098423		67 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma	Escitalopram			S				Not Reported	
	Lorazepam			C		1mg 1x Per Dag		Not Reported	
	Levocetirizine/Levocetirizine			C				Not Reported	
	Dihydrochloride								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769587	EXPEDITED (15-DAY)		OT	NL-ACCORD-098653		16 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea Haemorrhagic; Hypertension; Tachycardia	Escitalopram			S		1x Daily 2 Tablets,10mg		Not Reported	
	Quetiapine			S		25 Mg, Half A Tablet For The Night		Not Reported	
	Colecalciferol			C		1 X 1		Not Reported	
	Melatonin			C		1 Mg 1 X 1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769785	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE- HET2018DE01587			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Kidney Duplex	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero	

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Escitalopram	S		5 Mg, Qd	Hetero
Magnetrans	C	Transplacental	Unk	Not Reported
Ibuprofen	C	Transplacental	400 Mg, On Demand, Max Once Per Week	Not Reported
Cetirizine	C	Transplacental	Unk	Not Reported
Paracetamol	C	Transplacental	1500 Mg (1000-1500 Mg Per Day)	Not Reported
Cytotec	C	Transplacental	Unk	Not Reported
Olynth	C	Transplacental	If Required	Not Reported
Folio Forte	C	Transplacental	0.8 Mg, Qd	Not Reported
Folio Forte	C		0.4 Mg, Qd (From Week 14)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769884	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-194822		83 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Sun
	Candesartan			S	Oral	16 Milligram, Qd		Not Reported
	Omexel L.P. 0,4 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	1 Dosage Form, Qd		Not Reported
	Imovane			S	Oral	1 Dosage Form, Qd		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	1 Dosage Form, Qd		Not Reported
	Lasilix 40 Mg, Comprime			S	Oral	4 Dosage Form, Qd		Not Reported
	Secable							
	Tenordate, Gelule			S	Oral	1 Dosage Form, Qd		Not Reported
	Seebri Breezhaler			C	Unknown	()		Not Reported
	Lovenox 4 000 Ui Anti-Xa/0,4 Ml, Solution Injectable En Cartouche			C	Unknown	()		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-			C	Unknown	()		Not Reported

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Dose
Avodart 0,5 Mg, Capsule Molle

C

Unknown

()

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15769972	EXPEDITED (15-DAY)		OT	IT-ACCORD-098383		42 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15770637	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1000014091		46 YR	Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
Acute Sinusitis;	Champix			S	Oral	1 Mg, Bid		Not Reported
Adjustment Disorder With	Champix			S	Oral	0.5 Mg, Bid		Not Reported
Mixed Anxiety And	Champix			S	Oral	.5 Mg, Qd		Not Reported
Depressed Mood; Adrenal	Champix			S	Oral	50 Mg, Qd		Not Reported
Insufficiency; Aggression;	Rinexin			S	Oral	Unk		Not Reported
Agitation; Akathisia;	Metoclopramide			S	Unknown	50 Mg 1/2 Tablet, Qd		Not Reported
Anxiety; Blood Cholesterol	Sertraline			S	Unknown	2 Mg, Unk		Not Reported
Increased; Blood Glucose	Nicorette Gum			S	Transdermal	Unk		Not Reported
Increased;	Nicorette Patch			S	Oral	Unk		Not Reported
Cerebrovascular Accident;	Amoxin			S	Oral	Unk		Not Reported
Confusional State;	Amoxin			S	Oral	Unk		Not Reported
Confusional State;	Klacid			C		10 Days Course		Not Reported
Craniocerebral Injury;	Havrix			C		Unk		Not Reported
Depression; Depression;	Doximycin			C	Oral	Unk		Not Reported
Dizziness; Drug	Azithromycin			C	Oral	Unk		Not Reported
Interaction; Dyskinesia;	Toclase			C		Unk		Not Reported
Dyspnoea; Erectile								
Dysfunction; Erythema;								
Euphoric Mood; Fatigue;								
Fear; Feeling Abnormal;								
Feeling Cold; Gastric								
Disorder; General Physical								
Health Deterioration;								
Hallucination; Hepatic								

Steatosis; Hyperhidrosis;
Hypersensitivity;
Hypopituitarism;
Hyposmia;
Hypothyroidism;
Hypothyroidism; Increased
Appetite; Infection;
Influenza; Irritability; Loss
Of Libido; Loss Of
Personal Independence In
Daily Activities; Lower
Respiratory Tract
Infection; Medication
Error; Memory
Impairment; Mood Swings;
Musculoskeletal
Discomfort; Nausea;
Neurotoxicity; Nicotine
Dependence; Nightmare;
Obesity; Olfacto Genital
Dysplasia; Overweight;
Palpitations; Panic
Reaction; Parkinson'S
Disease; Personality
Change; Restlessness;
Secondary
Hypogonadism; Sense Of
Oppression; Sleep
Disorder; Snoring;
Swelling; Tinnitus; Tremor;
Upper Respiratory Tract
Infection; Vasodilatation;
Vertigo; Weight Increased;
Withdrawal Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15770638	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1859390US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan	

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Pregnancy; Kidney Duplex	Escitalopram Oxalate - Bp	S	Transplacental	10 Mg, Qd	Allergan
	Magnetrans	C	Transplacental	Additional Info: 20. - 36.6. Gestational Week	Not Reported
	Ibuprofen	C	Transplacental	400 Mg, Prn, Max Once Per Week; 0. - 28. Gestational Week, 0. - 28. Gestational Week	Not Reported
	Cetirizine	C	Transplacental	Additional Info: 25.4. - 29.6. Gestational Week	Not Reported
	Paracetamol	C	Transplacental	1500 Mg, Qd; 1000-1500 Mg/D, In Total 2-3 Times; Additional Info: 28. - 36.6. Gestational Week	Not Reported
	Cytotec	C	Transplacental	36.6. Gestational Week	Not Reported
	Olynth	C	Transplacental	Prn; Additional Info: 19.1. - 23.4. Gestational Week	Not Reported
	Folio Forte	C	Transplacental	0.8 Mg, Qd	Not Reported
	Folio Forte	C	Transplacental	0.4 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15772002	EXPEDITED (15-DAY)		HO, OT	PT-ENDO PHARMACEUTICALS INC-2018-043657		64 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mania	Tramadol Hydrochloride			S	Unknown	225 Mg, Daily		Par
	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported
	Amitriptyline			S	Unknown	25 Mg, Daily		Not Reported
	Levofloxacin			C	Unknown	500 Mg, Daily		Not Reported
	Acetaminophen			C	Unknown	3000 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15772389	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-991456		83 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	5 Milligram Daily;		Not Reported
	Candesartan Cilexetil			S	Oral	16 Milligram Daily;		Not Reported
	Spiroglactone			S	Oral	25 Milligram Daily;		Not Reported
	Imovane			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seresta 10 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported
	Lasilix 40 Mg, Comprimé			S	Oral	4 Dosage Forms Daily;		Not Reported
	Sécable							
	Omexel L.P. 0,4 Mg, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported
	Pelliculé À Libération Prolongée							
	Tenordate, Gélule			S	Oral	1 Dosage Forms Daily;		Not Reported
	Seebri Breezhaler			C				Not Reported
	Lovenox 4 000 Ui Anti-Xa/0,4 MI,			C				Not Reported
	Solution Injectable En Cartouche							
	Kardegic 75 Mg, Poudre Pour			C				Not Reported
	Solution Buvable En Sachet-Dose							
	Avodart 0,5 Mg, Capsule Molle			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15772781	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181233876		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Microcytic Anaemia	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15772914	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018019384			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	Unk, 10 [Mg/D]/ Dosage Reduction To 5mg/D		Macleods

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Paracetamol	C	Transplacental	Before Stop, 0. - 8. Gestational Week, 1 {Trimester}	Not Reported
Cetirizine	C	Transplacental	Unk, 1500 [Mg/D]/ 1000- 1500 Mg/D, In Total 2-3 Times, 28. - 36.6. Gestational Week, 3 {Trimester}	Not Reported
Cytotec	C	Transplacental	Unk, 25.4. - 29.6. Gestational Week, 2 {Trimester}	Not Reported
Folic Acid	C	Transplacental	Unk, 36.6. - 36.6. Gestational Week, 3 {Trimester}	Not Reported
Ibuprofen	C	Transplacental	Unk, 0.8 [Mg/D]/ From Week 14, 0.4mg/D, 0. - 36.6. Gestational Week, 1 {Trimester}	Not Reported
Magnesium Aspartate Hydrochloride	C	Transplacental	Unk, 400 [Mg/D]/ On Demand, Max Once Per Week, 0. - 28. Gestational Week, 1 {Trimester}	Not Reported
Olynth	C	Transplacental	Unk, 20. - 36.6. Gestational Week, 2 {Trimester}	Not Reported
	C	Transplacental	Unk, 19.1. - 23.4. Gestational Week , 2 {Trimester}, If Required	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15773522	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR- APL-2018-061107		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Metformin			S	Unknown			Aurobindo
	Glyburide			S	Unknown			Aurobindo

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Escitalopram	S	Oral	Aurobindo
Losartan	S	Oral	Aurobindo
Lorazepam	S	Oral	Aurobindo
Diltiazem	S	Unknown	Not Reported
Propranolol	S	Unknown	Not Reported
Levothyroxine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15773542	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR- APL-2018-061711		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Oral			Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Acetaminophen			S	Oral			Aurobindo
	Ethanol			S	Oral			Not Reported
	Propranolol			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Cocaine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15773546	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR- APL-2018-061733		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Flecainide			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Verapamil			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15773651	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR- APL-2018-063083		63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Diphenhydramine			S	Unknown			Aurobindo	
	Fluoxetine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Risperidone			S	Oral			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15773657	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063080		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Venlafaxine			S	Oral			Aurobindo	
	Escitalopram			S	Oral			Aurobindo	
	Bupropion			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15785334	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error	Escitalopram Oxalate			S	Oral			Not Reported	
	Escitalopram								
	Escitalopram Oxalate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15857362	DIRECT					19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hypersomnia; Malaise; Non-24-Hour Sleep-Wake Disorder; Presyncope; Sedation	Escitalopram (Generic Lexapro) 20mg	Y		S	Oral	Quantity:1 Df Dosage Form;		Not Reported	
	Escitalopram (Generic Lexapro) 20mg	Y		S				Not Reported	
	Deplin			C				Not Reported	

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		Vit C		C					Not Reported
		Fish Oil		C					Not Reported
		Zinc		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15725143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-059400		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous	Auro-Escitalopram Tablets			S	Oral	15 Milligram, Daily		Aurobindo	
	Acetaminophen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15773660	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-063091		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Losartan			S	Oral			Aurobindo	
	Salicylic Acid			S	Oral			Not Reported	
	Bupropion			S	Unknown			Not Reported	
	Levothyroxine			S	Oral			Not Reported	
	Ethanol			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15773727	EXPEDITED (15-DAY)		DE, LT, OT	US-AUROBINDO-AUR-APL-2018-063564		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Escitalopram			S	Oral			Aurobindo	
	Bupropion			S	Oral			Not Reported	

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15773856	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-063417			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kidney Duplex	Escitalopram			S	Transplacental	Unk, 10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Aurobindo
	Magnesium Aspartate			C	Transplacental	Unk		Not Reported
	Hydrochloride			C	Transplacental	Unk, 400 [Mg/D]/ On Demand, Max Once Per Week		Not Reported
	Ibuprofen			C	Transplacental	Unk		Not Reported
	Cetirizine			C	Transplacental	Unk		Not Reported
	Paracetamol			C	Transplacental	Unk, 1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Olynth			C	Transplacental	Unk		Not Reported
	Folic Acid			C	Transplacental	Unk, 0.8 [Mg/D]/ From Week 14 0.4mg/D		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15773915	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-061627		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Metformin			S	Oral	Unk		Aurobindo
	Alprazolam			S	Oral			Aurobindo
	Naproxen			S	Oral			Aurobindo
	Escitalopram			S	Oral			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15773939	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2018-062211		56 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Carvedilol			S	Oral			Aurobindo	
	Escitalopram			S	Oral			Aurobindo	
	Mirtazapine			S				Aurobindo	
	Divalproex			S	Oral			Aurobindo	
	Phenytoin			S				Aurobindo	
	Primidone			S	Oral			Not Reported	
	Sitagliptin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15774000	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR- APL-2018-063097		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Unknown			Aurobindo	
	Lamotrigine			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15774188	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR- APL-2018-061011		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral			Aurobindo	
	Lamotrigine			S	Oral			Aurobindo	
	Oxycodone+Acetaminophen			S	Oral			Aurobindo	
	Propranolol			S	Oral			Not Reported	
	Ibuprofen			S				Aurobindo	
	Montelukast			S				Aurobindo	
	Ondansetron			S				Aurobindo	
	Aciclovir			S				Aurobindo	
	Alprazolam			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15774430	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-063628			Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Medication Error	Escitalopram			S	Oral	30 Milligram, In Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	13553262	EXPEDITED (15-DAY)		HO	IT-ACCORD-051430		19 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Intentional Overdose; Intentional Self-Injury; Nausea; Tremor	Escitalopram			S	Oral	200 Mg Total		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	14600990	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2018-ES-864907		79 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Escitalopram			S	Oral			Ivax	
	Enoxaparina Sodica			S	Subcutaneous			Not Reported	
	Sintrom			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15756363	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2018519766		52 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Alprazolam			S		Unk		Pfizer	
	Zoledronic Acid			S	Intravenous (not otherwise specified)	4 Mg, Unk		Unknown	
	Gabapentin			S		Dosage Being Set At 300-600-600 Mg/Day		Pfizer	

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Trazodone	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Lidocaine	S		Not Reported
Betamethasone	S	Unk	Not Reported
Betamethasone	S	Unk	Not Reported
Heparin	S	Unk	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Not Reported
Morphine	S	Subcutaneous	60 Mg + 10 Mg Every 12 Hours
Morphine	S	Oral	60 Mg + 10 Mg Every 12 Hours
Valproic Acid	S		400 Mg, Diluted, Was Administered By Infusion Over Three Consecutive Days
Effentora	S	Buccal	400 Ug, 2x/Day
Sodium Phosphate	S		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775225	EXPEDITED (15-DAY)		HO	LT-ACCORD-098326		46 YR	Female	LTU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Dizziness; Insomnia; Speech Disorder	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Zolpidem			S	Oral			Not Reported
	Etoricoxib			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775260	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-098697		93 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Intracranial Haematoma	Escitalopram	S	Oral	Not Reported
	Kardegic	S		
	Levocetirizine	C		
	Amlodipine	C		
	Levothyroxine	C		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775271	EXPEDITED (15-DAY)		OT	FR-ACCORD-098473		90 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775404	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-992881		< 1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kidney Duplex	Escitalopram			S	Transplacental	10 [Mg/D]/ Dosage Reduction To 5mg/D Before Stop		Ivax
	Magnetrans			C	Transplacental			Not Reported
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Not Reported
	Cetirizine			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Not Reported
	Cytotec			C	Transplacental			Not Reported
	Olynth			C	Transplacental	If Required		Not Reported
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775512	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-993178		52 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Not Informed		Not Reported	
	Escitalopram			S	Unknown	Not Informed		Ivax	
	Dafalgan Codeine			S	Unknown	Not Informed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775913	EXPEDITED (15-DAY)		HO, OT	AT-ACCORD-060297		47 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Paraesthesia; Serotonin Syndrome	Escitalopram			S	Oral	Also Received At Dose Of 5 Mg From 16-Aug-2017 To 20-Aug-2017.		Accord	
	Alprazolam			S	Unknown	Also Received 1 Mg		Not Reported	
	Seropram (Citalopram Hydrobromide)			S	Intravenous (not otherwise specified)	Strength: 20 Mg 8 Infusions Total		Not Reported	
	Xanor			C				Not Reported	
	Temesta [Lorazepam]			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15777149	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1859386US		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Depression; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Valium			S	Unknown	Unk		Not Reported	
	Dapsone			C	Unknown	100 Mg, Qd		Not Reported	
	Infliximab			C	Unknown	10 Mg/Kg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2019	15779646	NON-EXPEDITED			DE-ALKEM LABORATORIES LIMITED-DE-ALKEM- 2018-03356			Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	0.5 G, Qd		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	14083049	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-M-EU-2017060449		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Ivabradine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Sertraline			S	Unknown	50 Mg Milligram(S) Every Days		Not Reported
	Zolpidem			S	Oral	10 Milligram, Hs		Not Reported
	Venlafaxine			S	Oral	150 Mg Milligram(S) Every Days		Not Reported
	Moklar			S		150 Mg Milligram(S) Every Days		Mylan
	Cyproheptadine			S				Mylan
	Sotalol			C				Mylan
	Warfarin			C		Unk		Mylan
	Ginkgo Biloba Extract			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	14332067	EXPEDITED (15-DAY)		HO	IN-CIPLA (EU) LIMITED-2017IN27246			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Incontinence;	Escitalopram			S	Unknown	10 Mg, Unk		Invagen

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General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Urinary Incontinence	Escitalopram	S	Unknown	20 Mg, Unk	Invagen
	Amlodipine	C	Unknown	10 Mg, Unk	Not Reported
	Rosuvastatin	C	Unknown	20 Mg, Unk	Not Reported
	Metformin	C	Unknown	1 G, Unk	Not Reported
	Sitagliptin	C	Unknown	100 Mg, Unk	Not Reported
	Aspirin /00002701/	C	Unknown	75 Mg, Unk	Not Reported
	Clonazepam	C	Unknown	0.5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	14699281	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1018471		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Hyponatraemia	Enalapril			S	Oral	20 Milligram, Qd (1-0-0)		Not Reported	
	Heipram			S	Oral	10 Milligram, Qd (0-0-1)		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15363277	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1843980US		65 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar I Disorder	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15525848	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1849435US		77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Agitation; Asthenia; Confusional State; Delusion; Drug Interaction; Hallucination; Hallucination, Visual; Hypertension; Major	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Unknown	Unk, Unknown		Allergan	
	Elavil			S	Unknown	Unk Unk, Unknown		Not Reported	
	Amitriptyline			S	Oral	25 Mg, Qd		Not Reported	
	Elenbecestat			S	Oral	5 Mg, Unk		Not Reported	

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Depression; Mental Status Changes; Paranoia	Lipitor	C	Unknown	Unk Unk, Unknown	Not Reported
	Diovan	C	Unknown	Unk Unk, Unknown	Not Reported
	Actos	C	Unknown	Unk Unk, Unknown	Not Reported
	Trazodone	C	Unknown	Unk Unk, Unknown	Not Reported
	Aricept	C	Unknown	Unk Unk, Unknown	Not Reported
	Magnesium Oxide	C	Unknown	Unk Unk, Unknown	Not Reported
	Vitamin D2	C	Unknown	Unk Unk, Unknown	Not Reported
	Centrum Silver	C	Unknown	Unk Unk, Unknown	Not Reported
	Lovaza	C	Unknown	Unk Unk, Unknown	Not Reported
	Pioglitazone	C	Unknown	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15762414	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1095041		71 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Risperidone			S	Oral	1 Milligram, Qd (0.5 Mg Matin Et Soir)		Not Reported
	Olanzapine Mylan			S	Oral	5 Milligram, Qd (5 Mg Le Soir)		Mylan
	Loxapine Succinate			S	Oral	5 Gtt Drops (5 Gouttes Si Besoin)		Mylan
	Escitalopram Arrow			S	Oral	10 Milligram, Qd (10 Mg Le Soir)		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15780361	EXPEDITED (15-DAY)		OT	ES-ACCORD-099271		40 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thyroid Mass	Escitalopram			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15780690	NON-EXPEDITED			US-TEVA-2018-US-984680			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Escitalopram			S	Unknown			Ivax	
	Alprazolam			C	Unknown	2 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15781856	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US040731		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatitis; Drug Interaction;	Asp2215			S	Oral			Astellas	
Electrocardiogram Qt Prolonged; Febrile Neutropenia; Febrile Neutropenia; Pneumonia; Sinus Bradycardia; Somnolence; Syncope	Asp2215			S	Oral			Astellas	
	Asp2215			S	Oral			Astellas	
	Amitriptyline			S	Oral			Not Reported	
	Amitriptyline			S	Oral	Unk Unk, Unknown Freq. (Reduced Doe)		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Escitalopram			S	Oral	Unk Unk, Unknown Freq. (Redced Dose)		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported	
	Voriconazole			S				Not Reported	
	Decadron /00016001/			S	Oral			Not Reported	
	Decadron /00016001/			S	Oral			Not Reported	
	Decadron /00016001/			S	Oral			Not Reported	
	Hydrea			C	Oral			Not Reported	
	Pentamidine			C	Unknown	Unk Unk, Monthly, Nebulized		Not Reported	
	Valtrex			C	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15782174	EXPEDITED (15-DAY)		OT	QA-IMPAX LABORATORIES, LLC- 2018-IPXL-04402		49 YR	Male	QAT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Oxybutynin Chloride Er			S	Oral	5 Milligram, Bid		Impax	
	Atorvastatin			S	Oral	40 Milligram, Daily		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15782524	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018533356		83 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Spironolactone			S	Oral	25 Mg, 1x/Day		Pfizer	
	Escitalopram			S	Oral	5 Mg, 1x/Day		Not Reported	
	Imovane			S	Oral	1 Df, 1x/Day		Not Reported	
	Seresta			S	Oral	1 Df, 1x/Day		Not Reported	
	Lasilix [Furosemide]			S	Oral	4 Df, 1x/Day		Not Reported	
	Omexel			S	Oral	1 Df, 1x/Day		Not Reported	
	Candesartan Cilexetil			S	Oral	16 Mg, 1x/Day		Not Reported	
	Tenordate			S	Oral	1 Df, 1x/Day		Not Reported	
	Seebri Breezhaler			C		Unk		Not Reported	
	Lovenox			C		Unk		Not Reported	
	Kardegic			C		Unk		Not Reported	
	Avodart			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15782557	EXPEDITED (15-DAY)		HO, OT	US-TORRENT- 00007345		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Catatonias; Condition	Risperidone	S	Unknown	Unknown
Aggravated; Depression;	Topiramate	S	Unknown	Unknown
Hallucination, Auditory;	Escitalopram	S	Unknown	Unknown
Joint Stiffness; Off Label	Lorazepam	S	Unknown	Unknown
Use; Orthostatic				
Hypotension; Suicidal				
Ideation				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15783056	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1900021US		55 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscular Weakness;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
Parkinson'S Disease	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15783057	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1859821US		35 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase	Escitalopram Oxalate - Bp			S	Oral			Allergan	
Increased; Gamma-	Solanax			C	Oral			Not Reported	
Glutamyltransferase	Loramet			C	Oral			Not Reported	
Increased; Seizure									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15783131	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-994258		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache;	Escitalopram Oxalate			S	Oral			Ivax	
Sluggishness	Alprazolam			S	Oral			Actavis	
	Omeprazole			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15783696	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1900022US		55 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Marrow Failure; Underdose; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	2.5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Nauzelin			C	Oral	10 Mg, Qd		Not Reported	
	Belsomra			C	Oral	20 Mg, Qd		Not Reported	
	Vitaneurin			C	Oral	50 Mg, Unk		Not Reported	
	Actos			C	Oral			Not Reported	
	Januvia			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15798601	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensed To Wrong Patient; Wrong Product Administered	Escitalopram 10mg			S				Not Reported	
	Alprazolam 0.25mg			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	13708554	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-BAUSCH-BL-2017-020458		62 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial	Venlafaxine			S	Oral	150 Mg; Every Day		Not Reported	
	Zolpidem			S	Oral	10 Mg, At Bedtime (Before A Sleep)		Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Ivabradine			S	Unknown			Not Reported	

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Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Metoprolol	S	Unknown		Not Reported
	Moklar	S	Oral	150 Mg In Afternoon	Not Reported
	Sertraline	S	Oral	50 Mg, At Night	Not Reported
	Moklar	S	Unknown	In The Afternoon	Not Reported
	Cyproheptadine	S	Oral		Not Reported
	Trazodone	S	Unknown		Not Reported
	Sotalol	C			Not Reported
	Warfarin	C			Not Reported
	Ginkgo Biloba Extract	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15784800	EXPEDITED (15-DAY)		OT	IN-HETERO LABS LIMITED- HET2018IN01599		22 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatomegaly; Typhoid Fever	Escitalopram			S	Oral	10 Mg, (0-0-1)		Not Reported	
	New Livfit			C	Unknown	Unk		Not Reported	
	Atarax /00058401/			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15786618	EXPEDITED (15-DAY)		DE, HO, OT	US- GLAXOSMITHKLINE- US2018GSK233918		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Glaxosmithkline	
	Escitalopram			S	Oral	Unk		Glaxosmithkline	
	Methylphenidate			S	Oral	Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15786683	EXPEDITED (15-DAY)		DE, HO, OT	US- GLAXOSMITHKLINE- US2018GSK233928		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Bupropion	S	Oral	Unk	Glaxosmithkline
	Escitalopram	S	Oral	Unk	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15787168	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1019393		73 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Drug Interaction	Escitalopram Mylan			S	Oral	Unk		Mylan	
	Amiodarona Hidrocloruro (392ch)			S	Oral	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15797671	DIRECT	Y				35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Headache; Nausea; Product Substitution Issue	Lexapro 10mg			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15787878	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-195125		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral	In Total		Not Reported	
	Alprazolam			S	Oral	In Total		Sun	
	Omeprazole			C	Unknown	()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15788051	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2018019429			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Medication Error	Escitalopram Oxalate			S	Oral	30 Milligram, Single, Total		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15788352	EXPEDITED (15-DAY)		OT	BE-ALLIED PHARMA, LLC-2060840		70 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage	Clarithromycin			S	Unknown			Allied Pharma	
	Rivaroxaban			S	Unknown			Not Reported	
	Diltiazem			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15788416	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029605		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Etanercept			S	Subcutaneous			Not Reported	
	Folic Acid			S	Oral	5 Mg Tablet		Not Reported	
	Prednisone			S	Oral			Not Reported	
	Valaciclovir			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Codeine			S	Oral			Not Reported	
	Desloratadine			S	Oral			Not Reported	
	Paracetamol			S	Oral			Not Reported	
	Lisinopril			S	Oral			Not Reported	
	Colecalciferol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Calcium			S	Oral			Not Reported	
	Risedronic Acid			S	Oral			Zydus Pharm	

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04-Jan-2019	15788472	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2019SE00412		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Toxicity To Various Agents	Propranolol			S	Oral			Not Reported	
	Quetiapine			S	Oral			Zeneca	
	Amlodipine			S	Oral			Not Reported	
	Primidone			S	Oral			Not Reported	
	Trazodone			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15790266	EXPEDITED (15-DAY)		DE	PHHY2019FR000743			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Depression	Infliximab			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Zolpidem			S	Unknown	Unk		Novartis	
	Cyamemazine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15790697	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2019SE00085		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Metoprolol			S	Oral			Not Reported	
	Quetiapine			S	Oral			Zeneca	
	Escitalopram			S	Oral			Not Reported	
	Hydrochlorothiazide			S	Oral			Not Reported	
	Potassium Chloride			S	Oral			Not Reported	

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Amlodipine			S		Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15790950	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2018-036395		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Venlafaxine			S	Oral	Extended Release		Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15793152	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Product Dispensing Error	Escitalopram Oxalate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2019	15368660	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-044136		64 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disinhibition; Euphoric Mood; Hallucination, Visual; Insomnia; Mania; Psychomotor Hyperactivity; Restlessness	Tramadol			S	Unknown	225 Milligram, Once A Day		Aurobindo	
	Tramadol			S				Aurobindo	
	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo	
	Amitriptyline			S	Unknown	25 Milligram, Once A Day		Not Reported	
	Levofloxacin			C	Unknown	500 Milligram, Once A Day		Not Reported	
	Acetaminophen			C	Unknown	3000 Milligram, Once A Day		Not Reported	
	Acetaminophen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	14839063	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018173096		56 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyp2d6 Polymorphism; Drug Metabolising Enzyme Test Abnormal; Dyskinesia; Malaise; Nausea; Suicidal Ideation; Tic	Geodon			S		Unk		Pfizer
	Wellbutrin			S		Unk		Not Reported
	Pamelor			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15698375	NON-EXPEDITED			US-PFIZER INC- 2018498459			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Cefdinir			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Promethazine Hcl			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Erythromycin Base			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Zolmitriptan			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15793675	EXPEDITED (15-DAY)		HO	US-TARO PHARMACEUTICALS USA.,INC- 2018SUN00643		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Unknown	Unk		Taro
	Metoprolol			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794558	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190104001		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Methylphenidate			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Melatonin			S	Oral			Not Reported	
	Olanzapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794560	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190103991		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Methylphenidate			S	Oral			Not Reported	
	Bupropion			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794584	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20190102939		29 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Vomiting	Risperdal			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794784	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-		39 YR	Female	USA

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2019GMK039028

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Potassium Chloride			S	Oral	Unk		Glenmark
	Metoprolol			S	Oral	Unk; Extended Release		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794802	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS- 2019GMK039027		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Gabapentin			S	Oral	Unk		Glenmark
	Propranolol			S	Oral	Unk		Not Reported
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	14719327	EXPEDITED (15-DAY)		HO	DE-ACCORD-065278		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bedridden; Dizziness; Nausea; Stupor; Vertigo	Escitalopram			S	Oral	10 Mg, Qd Also 15 Mg, Qd From 30-Aug-2016 For Depression		Not Reported
	Aripiprazole			S	Oral	10 Mg, Qd Also 5 Mg, Qd		Not Reported

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				From 17-Sep-2016	
Candesartan	S	Oral	16 Mg, Qd		Not Reported
Acetylsalicylic Acid	C	Oral	100 Mg, Qd		Not Reported
Risperdal	C		1.5 Mg, Qd Also, 2 Mg (For Nights)		Not Reported
Levothyroxine	C	Oral	100 Microgm, Qd		Not Reported
Amisulpride	C		200 Mg, Qd		Not Reported
Metformin	C	Oral	1500 Mg, Qd		Not Reported
Atorvastatin	C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15796928	NON-EXPEDITED			US-APOTEX- 2018AP023509		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Bruxism; Gynaecomastia; Intentional Product Use Issue; Pain; Polydipsia; Polyuria; Tenderness; Toothache; Tremor; Withdrawal Syndrome	Aripiprazole			S	Unknown	2 Mg, Q.H.S.		Apotex
	Aripiprazole			S	Unknown	4 Mg, Q.H.S.		Apotex
	Escitalopram			S	Unknown	5 Mg, Q.Am		Apotex
	Escitalopram			S	Unknown	15 Mg, Q.Am, Followed By A Gradual Taper (2.5 Mg/Week)		Apotex
	Buspirone			S	Unknown	7.5 Mg, Bid		Apotex
	Buspirone			S	Unknown	20 Mg, Qd		Apotex
	Buspirone			S	Unknown	15 Mg, Tid		Apotex
	Buspirone			S	Unknown	15 Mg, Bid		Apotex
	Buspirone			S	Unknown	7.5 Mg, Bid		Apotex
	Lithium Carbonate			S	Unknown	600 Mg, Q.H.S.		Apotex
	Lurasidone			S	Unknown	40 Mg, Qd, At Dinner		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15798233	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019006001		52 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Unk		Pfizer
	Escitalopram			S	Unknown	Unk		Not Reported
	Dafalgan Codeine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15798932	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007274		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown
	Methylphenidate Hydrochloride			S	Oral	Unk, (Extended Release)		Pfizer
	Diazepam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15799336	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS-2019GMK038912		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Gabapentin			S	Oral	Unk		Glenmark
	Tramadol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15799628	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007065		19 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Venlafaxine Hcl			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15800025	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019006935		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer	
	Alprazolam			S	Oral	Unk		Pfizer	
	Lisinopril			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15803265	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensed To Wrong Patient	Metformin Hcl Extended Release			S				Not Reported	
	Metformin Er Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15811903	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error; Product Dispensing Error	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	7382300	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2007078093		46 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Discomfort;	Champix	S	Oral	0.5 Mg, 1x/Day	Pfizer
Acute Sinusitis;	Champix	S	Oral	0.5 Mg, 2x/Day	Pfizer
Adjustment Disorder With	Champix	S	Oral	1 Mg, 2x/Day	Pfizer
Mixed Anxiety And	Zoloft	S		Unk	Pfizer
Depressed Mood; Adrenal	Amoxin	S	Oral	Unk	Not Reported
Insufficiency; Aggression;	Amoxin	S			Not Reported
Agitation; Akathisia;	Rinexin	S	Oral	100 Mg, Unk	Not Reported
Anxiety; Blood Cholesterol	Nicorette Gum	S		4 Mg, Unk	Not Reported
Increased; Blood Glucose	Nicorette Gum	S		2 Unk, Unk	Not Reported
Increased; Confusional	Nicorette Patch	S		Unk	Not Reported
State; Craniocerebral	Sertraline	S		50mg, 1/2 Tablet Daily	Not Reported
Injury; Depression;	Cipralax	S		Unk	Not Reported
Dizziness; Drug	Metoclopramide	S			Not Reported
Dependence; Drug	Azithromycin	C	Oral	3	Not Reported
Interaction; Dyskinesia;	Doximycin	C	Oral	Unk	Not Reported
Dyspnoea; Erectile	Klacid /00984601/	C	Oral	Ten Days Course	Not Reported
Dysfunction; Euphoric	Havrix	C	Intramuscular	Unk	Not Reported
Mood; Fatigue; Fear;	Toclase	C		Unk	Not Reported
Feeling Abnormal; Feeling					
Cold; Gastric Disorder;					
Hallucination; Hepatic					
Steatosis; Hyperhidrosis;					
Hypersensitivity;					
Hypopituitarism;					
Hyporeflexia; Hyposmia;					
Hypothyroidism; Increased					
Appetite; Infection;					
Influenza; Irritability; Loss					
Of Libido; Loss Of					
Personal Independence In					
Daily Activities; Lower					
Respiratory Tract					
Infection; Memory					
Impairment; Mood Swings;					
Musculoskeletal					
Discomfort; Nausea;					
Neurotoxicity; Nightmare;					
Obesity; Olfacto Genital					
Dysplasia; Palpitations;					
Panic Reaction;					
Parkinson'S Disease;					
Personality Change;					

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Poisoning; Restlessness;
Secondary
Hypogonadism; Sense Of
Oppression; Sleep
Disorder; Snoring;
Somnolence; Swelling;
Tinnitus; Tremor; Upper
Respiratory Tract
Infection; Vasodilatation;
Vertigo; Weight Increased;
Withdrawal Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	14700276	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1816507US		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Lipanthyl			S	Oral	145 Mg, Qd		Not Reported	
	Esomeprazole			S	Oral	Unk, Unknown		Not Reported	
	Xtandi			S	Oral	120 Mg, Qd		Not Reported	
	Decapeptyl [Gonadorelin]			S	Intramuscular	1 Df, Cyclical		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Amlor			S	Oral	Unk		Not Reported	
	Novonorm			S	Oral	Unk		Not Reported	
	Innohep			S	Subcutaneous	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15800862	NON-EXPEDITED			US-TEVA-2018-US-990294			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Muscular Weakness	Lexapro			S	Unknown			Ivax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15800913	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029584		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Melaena; Microcytic Anaemia	Escitalopram			S	Oral			Zydus Pharm	
	Clopidogrel			S	Oral	75 Mg Film-Coated Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15802046	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2018-036444		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Primidone			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Trazodone			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15802357	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP028612		27 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Headache; Muscle Spasms; Tinnitus; Tremor	Escitalopram Apotex			S	Oral	Un Comprimido Al Día Por La Mañana		Apotex	
	Terbinafina /00992601/			C	Unknown	Un Mes 1comprimido Al Día		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803359	EXPEDITED (15-DAY)		DE, LT	NO-B.I. PHARMACEUTICALS,I		20 YR	Female	NOR

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12-00

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Intentional Self-Injury	Catapresan			S	Unknown	50 Mg, Unk		Boehringer Ingelheim	
	Rivotril			S	Unknown	Unk		Not Reported	
	Lamictal			S	Unknown	100 Mg, Unk		Not Reported	
	Sarotex			S	Unknown	Unk		Not Reported	
	Truxal			S	Unknown	Unk		Not Reported	
	Pinex Forte			S	Unknown	Unk		Not Reported	
	Atarax /00058402/			S	Unknown	Unk		Not Reported	
	Nozinan /00038601/			S	Unknown	Unk		Not Reported	
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported	
	Cipralex			S	Unknown	Unk		Not Reported	
	Nobligan			S	Unknown	200 Mg, Unk		Not Reported	
	Seroquel			S	Unknown	Unk		Not Reported	
	Vival			S	Unknown	Unk		Not Reported	
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported	
	Remeron			S	Unknown	Unk		Not Reported	
	Sobril			S	Unknown	Unk		Not Reported	
	Cipramil /00582602/			S	Unknown	Unk		Not Reported	
	Imovane			S	Oral	Unk		Not Reported	
	Oxynorm			S	Unknown	10 Mg, Unk		Not Reported	
	Diamorphine /00197602/			C	Unknown			Not Reported	
	Cyanocobalamin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803366	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC- 20190105582		42 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Tramadol			S	Oral			Not Reported	
	Propranolol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Gabapentin			S	Oral			Not Reported	
	Ethanol			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803768	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC- 2019007277		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Propanolol Hcl			S	Oral	Unk		Unknown	
	Gabapentin			S	Oral	Unk		Pfizer	
	Levetiracetam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Acetaminophen;Chlorzoxazone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803927	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC- 2019006902		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	Unk		Not Reported	
	Naproxen			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15804147	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC- 2019007271		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Propanolol Hcl	S	Oral	Unk	Unknown
	Gabapentin	S	Oral	Unk	Pfizer
	Tramadol	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15804148	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007926		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Alprazolam			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
	Acetaminophen;Hydrocodone			S	Oral	Unk		Not Reported	
	Acetaminophen;Oxycodone Hydrochloride			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15804170	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007287		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Verapamil Hcl			S	Oral	Unk		Pfizer	
	Diphenhydramine Hcl			S	Oral	Unk		Unknown	
	Bupropion			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Lisinopril			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15755320	EXPEDITED (15-DAY)		OT	US-LUPIN HEALTHCARE (UK) LIMITED-2018-08921			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Pruritus; Rash Erythematous; Rash Macular; Syphilis	Escitalopram Oxalate Tablets	S	Oral	10 Mg, Qd	Lupin
	Usp, 10 Mg				
	Prezista	C	Unknown	Unk	Not Reported
	Isentress	C	Unknown	Unk	Not Reported
	Norvir	C	Unknown	Unk	Not Reported
	Descovy	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Finasteride	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15760958	NON-EXPEDITED			US-PFIZER INC- 2018529148		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Celexa [Celecoxib]			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15802547	EXPEDITED (15-DAY)		HO, OT	QA-ALLERGAN- 1900852US		49 YR	Male	QAT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug-Induced Liver Injury; Hypertonic Bladder	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
	Atorvastatin	S	Oral	40 Mg, Qd	Not Reported
	Oxybutynin	S	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15804992	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-996931		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram Daily;		Ivax	
	L-Thyroxin			C	Transplacental	75 Microgram Daily;		Not Reported	
	Xanaflu			C	Transplacental			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15805287	NON-EXPEDITED			US-TEVA-2018-US-988265			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Feeling Hot; Gastrointestinal Disorder; Thinking Abnormal; Tremor; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Clonazepam Teva			S	Unknown			Teva	
	Clonazepam Teva			S	Unknown			Teva	
	Clonazepam Teva			S	Unknown			Teva	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15805684	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20190100948		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Diphenhydramine		Y	S	Oral			Not Reported	
	Bupropion			S	Oral			Not Reported	

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Verapamil	S	Oral	Not Reported
Escitalopram	S	Oral	Not Reported
Ethanol	S	Oral	Not Reported
Hydrochlorothiazide	S	Oral	Not Reported
Lisinopril	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15806165	EXPEDITED (15-DAY)		OT	QA-MACLEODS PHARMACEUTICALS US LTD- MAC2018017426			Unknown	QAT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased; Hepatotoxicity	Escitalopram Oxalate			S	Oral	20 Milligram, Qd		Macleods
	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported
	Oxybutynin			S	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15806203	NON-EXPEDITED			US-PFIZER INC- 2019008264			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Weight Increased	Effexor			S	Unknown	Unk		Pfizer
	Rexulti			S	Oral	2 Mg, 1x/Day		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15807078	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC- 2019007280		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Propanolol Hcl			S	Oral	Unk		Unknown
	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Quetiapine			S	Oral	Unk		Not Reported

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	Primidone	S	Oral	Unk		Not Reported			
	Trazodone	S	Oral	Unk		Not Reported			
	Escitalopram	S	Oral	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15807118	EXPEDITED (15-DAY)		HO	QA-MYLANLABS-2019M1001257		49 YR	Male	QAT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Oxybutynin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15808086	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2019-007558		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Toxicity To Various Agents	Paracetamol		Y	S	Oral			Bayer	
	Escitalopram			S	Oral			Not Reported	
	Doxepin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15808503	EXPEDITED (15-DAY)		DE	US-BAYER-2019-008332		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral	Unk		Bayer	
	Amlodipine			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Zolpidem			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15808782	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1901146US		87 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
Noncompliance; Tremor;	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Unk		Allergan	
Unresponsive To Stimuli	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15809186	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1001933		26 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness; Dyschezia; Nausea; Rectal Haemorrhage; Vomiting	Escitalopram			S	Oral	Unk Unk, Am (1x Täglich Morgens)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	8225828	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2011DK96141		72 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Hypertrophy;	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported	
Confusional State;	Mirtazapine			S				Not Reported	
Constipation; Dyspnoea;	Zeldox			S	Oral	80 Mg, Qd		Not Reported	
Fall; Hepatic Cirrhosis;	Cipraxel			S	Oral	30 Mg, Qd (Daily Dose Of		Not Reported	
Humerus Fracture;						1 Tablet In The Morning			
Hypertension;						And 1.5 Tablet In The			
Hyperventilation; Lactic						Evening)			
Acidosis; Lacunar	Litarex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported	
Infarction; Myocardial	Litarex (Lithium Citrate)			S	Oral	1.5 Df (In The Evening)		Not Reported	
Infarction; Neuroleptic	Alprazolam			C		0.5 Mg, Qd		Not Reported	
Malignant Syndrome;									
Organ Failure; Pyrexia;									
Renal Failure;									
Rhabdomyolysis; Urinary									

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Tract Infection	Alprazolam	C		0.5 Mg, Qd	Not Reported
	Alprazolam	C		.5 Milligram Daily;	Not Reported
	Alprazolam	C		Unk	Not Reported
	Centyl Med Kaliumklorid	C	Unknown	1 Df, Qd	Not Reported
	Ferro Duretter	C	Unknown	100 Mg Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	14173870	NON-EXPEDITED			US-PFIZER INC-2017481476		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Percocet			S		Unk		Not Reported
	Cognex			S		Unk		Not Reported
	Reminyl			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	14316933	EXPEDITED (15-DAY)		DE	FI-ACCORD-062227			Unknown	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram			S	Unknown			Accord
Ventricular Fibrillation	Ciprofloxacin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	14731369	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-017087		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Prescribed Underdose	Esomeprazole			S	Oral	Not Reported		Aurobindo
	Tramadol			S	Oral	Unk, Unknown Freq.		Aurobindo
	Decapeptyl /00486501/			S	Intramuscular	1 Dosage Form, Cyclical		Not Reported

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Innohep	S	Subcutaneous	1 Dosage Form, Once A Day	Not Reported
Amlor	S	Oral	Unk, Unknown Freq.	Not Reported
Novonorm	S	Oral	Unk, Unknown Freq.	Not Reported
Xtandi	S	Oral	120 Milligram	Not Reported
Xtandi	S	Oral	40 Milligram, Once A Day	Not Reported
Lipanthyl	S	Oral	145 Milligram	Not Reported
Seroplex	S	Oral	10 Milligram	Not Reported
Decapeptyl /00975902/	S	Intramuscular	1 Dosage Form, Cyclical	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	14943669	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1772846US		23 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Abilify			S	Unknown	10 Mg, Qd		Not Reported	
	Abilify			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15443230	EXPEDITED (15-DAY)		HO, OT	US-OTSUKA-2018_016557		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Asthenia; Back Pain; Blood 1,25-Dihydroxycholecalciferol Decreased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Calcium Decreased; Blood Magnesium Decreased; Blood Potassium Increased; Blood Pressure	Abilify			S	Oral	5 Mg, Qd		Otsuka	
	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Abilify			S	Oral	20 Mg, Qd		Otsuka	
	Abilify			S	Oral	15 Mg, Qd (Qam)		Otsuka	
	Abilify			S	Oral	10 Mg, Qd		Otsuka	
	Lexapro			S	Oral	20 Mg, Qd (Qhs)		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	

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Fluctuation; Blood Sodium Decreased; Blood Urea Increased; Compulsions; Compulsive Sexual Behaviour; Condition Aggravated; Confusional State; Constipation; Crying; Decreased Appetite; Diabetes Mellitus; Disturbance In Attention; Economic Problem; Gambling Disorder; Hallucination, Auditory; Hyperreflexia; Impulse-Control Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Intervertebral Disc Disorder; Irritability; Lumbar Spinal Stenosis; Memory Impairment; Musculoskeletal Discomfort; Nocturia; Pain; Paralysis; Personal Relationship Issue; Pollakiuria; Poor Quality Sleep; Product Dose Omission; Product Use In Unapproved Indication; Protein Total Increased; Radiculopathy; Restlessness; Self-Medication; Supraventricular Tachycardia; Tearfulness; Tinnitus; Transient Ischaemic Attack; Weight Decreased	Rexulti Rexulti Ibuprofen Trazodone Amoxicillin Promethazine - Codeine Escitalopram	C C C C C C C	Oral Oral Unknown Oral Unknown Unknown Unknown	0.5 Mg, Qd 1 Mg, Qd 800 Mg, Tid 50 Mg, Qd (Qhs) Unk Unk Unk	Otsuka Otsuka Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15791403	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-		49 YR	Female	USA

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US2018GSK233950

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Overdose	Bupropion			S	Oral	Unk		Glaxosmithkline
	Verapamil			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Ethanol			S	Oral	Unk		Glaxosmithkline
	Diphenhydramine			S	Oral	Unk		Glaxosmithkline
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Lisinopril			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15804615	EXPEDITED (15-DAY)		HO, OT	IN-ALLERGAN-1900877US		39 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Sodium Valproate			S	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15809441	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS- 2019GMK038989		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Verapamil			S	Oral	Unk		Glenmark
	Bupropion			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported
	Diphenhydramine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported

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Lisinopril			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jan-2019	15809443	EXPEDITED (15-DAY)		DE, HO	US-GLENMARK PHARMACEUTICALS- 2019GMK039022		33 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Lamotrigine			S	Oral	Unk		Glenmark		
	Propranolol			S	Oral	Unk		Not Reported		
	Escitalopram			S	Oral	Unk		Not Reported		
	Methylphenidate			S	Oral	Unk; Extended Release		Not Reported		
	Diazepam			S	Oral	Unk		Not Reported		
	Melatonin			S	Oral	Unk		Not Reported		
	Olanzapine			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jan-2019	15810712	NON-EXPEDITED			US-TEVA-2018-US- 988374			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Nausea	Escitalopmm 20 Mg Tablets			S	Unknown			Ivax		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jan-2019	15810941	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC- 20190101266		51 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Toxicity To Various Agents	Acetaminophen		Y	S	Oral			Not Reported		
	Acetaminophen			S	Oral			Not Reported		
	Escitalopram			S	Oral			Not Reported		
	Doxepin			S	Oral			Not Reported		

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11-Jan-2019	15811770	EXPEDITED (15-DAY)		HO	PHHY2019ES002963		91 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Carbamazepine			S	Oral	50 Mg, Q24h (200 Mg Por Las Mañanas Un Cuarto De Comprimido)		Not Reported	
	Irbesartan+Hydrochlorothiazide			S	Oral	Unk		Novartis	
	Gabapentin			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15813056	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007638		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Doxepin Hcl			S	Oral	Unk		Pfizer	
	Hydroxyzine Pamoate			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15814437	EXPEDITED (15-DAY)		DS, OT	GB-ALLERGAN-1901442US		22 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Insomnia; Irritability; Tension	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	Kalms			C	Unknown	1 Df, Qhs		Not Reported	
	Sleeppezy			C	Unknown	Unk		Not Reported	
	Lansoprazole			C	Unknown	Unk		Not Reported	
	Diazepam			C	Unknown	2 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15814872	EXPEDITED (15-DAY)		HO	ES-ACCORD-101741		38 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cushing'S Syndrome; Drug Interaction	Escitalopram			S	Oral			Not Reported	
	Dexamethasone			S	Oral			Not Reported	
	Hidroaltesona			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15814935	EXPEDITED (15-DAY)		HO	FR-ACCORD-101613		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral			Not Reported	
	Esomeprazole/Esomeprazole			S	Oral			Not Reported	
	Magnesium/Esomeprazole								
	Sodium								
	Ramipril			S	Oral			Accord	
	Valaciclovir			S	Oral			Not Reported	
	Metoclopramide			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15594012	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT147757		56 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Hyperhidrosis; Tachycardia; Toxicity To Various Agents; Tremor	Metoprolol			S	Oral	Unk		Novartis	
	Escitalopram			S	Oral	Unk		Not Reported	
	Xarelto			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15768054	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-992665		67 YR	Female	BEL

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Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown			Actavis	
	Escitalopram			S	Unknown			Not Reported	
	Rivaroxaban			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15768125	EXPEDITED (15-DAY)		HO	BE-TEVA-2018-BE-992669		70 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Interaction; Gastrointestinal Haemorrhage	Diltiazem			S	Unknown			Teva	
	Clarithromycin			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Ivax	
	Rivaroxaban			S	Oral	15 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15768154	EXPEDITED (15-DAY)		DE, HO, LT	DK-TEVA-2018-DK-992658		82 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Atrial Fibrillation; Bradycardia; Bundle Branch Block Left; Cardiotoxicity; Completed Suicide; Hypercapnia; Muscle Spasms; Muscle Twitching; Overdose; Somnolence; Toxicity To Various Agents	Escitalopram			S	Unknown			Ivax	
	Verapamil			S	Oral	Formulation: Extended Release		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15814981	EXPEDITED (15-DAY)		DE	US-GLENMARK PHARMACEUTICALS- 2019GMK039058		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide	Naproxen	S	Oral	Unk	Glenmark
	Amlodipine	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Zolpidem	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15815497	EXPEDITED (15-DAY)	HO		PHHY2018RO184720		54 YR	Male	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety;	Quetiapine			S	Unknown	300 Mg, Qd		Novartis
Bronchitis; Chest	Quetiapine			S	Unknown	800 Mg, Qd		Novartis
Discomfort; Chronic	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
Gastritis; Condition	Risperidone			S	Unknown	6 Mg, Qd		Not Reported
Aggravated; Decreased	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
Appetite; Depressed	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
Mood; Depression;	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
Depressive Symptom;	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
Dizziness; Drug	Doxepine			S	Unknown	100 Mg, Qd		Not Reported
Ineffective; Dyspnoea;								
Fatigue; Feeling Guilty;								
Headache; Helplessness;								
Hypertension; Illness								
Anxiety Disorder;								
Insomnia; Libido								
Decreased; Memory								
Impairment; Obsessive-								
Compulsive Personality								
Disorder; Self Esteem								
Decreased; Somatic								
Symptom Disorder;								
Weight Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2019	15816586	EXPEDITED (15-DAY)	DE		FR-ZYDUS-029556		81 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrocephalus; Intraventricular Haemorrhage	Acetylsalicylic Acid	S	Oral	75 Mg Powder For Oral Solution In Sachet-Dose	Not Reported
	Escitalopram	S	Oral		Zydus Pharm
	Rivaroxaban	S	Oral	20 Mg Film-Coated Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2019	15817747	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-998246			Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Communication Disorder; Dyskinesia; Suicide Attempt	Loquen			S	Oral	4 Gram Daily;		Teva
	Mirzaten Filmom Oblozene Tablet 30 Mg			S	Oral	900 Milligram Daily;		Not Reported
	Elicea			S	Oral	280 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15183944	EXPEDITED (15-DAY)		HO	DK-TAKEDA-2018TUS022777		32 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Bile Acid Malabsorption; Clostridium Difficile Colitis; Drug Ineffective; Drug Ineffective For Unapproved Indication; Functional Gastrointestinal Disorder; Product Use In Unapproved Indication; Therapeutic Response Decreased	Entyvio			S	Unknown	Unk		Takeda
	Spironolactone			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Natalizumab			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Liraglutide			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	40 Mg, Qd		Not Reported
	Octreotide /00821002/			S	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	400 Mg, Qd		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Levetiracetam	C	Unknown	1500 Mg, Qd		Not Reported
	Colesevelam	C	Unknown	625 Mg, Tid		Not Reported
	Colesevelam	C				Not Reported
	Codeine Phosphate	C	Unknown	Unk		Not Reported
	Colestyramine	C	Unknown	Unk		Not Reported
	Venlafaxin	C	Unknown	225 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15298289	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1840590US		1 DAY	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Newborn Persistent Pulmonary Hypertension	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Ronlax			C	Transplacental	0.5 Mg, Qd		Not Reported
	Solanax			C	Transplacental	0.4 Mg, As Needed During Anxiety		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15761731	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181221616			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depression; Drug Interaction; Haemorrhagic Diathesis	Imbruvica			S	Oral	Strength = 140 Mg		Not Reported
	Cipralax			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15819399	EXPEDITED (15-DAY)		OT	AU-TEVA-2019-AU-997060		36 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersomnia; Malaise; Neutropenia; Schizophrenia; Self-Medication	Tevaripiprazole			S	Unknown	Dosage Unknown		Teva
	Escitalopram			S	Unknown			Not Reported
	Clozaril			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15819423	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-998413		36 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Persistent Genital Arousal Disorder	Escitalopram			S	Unknown	15 Milligram Daily; One Tablet Daily		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15819502	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2019-ES-998374		91 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Gabapentina (2641a)			S	Oral			Actavis	
	Irbesartan / Hidroclorotiazida			S	Oral			Teva	
	Escitalopram (2858a)			S	Oral	10 Milligram Daily; 10 Mg		Not Reported	
	Carbamazepina (561a)			S	Oral	50 Milligram Daily; 200 Mg Per Morning A Quarter Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15820322	EXPEDITED (15-DAY)		HO, OT	PHHY2018BE185966		67 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac			S	Unknown	Unk		Novartis	
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15821145	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1901610US		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram Oxalate - Bp L-Thyroxin Xanaflu	S C C	Transplacental Transplacental Transplacental	10 Mg, Qd 75 Mg, Qd Unk, Single	Allergan Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15822091	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Unevaluable Event	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15823758	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-000855		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Depression; Drug Ineffective	Diazepam			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15574742	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018445210		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Lorazepam			S		0.5 Mg, 3x/Day (As Necessary)		Pfizer
	Lorazepam			S		1 Mg, 3x/Day (As Necessary)		Pfizer
	Lorazepam			S		0.5 Mg, 2x/Day (As Necessary)		Pfizer

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Amphetamine, Dextroamphetamine	S	20 Mg, 1x/Day(Extended Release, Every Morning)	Not Reported
Amphetamine, Dextroamphetamine	S	10 Mg, 1x/Day(Extended Release, Every Morning)	Not Reported
Aripiprazole	S	4 Mg, 1x/Day (Every Bedtime)	Not Reported
Aripiprazole	S	2 Mg, 1x/Day (Every Bedtime)	Not Reported
Bupropion	S	150 Mg, 1x/Day (Every Morning)	Not Reported
Bupropion	S	200 Mg, 1x/Day (Every Morning)	Not Reported
Bupropion	S	300 Mg, 1x/Day (Every Morning)	Not Reported
Buspirone	S	15 Mg, 2x/Day	Not Reported
Buspirone	S	15 Mg, 3x/Day	Not Reported
Buspirone	S	10 Mg, 1x/Day	Not Reported
Buspirone	S	17.5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 3x/Day	Not Reported
Buspirone	S	15 Mg, 3x/Day	Not Reported
Buspirone	S	15 Mg, 1x/Day	Not Reported
Buspirone	S	2.5 Mg, 1x/Day	Not Reported
Buspirone	S	22.5 Mg, 1x/Day	Not Reported
Buspirone	S	5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 1x/Day	Not Reported
Buspirone	S	7.5 Mg, 2x/Day	Not Reported
Buspirone	S	7.5 Mg, 3x/Day	Not Reported
Buspirone	S	20 Mg, 1x/Day	Not Reported
Escitalopram	S	5 Mg, 1x/Day (Every Morning, Q.A.M)	Not Reported
Escitalopram	S	20 Mg, 1x/Day	Not Reported
Escitalopram	S	10 Mg, 1x/Day (Every	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram	S		Morning) 15 Mg, 1x/Day (Every Morning)	Not Reported
Escitalopram	S		2.5 Mg, Weekly	Not Reported
Escitalopram	S		7.5 Mg, 1x/Day (Every Morning)	Not Reported
Lamotrigine	S		150 Mg, 1x/Day	Not Reported
Lamotrigine	S		100 Mg, 1x/Day	Not Reported
Lithium	S		600 Mg, 1x/Day (Every Bedtime)	Not Reported
Lurasidone	S		40 Mg, 1x/Day (After Dinner)	Not Reported
Testosterone	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
Benztropine Mesylate	C		0.5 Mg, 2x/Day (As Necessary)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15741249	EXPEDITED (15-DAY)		HO, OT	BE-GLAXOSMITHKLINE-BE2018227367		67 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Gastrointestinal Haemorrhage	Diclofenac (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	Unk		Glaxosmithkline
	Rivaroxaban			S	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15763004	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1859365US		65 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Burnout Syndrome;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Platelet Count Decreased;
Serum Serotonin
Decreased; Sleep
Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15803909	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019006901		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer	
	Metoprolol Tartrate			S	Oral	Unk		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Clonazepam			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15807850	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019007020		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besilate			S	Oral	Unk		Pfizer	
	Potassium Chloride			S	Oral	Unk		Not Reported	
	Metoprolol Tartrate			S	Oral	Unk (Extended Release)		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Quetiapine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15811040	EXPEDITED (15-DAY)		OT	AU-ROCHE-2241007		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Rash; Swelling Face	Ceftriaxone			S	Unknown			Not Reported	

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Ceftriaxone	S		Not Reported
Metronidazole	S	Unknown	Not Reported
Metronidazole	S		Not Reported
Cephalexin	S	Unknown	Not Reported
Oseltamivir	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Benzylpenicillin	S	Unknown	Not Reported
Tazocin	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Mesalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15821141	EXPEDITED (15-DAY)		HO	QA-ALLERGAN-1901601US		34 YR	Female	QAT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Generalised Tonic-Clonic Seizure; Urinary Incontinence	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Memantine Hcl - Bp			S	Unknown	20 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824261	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900648		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Methylphenidate Hydrochloride			S	Oral	Unk		Mallinckrodt
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Lamotrigine			S	Oral	Unk		Not Reported
	Diazepam			S	Oral	Unk		Not Reported
	Melatonin			S	Oral	Unk		Not Reported

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Olanzapine			S	Oral	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824264	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900609		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Hydrocodone/Acetaminophen			S	Oral	Unk		Mallinckrodt	
	Oxycodone/Acetaminophen			S	Oral	Unk		Mallinckrodt	
	Escitalopram			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824271	EXPEDITED (15-DAY)		DE	US-MALLINCKRODT-T201900611		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Methylphenidate Hydrochloride			S	Oral	Unk		Mallinckrodt	
	Bupropion			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824623	EXPEDITED (15-DAY)		CA, DS, OT	DE-TORRENT-00012944			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	L-Thyroxin			C	Transplacental	75 [G/D]		Unknown	
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown	
	Xanaflu			C	Transplacental	Unknown		Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15827871	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1901867US		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Daily		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Ciprallex			S	Unknown			Not Reported	
	Acacia			C	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Aczone			C	Unknown			Not Reported	
	Azithromycin			C	Unknown			Not Reported	
	Benzoyl Peroxide W/Clindamycin Phosphate			C	Unknown			Not Reported	
	Calcium			C	Unknown			Not Reported	
	Canesten-Hc			C	Unknown			Not Reported	
	Cetaphil Acne Principles			C	Unknown			Not Reported	
	Cetaphil			C	Unknown			Not Reported	
	Cetaphil Cleansers Oily Skin			C	Unknown			Not Reported	
	Constella			C	Unknown			Not Reported	
	Diclofenac			C	Unknown			Not Reported	
	Domperidone			C	Unknown			Not Reported	
	Epival			C	Unknown			Not Reported	
	Flovent			C	Unknown	Flovent Diskus		Not Reported	
	Flovent Hfa			C	Unknown			Not Reported	
	Genteal			C	Unknown			Not Reported	
	Nasacort Aq			C	Unknown			Not Reported	
	Omega 3-6-9			C	Unknown			Not Reported	
	Otrivin Saline			C	Nasal			Not Reported	
	Seroquel			C	Unknown	Unk		Not Reported	

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Seroquel	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown		Not Reported
Tears Plus	C	Unknown		Not Reported
Tecta	C	Unknown		Not Reported
Toviaz	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Tylenol Extra Strength	C	Unknown		Not Reported
Vitamin D2	C	Unknown		Not Reported
Zinc Gluconate	C	Unknown		Not Reported
Zyloprim	C	Unknown		Not Reported
Clotrimazole W/Hydrocortisone	C	Unknown		Not Reported
Valproate Semisodium	C	Unknown		Not Reported
Polyvinyl Alcohol/Povidone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15827872	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1901807US		36 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Persistent Genital Arousal Disorder	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15828033	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2019-001578		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Extended Release		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Methylphenidate			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15832005	DIRECT	Y	HO			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose	Lexapro Sudafed Pe		Y	S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	14895470	EXPEDITED (15-DAY)		LT	FR- ELI_LILLY_AND_COMP ANY-FR201805004403		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Mg, Unknown		Eli Lilly And Co	
	Teralithe			S	Oral	2 Df, Unknown		Not Reported	
	Seroplex			S	Oral	1 Df, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15565762	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018- 029468		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Bupropion			S	Unknown	Every Morning		Not Reported	
	Bupropion			S	Unknown	Every Morning		Not Reported	
	Bupropion			S	Unknown	Every Morning		Not Reported	
	Lorazepam			S	Unknown	As Necessary		Not Reported	
	Lorazepam			S	Unknown	As Necessary		Not Reported	
	Escitalopram			S	Unknown	Every Morning		Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	Every Morning		Not Reported	
	Escitalopram			S	Unknown	Every Morning		Not Reported	
	Amphetamine, Dextroamphetamine			S	Unknown	Extended Release, Every Morning		Not Reported	

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Amphetamine, Dextroamphetamine	S	Unknown	Extended Release, Every Morning	Not Reported
Testosterone	S	Topical	50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
Lithium	S	Unknown	Every Bedtime	Not Reported
Lurasidone	S	Unknown	After Dinner	Not Reported
Lamotrigine	S	Unknown		Not Reported
Lamotrigine	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Buspirone	S	Unknown		Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Benzotropine Mesylate	C		As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15802506	EXPEDITED (15-DAY)		HO	HR-ALLERGAN- 1900604US			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Drug Intolerance; Product Use In Unapproved Indication	Botox	S	Intramuscular	Unk Unk, Single	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Unk	Allergan
	Propranolol	S	Unknown	180 Mg, Unk	Not Reported
	Propranolol	S	Unknown	120 Mg, Unk	Not Reported
	Ketonal	S	Unknown	Unk	Not Reported
	Helex	S	Unknown	Unk	Not Reported
	Elicea	S	Unknown	Unk	Not Reported
	Plivadon (Caffeine/Phenacetin/Propyphenazone)	S	Unknown	Unk	Not Reported
	Normabel	S	Unknown	Unk	Not Reported
	Amyzol	S	Unknown	Unk	Not Reported
	Knavon	S	Unknown	Unk	Not Reported
	Imigran	S	Unknown	Unk	Not Reported
	Topiramate	S	Unknown	Unk	Not Reported
	Erenumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15831214	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005715		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Acetaminophen			S	Oral			Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Doxepin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15831947	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-09237		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Serotonin Syndrome	Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
	Linezolid	S	Unknown	Unk	Alkem
	Trazodone	S	Unknown	300 Mg, Nightly	Not Reported
	Trazodone	S	Oral	150 Mg, Nightly	Not Reported
	Clonazepam	S	Unknown	0.5 Mg, Bid	Not Reported
	Ceftriaxone	C	Unknown	Unk	Not Reported
	Azithromycin	C	Unknown	Unk	Not Reported
	Piperacillin-Tazobactam	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15831950	EXPEDITED (15-DAY)		LT, OT	IN-ALKEM LABORATORIES LIMITED-IN-ALKEM- 2018-09546		65 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Interaction; Serotonin Syndrome	Amoxicillin (As Trihydrate) And Clavulanic Acid (As Potassium) Linezolid			S	Unknown	Unk		Not Reported
				S	Intravenous (not otherwise specified)	600 Mg, Bid		Alkem
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Etophylline			C	Unknown	Unk		Not Reported
	Guaiphenesin			C	Unknown	Unk		Not Reported
	Ambroxol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15831954	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-09555		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported

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Serotonin Syndrome	Linezolid	S	Intravenous (not otherwise specified)	600 Mg, Bid	Alkem
	Cefepime	C	Unknown	1 G, Bid	Not Reported
	Metoclopramide	C	Unknown	10 Mg, Qid	Not Reported
	Ondansetron	C	Unknown	4 Mg, Qid	Not Reported
	Ciprofloxacin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15831959	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-10318		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S	Intravenous (not otherwise specified)	Unk		Alkem	
	Duloxetine Hydrochloride			S	Unknown	Unk		Alkem	
	Escitalopram			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15833893	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2019M1003344		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Diarrhoea	Escitalopram			S	Unknown	Unk		Not Reported	
	Seroplex			S	Unknown	10 Milligram, Qd		Mylan	
	Meteospasmyl /01017401/			C	Unknown	Unk		Mylan	
	Meteospasmyl /01017401/			C				Mylan	
	Copper Iud			C	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15834797	EXPEDITED (15-DAY)		OT	DE-ALLERGAN- 1857928US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hepatitis; Infectious Mononucleosis; Liver Function Test Increased; Malaise	Escitalopram Oxalate - Bp Telfast	S	10 Mg, Qd	Allergan
		C	Unknown	Not Reported

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16-Jan-2019	15834944	EXPEDITED (15-DAY)		DE	US-INTELLIPHARMACEUTI CS CORP.-2061314		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Quetiapine Fumarate			S	Oral			Intellipharmaeutics
	Metoprolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Potassium Chloride			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15835261	EXPEDITED (15-DAY)		OT	CH-AMGEN- CHESP2019002686		59 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Density Decreased; Rebound Effect	Prolia			S	Subcutaneous	60 Mg, Q6mo		Amgen
	Ciprallex			S	Oral	10 Mg, Qd		Not Reported
	Calcimagom D3			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	14813550	EXPEDITED (15-DAY)		HO	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-036074		95 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma	Eliquis			S	Oral	10 Mg/Day		Bristol Myers Squibb
	Escitalopram Arrow			S	Oral	10 Mg/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15721010	EXPEDITED (15-DAY)		HO, OT	AU-ASTELLAS-2018US052496		73 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blindness; Cellulitis Orbital; Diabetes Mellitus; Hypomagnesaemia; Lethargy; Mucormycosis; Myalgia; Nausea; Paraesthesia; Vomiting	Metoclopramide			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Isavuconazole			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Amphotericin B, Liposome			S	Unknown			Astellas
	Posaconazole			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Irbesartan			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Metformin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Caspofungin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ondansetron			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ranitidine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Amlodipine			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Aspirin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Tapentadol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Gliclazide			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rosuvastatin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Oxycodone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Ceftriaxone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Clindamycin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Doxycycline			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15762929	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2018521806			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggression; Agitation;	Pregabalin	S	Oral	50 Mg, Unk	Pfizer
Alcoholism; Apraxia;	Pregabalin	S	Oral	25 Mg, 2x/Day	Pfizer
Behaviour Disorder;	Lorazepam	S		Unk	Pfizer
Cognitive Disorder;	Quetiapine Fumarate	S	Oral	25 Mg, 1x/Day, In The Evening	Not Reported
Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective;	Quetiapine Fumarate	S	Oral	Slowly Increased	Not Reported
Dysphoria; Hallucination; Hallucination, Visual;	Quetiapine Fumarate	S	Oral	100 Mg, Unk	Not Reported
Insomnia; Korsakoff'S Syndrome; Mania; Muscle Rigidity; Parkinsonism;	Piracetam	S		1200 Mg, Unk	Not Reported
Restlessness; Sleep Disorder; Tremor; Urinary Incontinence	Naltrexone	S		Unk	Not Reported
	Rivastigmine	S	Transdermal	Unk (Dose Increased).	Not Reported
	Rivastigmine	S	Transdermal	4.6 Mg, 1x/Day	Not Reported
	Risperidone	S		3 Mg, 1x/Day	Not Reported
	Risperidone	S		Unk	Not Reported
	Risperidone	S		1 Mg, Unk	Not Reported
	Escitalopram	S		10 Mg, Unk	Not Reported
	Escitalopram	S		3 Mg, 1x/Day	Not Reported
	Risperdal	S		Unk	Not Reported
	Cerebrolysin	S		Unk	Not Reported
	Oxazepam	S		Unk	Not Reported
	Mirtazapine	S		15 Mg, Unk	Not Reported
	Valproic Acid	S		1000 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15823280	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1901460US		55 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Hyperhidrosis;	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
Hypertensive Crisis;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Insomnia; Malaise; Panic Attack; Tachycardia;	Thiocolchicoside			S	Unknown	Unk		Not Reported
Tremor	Ibuprofen			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bromazepam	S	Unknown	1.5 Mg, Qid	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Perindopril	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15827185	EXPEDITED (15-DAY)		HO, OT	AU-ALLERGAN-1901797US		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	
	Cephalexin			S	Unknown	Unk		Not Reported	
	Metronidazole			S	Unknown	Unk		Not Reported	
	Metronidazole			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15835441	EXPEDITED (15-DAY)		HO	RO-AUROBINDO-AUR-APL-2019-000452		54 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Escitalopram			S	Unknown	10 Mg		Aurobindo	
	Quetiapine Fumarate			S	Unknown	300 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15835628	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005982		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Apotex	
	Verapamil			S	Oral	Unk		Apotex	

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	Escitalopram	S	Oral	Unk	Apotex
	Diphenhydramine	S	Oral	Unk	Apotex
	Hydrochlorothiazide	S	Oral	Unk	Apotex
	Lisinopril	S	Oral	Unk	Apotex
	Ethanol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15835803	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006124		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Use Issue	Amlodipine			S	Oral	Unk		Apotex
	Quetiapine			S	Oral	Unk		Apotex
	Trazodone			S	Oral	Unk		Apotex
	Escitalopram			S	Oral			Apotex
	Propranolol			S	Oral	Unk		Not Reported
	Primidone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15836469	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006251		88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Alprazolam			S	Oral	Unk		Apotex
	Lisinopril			S	Oral	Unk		Apotex
	Escitalopram			S	Oral			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15836806	EXPEDITED (15-DAY)		OT	HR-ROCHE-2246075			Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Clonazepam	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Caffeine	S	Oral	Not Reported
	[Acetaminophen\Caffeine\Codeine\Propyphenazone] Alprazolam	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15837476	EXPEDITED (15-DAY)		DE	US- INTELLIPHARMACEUTI CS CORP.-2061333		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Quetiapine Fumarate			S	Oral			Intellipharmaeueutics
	Propranolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Primidone			S	Oral			Not Reported
	Trazodone			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15838044	EXPEDITED (15-DAY)		DE, HO, OT	FR-BAUSCH-BL-2019- 001367		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death; Agitation; Delirium; Drug Intolerance; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Seroplex			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Lysanxia			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15838936	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019019512			Unknown	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram, Qd, 0. - 22.4. Gestational Week During 1 {Trimester}		Macleods	
	L-Thyroxine Sodium			C	Transplacental	75 Microgram, Qd, 0. - 22.4. Gestational Week During 1 {Trimester}		Not Reported	
	Xanaflu			C	Transplacental	Unk, 20.3. - 20.3. Gestational Week During 2 {Trimester}		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839437	EXPEDITED (15-DAY)		HO, LT, OT	ES-MYLANLABS-2019M1003844		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypocoagulable State; Suicide Attempt	Ibuprofen			S	Oral	2800 Milligram, Total (400 Mg X 7 Cps)		Not Reported	
	Paracetamol			S	Oral	12 Gram, Total (12gr Dia)		Not Reported	
	Escitalopram			S	Oral	5 Cps		Not Reported	
	Exforge			S	Oral	5 Dosage Form (5 Cps)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839635	EXPEDITED (15-DAY)		DS, OT	GB-TEVA-2019-GB-999868		22 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Insomnia; Irritability; Tension	Escitalopram			S	Oral			Ivax	
	Kalms			C		1 Dosage Forms Daily; Night		Not Reported	
	Sleepeezy Valerian			C				Not Reported	
	Lansoprazole			C				Not Reported	
	Diazepam			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839649	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2019M1003515		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Escitalopram			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Ceftriaxone			S				Not Reported	
	Ceftriaxone			S				Not Reported	
	Benzylpenicillin			S	Unknown			Mylan	
	Cephalexin /00145501/			S	Unknown			Mylan	
	Tazocin			S	Unknown			Mylan	
	Oseltamivir			C	Unknown			Mylan	
	Mesalazine			C	Unknown			Mylan	
	Metronidazole			C	Unknown			Mylan	
	Metronidazole			C				Mylan	
	Metronidazole			C				Mylan	
	Clindamycin			C	Unknown			Mylan	
	Ciprofloxacin			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839970	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1003433		23 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15840064	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1902287US		72 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness;	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	

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Respiratory Depression	Neurontin	S	Oral	300 Mg, Q8hr	Not Reported
	Trankimazin 1 Mg Comprimidos	S	Oral	1 Mg, Qd	Not Reported
	Durogesic	S	Transdermal	150 Mg, Q72hr	Not Reported
	Sevredol	S	Oral	10 Mg, Prn	Not Reported
	Zovirax	C	Unknown	Unk, Unknown	Not Reported
	Nolotil	C	Unknown	Unk, Unknown	Not Reported
	Paracetamol	C	Unknown	Unk, Unknown	Not Reported
	Zyloric	C	Unknown	Unk, Unknown	Not Reported
	Seguril	C	Unknown	Unk, Unknown	Not Reported
	Binocrit	C	Subcutaneous	Unk, Unknown	Not Reported
	Clexane	C	Subcutaneous	Unk, Unknown	Not Reported
	Pantoprazol	C	Unknown	Unk, Unknown	Not Reported
	Natecal D	C	Unknown	Unk, Unknown	Not Reported
	Mycostatin	C	Unknown	Unk, Unknown	Not Reported
	Hidroxil B1-B6-B12	C	Unknown	Unk, Unknown	Not Reported
	Seretide Accuhaler	C	Unknown	Unk, Unknown	Not Reported
	Borea	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	14371912	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1001918		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Sopor; Suicide Attempt	Escitalopram			S	Oral	400 Mg, Total		Not Reported	
	Venlafaxine			S	Oral	525 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15700963	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1856633US		30 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Overdose; Serotonin Syndrome	Escitalopram Oxalate - Bp	S	Oral	Overdose: 15 Tablets	Allergan
	Lunesta	C	Oral	15 Df, Unk (Overdose)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15760225	EXPEDITED (15-DAY)			BR-PFIZER INC-2018523766		56 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Feeling Abnormal; Palpitations; Tachycardia	Frontal Xr			S		0.5 Mg, 1x/Day		Pfizer	
	Frontal Xr			S				Pfizer	
	Reconter			S		Unk		Not Reported	
	Procimax			S		Unk		Not Reported	
	Xarelto			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15841001	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005950		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15841181	EXPEDITED (15-DAY)		DE	US-UCBSA-2019002093		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Levetiracetam			S	Oral	Unknown Dose		Ucb	
	Propranolol			S	Oral	Unknown Dose		Not Reported	
	Escitalopram			S	Oral	Unknown Dose		Not Reported	
	Gabapentin			S	Oral	Unknown Dose		Not Reported	
	Chlorzoxazone W/Acetaminophen			S	Oral	Unknown Dose		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15841678	EXPEDITED (15-DAY)		HO, OT	AU-STRIDES ARCOLAB LIMITED- 2019SP000504		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Swelling Face	Metronidazole			S	Unknown	Unk, As Necessary		Strides	
	Metronidazole			S				Strides	
	Ciprofloxacin			S	Unknown	Unk		Not Reported	
	Cefalexin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Clindamycin			S	Unknown	Unk		Not Reported	
	Benzylpenicillin			S	Unknown	Unk		Not Reported	
	Tazocin			S	Unknown	Unk		Not Reported	
	Mesalazine			C	Unknown	Unk, As Necessary		Not Reported	
	Oseltamivir			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15842054	EXPEDITED (15-DAY)		HO	RO-ROCHE-2244524		54 YR	Unknown	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Drug Resistance; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness;	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported	
	Quetiapine			S	Unknown	800 Milligram, Daily		Not Reported	
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported	
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported	
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported	
	Escitalopram			S	Unknown	10 Milligram		Not Reported	
	Doxepine			S	Unknown	100 Milligram, Daily		Not Reported	
	Olanzapine			S	Unknown	15 Milligram, Daily		Not Reported	

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Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive- Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Duloxetine	S	Unknown	60 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15842115	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX- 2019AP006089		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex
	Hydrochlorothiazide			S	Oral	Unk		Apotex
	Quetiapine			S	Oral	Unk		Apotex
	Potassium Chloride			S	Oral	Unk		Apotex
	Escitalopram			S	Oral	Unk		Apotex
	Metoprolol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15842947	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Lexapro			S				Not Reported
	Metformin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15843364	EXPEDITED (15-DAY)		OT	DE-ALLERGAN- 1902048US		32 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Pregnancy; Stillbirth	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
	Quetiapine	S	Oral	25 Mg, Qd	Not Reported
	Presinol	S	Oral	500 Mg, Qd (2 X 250)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15843368	EXPEDITED (15-DAY)		DE	NO-ALLERGAN-1902312US			Unknown	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Vallergan			S	Unknown	Unk		Not Reported
	Codeine Phosphate/Paracetamol			S	Unknown	Unk		Not Reported
	Haldol			S	Subcutaneous	Unk		Not Reported
	Haldol			S	Intramuscular	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15844265	EXPEDITED (15-DAY)		OT	FR-OTSUKA-2019_001172		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Mg, Qd		Otsuka
	Seresta			S	Oral	100 Mg, Qd(1/2cp-1/2cp-1cp)		Not Reported
	Tercian			S	Oral	50 Mg, Qd		Not Reported
	Zyprexa			S	Oral	2 Df, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	3 Df, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported

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Oxycontin Lp			S		Oral		2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2019	15845716	EXPEDITED (15-DAY)		DE, HO, OT		US-APOTEX-2019AP006087		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Completed Suicide	Levetiracetam				S	Oral	Unk			Apotex
	Escitalopram				S	Oral	Unk			Apotex
	Gabapentin				S	Oral	Unk			Apotex
	Propranolol				S	Oral				Not Reported
	Acetaminophen W/Chlorzoxazone				S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2019	15845746	EXPEDITED (15-DAY)		CA, OT		DE-AUROBINDO-AUR-APL-2019-001076		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram				S	Transplacental	10 Milligram, Daily			Aurobindo
	L-Thyroxin /00068002/				C	Transplacental	75 Microgram, Daily			Not Reported
	Xanaflu				C	Transplacental				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2019	15845843	NON-EXPEDITED				US-DEXPHARM-20180017		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Dizziness; Drug Interaction; Food Interaction; Heart Rate Decreased; Malaise; Pulse Abnormal	Omeprazole Delayed Release Tablets 20 Mg				S	Oral	20 Mg, Single			Dexcel
	Lorazepam				S	Oral				Not Reported
	Lexapro				S	Oral				Not Reported

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20-Jan-2019	15846340	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100538		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Zolpidem Tartrate			S	Oral	Unk Unknown, Unknown		Vintage	
	Amlodipine			S	Oral	Unk Unknown, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk Unknown, Unknown		Not Reported	
	Naproxen			S	Oral	Unk Unknown, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847508	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX- 2019AP005923		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Alprazolam			S	Oral			Apotex	
	Acetaminophen W/Hydrocodone			S	Oral	Unk		Not Reported	
	Acetaminophen W/Oxycodone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847549	NON-EXPEDITED		DE, HO, OT	US-APOTEX- 2019AP005935		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Bupropion Hcl Er			S	Oral	Unk		Not Reported	
	Methylphenidate			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847550	NON-EXPEDITED		DE, HO, OT	US-APOTEX- 2019AP005977		48 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Doxepin			S	Oral	Unk		Not Reported	
	Hydroxyzine			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847552	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2019AP005929		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Venlafaxine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847621	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP005634		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Tramadol			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Gabapentin			S	Oral	Unk		Apotex	
	Propranolol			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847753	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-001499		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Depression; Drug Ineffective	Diazepam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Aurobindo	

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	Dapsone		C	Unknown	100 Milligram, Once A Day			Not Reported	
	Infliximab		C	Unknown	10 Milligram/Kilogram			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15848067	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006173		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex	
	Hydrochlorothiazide			S	Oral	Unk		Apotex	
	Clonazepam			S	Oral			Apotex	
	Escitalopram			S	Oral			Apotex	
	Metoprolol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15848070	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2019AP006174		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine			S	Oral	Unk		Apotex	
	Zolpidem			S	Oral	Unk		Apotex	
	Escitalopram			S	Oral	Unk		Apotex	
	Naproxen			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15848116	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1004137		35 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Lamotrigine			S	Oral	100 Milligram, Qd		Mylan	
	Seroquel			S	Oral	1 Dosage Form, Qd		Mylan	
	Seroquel			S	Oral	1 Dosage Form, Qd		Mylan	

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21-Jan-2019	15849090	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006076		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Apotex	
	Lamotrigine			S	Oral	Unk		Apotex	
	Olanzapine			S	Oral	Unk		Apotex	
	Propranolol			S	Oral	Unk		Not Reported	
	Methylphenidate			S	Oral	Unk		Not Reported	
	Diazepam			S	Oral	Unk		Not Reported	
	Melatonin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15849628	EXPEDITED (15-DAY)		OT	PHHY2019DE009754		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stillbirth	Quetiapine			S	Oral	25 Mg, Qd		Novartis	
	Quetiapine			S	Oral	25 Mg, Qd		Novartis	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Presinol			S	Oral	500 Mg, Qd		Not Reported	
	Presinol			S	Oral	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15849707	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1004543		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Meningioma	Estradiol Mylan			S	Transdermal	Unk		Mylan	
	Androcur			S	Oral	Unk		Mylan	

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Seroplex			S		Oral		10 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Jan-2019	15849877	EXPEDITED (15-DAY)		HO	HR-PFM-2019-00458			Unknown	HRV	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Drug Intolerance; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Unknown	120 Mg, Unk		Pierre Fabre Medicament		
	Propranolol			S	Unknown	180 Mg, Unk		Pierre Fabre Medicament		
	Ketonal			S	Unknown	Unk		Not Reported		
	Helex			S	Unknown	Unk		Not Reported		
	Elicea			S	Unknown	Unk		Not Reported		
	Plivadon (Caffeine/Phenacetin/Propyphenazone)			S	Unknown			Not Reported		
	Normabel			S	Unknown	Unk		Not Reported		
	Amyzol			S	Unknown	Unk		Not Reported		
	Cipralex			S	Unknown			Not Reported		
	Knavon			S	Unknown			Not Reported		
	Botox			S	Unknown	Unk		Not Reported		
	Imigran			S	Unknown	Unk		Not Reported		
	Topiramate			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Jan-2019	15850463	EXPEDITED (15-DAY)		DE	PHHY2019NO011937			Unknown	NOR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Abuse; Wrong Product Administered	Risperidone			S	Unknown	Unk Unk, Unk		Novartis		
	Cipralex			S	Unknown	Unk Unk, Unk		Not Reported		
	Vallergan			S	Unknown	Unk Unk, Unk		Not Reported		
	Codeine Phosphate			S	Unknown	Unk Unk, Unk		Not Reported		

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	Haldol	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Haldol	S	Intramuscular	Unk Unk, Unk	Not Reported
	Oxazepam	S	Unknown	Unk Unk, Unk	Not Reported
	Zopiclone	S	Unknown	Unk Unk, Unk	Not Reported
	Paracetamol	S	Unknown	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15955418	DIRECT	Y	OT			47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Withdrawal Syndrome	Escitalopram (Lexapro) 10mg			S	Oral			Aurobindo	
	Aurobindo								
	Escitalopram (Lexapro) 20mg			S	Oral			Accord	
	Accord Health								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	10511006	NON-EXPEDITED			US-PFIZER INC- 2014275816			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Pantoprazole			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Elavil			S		Unk		Not Reported	
	Victoza			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Trintellix			S		Unk		Not Reported	

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Valsartan	S	Unk	Not Reported
Levomenol	S	Unk	Not Reported
Bupropion	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Vortioxetine	S	Unk	Not Reported
Liraglutide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	12465777	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016290972		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clonus; Confusional State; Electrocardiogram Qt Prolonged; Hypoglycaemia; Intentional Overdose; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Venlafaxine Hcl			S	Oral	7875 Mg, Single		Pfizer
	Bromazepam			S	Oral	180 Mg, Single		Not Reported
	Escitalopram			S	Oral	840 Mg, Single		Not Reported
	Lormetazepam			S	Oral	14 Mg, Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	13406285	EXPEDITED (15-DAY)		OT	ES-ACCORD-049440		28 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sialoadenitis	Escitalopram			S	Oral			Not Reported
	Ondansetron			S				Accord
	Cipralext			S				Not Reported
	Temozolomide			C				Not Reported
	Levetiracetam			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	14278255	NON-EXPEDITED			US-PFIZER INC-2017528959		55 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Lithium			S		Unk		Not Reported
	Risperdal			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil [Piroxicam]			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Vraylar			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15580271	EXPEDITED (15-DAY)		OT	US- GLAXOSMITHKLINE- US2018GSK199615		21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia	Bupropion			S	Unknown	150 Mg, 1d Every Morning		Glaxosmithkline
	Bupropion			S	Unknown	200 Mg, 1d		Glaxosmithkline
	Bupropion			S	Unknown	300 Mg, 1d		Glaxosmithkline
	Lorazepam			S	Unknown	0.5 Mg, In 8 Hr As Necessary		Glaxosmithkline
	Lorazepam			S	Unknown	1 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Unknown	5 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	20 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	10 Mg, 1d		Glaxosmithkline
	Escitalopram			S	Unknown	15 Mg, 1d		Glaxosmithkline
	Lithium			S	Unknown	600 Mg, 1d Every Bedtime		Glaxosmithkline
	Lamotrigine			S	Unknown	150 Mg, 1d		Glaxosmithkline
	Lamotrigine			S	Unknown	100 Mg, 1d		Glaxosmithkline

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Amphetamine + Dextroamphetamine Extended- Release (Generic Adderall)	S	Unknown	20 Mg, 1d	Not Reported
Amphetamine + Dextroamphetamine Extended- Release (Generic Adderall)	S	Unknown	10 Mg, 1d	Not Reported
Testosterone	S	Topical	1 Df, 1d 50 Mg/5 G Every Morning On The Right Upper Extremity	Not Reported
Lurasidone	S	Unknown	40 Mg, 1d After Dinner	Not Reported
Buspirone	S	Unknown	30 Mg, Unk 15 Mg,1 In 12 Hr	Not Reported
Buspirone	S	Unknown	45 Mg, Unk	Not Reported
Buspirone	S	Unknown	10 Mg, 1d	Not Reported
Buspirone	S	Unknown	17.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	22.5 Mg, Unk	Not Reported
Buspirone	S	Unknown	45 Mg, Unk	Not Reported
Buspirone	S	Unknown	15 Mg, 1d	Not Reported
Buspirone	S	Unknown	2.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	22.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	5 Mg, 1d	Not Reported
Buspirone	S	Unknown	7.5 Mg, 1d	Not Reported
Buspirone	S	Unknown	15 Mg, Unk	Not Reported
Buspirone	S	Unknown	22.5 Mg, Unk	Not Reported
Buspirone	S	Unknown	20 Mg, 1d	Not Reported
Aripiprazole	S	Unknown	4 Mg, 1d Every Bedtime	Not Reported
Aripiprazole	S	Unknown	2 Mg, 1d	Not Reported
Benztropine (Benzatropine Mesilate)	C	Unknown	0.5 Mg, Bid As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15762497	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2018M1095140		45 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Erythema; Intentional Overdose; Sopor; Suicide Attempt	Lorazepam			S	Oral	20 Milligram, Total		Not Reported	
	Lorazepam			S	Oral	20 Milligram, Unk		Not Reported	
	Tachipirina			S	Oral	2 Gram, Total		Mylan	
	Cipralex /01588501/			S	Oral	15 Milliliter, Total		Mylan	
	Cipralex /01588501/			S	Oral	15 Milliliter, Unk		Mylan	
	Tolep			S	Oral	38 Dosage Form, Total		Mylan	
	Brintellix			S	Oral	15 Milliliter, Total		Mylan	
	Brintellix			S	Oral	15 Milliliter, Unk		Mylan	
	Oxcarbazepine			S	Oral	Unk		Mylan	
	Paracetamol			S	Oral	2 Gram, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15773358	EXPEDITED (15-DAY)			JP-ALLERGAN-1859521US		45 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15813040	EXPEDITED (15-DAY)		HO	HR-GLAXOSMITHKLINE-HR2019002976			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Product Use In Unapproved Indication	Botox			S	Intramuscular	Unk Unk, Single		Glaxosmithkline	
	Propranolol			S	Unknown	180 Mg, Unk		Glaxosmithkline	
	Propranolol			S	Unknown	120 Mg, Unk		Glaxosmithkline	
	Imigran			S	Unknown	Unk		Glaxosmithkline	
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported	
	Ketonal (Ketoprofen)			S	Unknown	Unk		Not Reported	
	Helex			S	Unknown	Unk		Not Reported	

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Elicea	S	Unknown	Unk	Not Reported
Propyphenazone + Caffeine	S	Unknown	Unk	Not Reported
Normabel	S	Unknown	Unk	Not Reported
Amyzol	S	Unknown	Unk	Not Reported
Knavon	S	Unknown	Unk	Not Reported
Topiramate	S	Unknown	Unk	Not Reported
Erenumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15846435	EXPEDITED (15-DAY)	CA, OT		DE-HETERO CORPORATE- HET2019DE00047			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect;	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero	
Congenital Laryngeal	Levothyroxine			C	Transplacental	75 Mg, Qd		Not Reported	
Stridor; Congenital	Xanaflu			C	Transplacental	Unk		Not Reported	
Tracheomalacia; Foetal									
Exposure During									
Pregnancy; Pectus									
Excavatum									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15851639	EXPEDITED (15-DAY)	HO, OT		AU-FLAMINGO-002651		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury;	Metronidazole			S				Not Reported	
Hepatitis Infectious	Piperacillin Sodium/Tazobactam			S				Not Reported	
Mononucleosis;	Sodium								
Hypersensitivity;	Cefalexin			S				Not Reported	
Idiosyncratic Drug	Ciprofloxacin			S				Not Reported	
Reaction; Rash; Swelling	Oseltamivir/Oseltamivir			C				Not Reported	
Face	Phosphate								
	Ceftriaxone			S				Not Reported	
	Escitalopram			S				Not Reported	
	Clindamycin			S				Not Reported	
	Benzylpenicillin			S				Not Reported	

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	Mesalazine			C					Not Reported
	Ceftriaxone			S					Not Reported
	Metronidazole			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15851668	EXPEDITED (15-DAY)		OT	IT-ACCORD-102897		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Overdose; Poisoning Deliberate; Sopor	Escitalopram			S	Oral	10 Df Units In Total		Not Reported	
	Xanax			S	Oral	12 Df Units In Total		Not Reported	
	Haldol			S	Oral	15 MI In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15852023	NON-EXPEDITED			DE-ALKEM LABORATORIES LIMITED-DE-ALKEM- 2018-06133		45 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Logorrhoea; Mood Swings; Restlessness; Toxicity To Various Agents	Amlodipine Besylate			S	Unknown	Unk		Alkem	
	Methadone Hydrochloride			S	Unknown	Unk		Alkem	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
	3,4 Methylenedioxypyrovalerone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15852235	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX- 2019AP006662		30 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Substance Abuse	Quetiapine			S	Oral	25 Mg, In Total		Apotex	
	Escitalopram Oxalate			S	Oral	20 Mg, In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15852521	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2019-002166		91 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Gabapentin			S	Oral	Unk		Aurobindo	
	Irbesartan And Hydrochlorothiazide			S	Oral	Unk		Aurobindo	
	Carbamazepine			S	Oral	50 Milligram, Daily(200 Mg In The Morning A Quarter Of A Tablet)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15852523	EXPEDITED (15-DAY)		HO, OT	AU-MICRO LABS LIMITED-ML2019-00065		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling Face	Escitalopram			S				Not Reported	
	Clindamycin			S				Micro Labs	
	Ciprofloxacin			S				Not Reported	
	Ceftriaxone			S				Not Reported	
	Ceftriaxone			S				Not Reported	
	Benzylpenicillin			S				Not Reported	
	Metronidazole			S				Not Reported	
	Metronidazole			S				Not Reported	
	Tazocin			S				Not Reported	
	Cephalexin			S				Not Reported	
	Oseltamivir			C				Not Reported	
	Mesalazine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15854047	NON-EXPEDITED			US-PFIZER INC-2019027775		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine Besilate			S		5 Mg, 1x/Day (Every Night		Pfizer	

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Asa	S	At Bedtime)	Not Reported
Avodart	S	8 Mg, Unk	Not Reported
Lexapro	S	Unk, Daily (0.5 Daily)	Not Reported
Lisinopril	S	10 Mg, 1x/Day (Every Night At Bedtime)	Not Reported
Simvastatin	S	10 Mg, Daily	Not Reported
Tamsulosin	S	20 Mg, Daily	Not Reported
		Unk, Daily (0.4 Daily)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855359	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902418US		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haemorrhagic Stroke	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Kardegic			S	Oral	1 Df, Qd		Not Reported
	Cardensiel			C	Oral	1 Df, Qd		Not Reported
	Esomeprazole			C	Oral	20 Mg, Qd		Not Reported
	Lasilix			C	Oral	60 Mg, Qd		Not Reported
	Spironolactone			C	Oral	75 Mg, Qd		Not Reported
	Inegy			C	Oral	10 Mg/40 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855423	EXPEDITED (15-DAY)		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000018		92 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Dyspnoea; Feeling Abnormal; Feeling Jittery; Gastrooesophageal Reflux Disease; Haematuria; Insomnia; Unevaluable	Lasix			S	Oral	20 Mg, Qd		Validus
	Coumadin			S	Oral	5 Mg, Qd		Not Reported
	Coumadin			S	Oral	7.5 Saturday And Sunday		Not Reported
	Preservision Areds			S	Oral	2 Df, Qd		Not Reported

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Event	Pyridostigmine Bromide	S	Oral	60 Mg, Bid	Not Reported
	Fludrocortisone	S	Oral	0.1 Mg, Qod	Not Reported
	Midodrine	S	Oral	5 Mg, Tid	Not Reported
	Stool Softener	S	Oral	Unk, Qd	Not Reported
	Northera	S	Oral	100 Mg, Tid	Not Reported
	Lexapro	S	Oral	10 Mg, Qd	Not Reported
	Caffeine	S	Oral	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855537	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMP ANY-FR201901006324		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Zyprexa 5mg			S	Oral	2 Df, Daily		Not Reported	
	Seresta			S	Oral	100 Mg, Daily		Not Reported	
	Aripiprazole			S	Oral	10 Mg, Daily		Not Reported	
	Cyamemazine Tartrate			S	Oral	50 Mg, Daily		Not Reported	
	Dafalgan			S	Unknown	3 Df, Daily		Not Reported	
	Seroplex			S	Oral	1 Df, Daily		Not Reported	
	Oxycontin			S	Oral	2 Df, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855705	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN-1902733US		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Kardegic			S	Oral	75 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855709	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902748US			Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855710	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1902754US		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Not Reported	
	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Not Reported	
	Aripiprazole			S	Oral	10 Mg, Qd		Not Reported	
	Tercian			S	Oral	1/2cp-1/2cp-/1cp/J		Not Reported	
	Zyprexa			S	Oral	Unk Unk, Qd		Not Reported	
	Zyprexa			S	Oral	2 Df, Qd		Not Reported	
	Dafalgan Codeine			S	Unknown	3 Df, Qd		Not Reported	
	Oxycontin Lp			S	Oral	2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15856890	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Celexa			S				Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15946703	DIRECT					72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Nasal Dryness; Rhinalgia; Skin Discolouration	Mupirocin 2% Ointment	S	Nasal	Quantity:2 % Percent;Other Frequency:2xday For 7- 10days;	Taro
	Synthroid	C			Not Reported
	Escitalopram	S			Not Reported
	Vitamin A	C			Not Reported
	Vitamin A	C			Not Reported
	Methylcobalamin (Vitamin B-12)	C			Not Reported
	Vitamin C With Bioflavonoids	C			Not Reported
	Vitamin D3	C			Not Reported
	Biotin	C			Not Reported
	Calcium	C			Not Reported
	Magnesium With Vitamin D-3	C			Not Reported
	Cholacol (Bile Salt)	C			Not Reported
	Curamin (Bcm-95 Curcumin)	C			Not Reported
	Papaya Enzyme With Chlorophyll Tablet	C			Not Reported
	Potassium	C			Not Reported
	Priobiotic	C			Not Reported
	Zinc	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	14307642	EXPEDITED (15-DAY)	HO		PHHY2017FR185849		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Metformin			S	Oral	500 Mg, Bid		Novartis
	Bisoprolol Fumarate			S	Oral	1.25 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Tid		Not Reported
	Irbesartan			S	Oral	300 Mg, Qd		Not Reported
	Terbutaline Sulfate			S	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Furosemide			S	Oral	30 Mg, Bid		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported

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	Nefopam Hydrochloride	S	Oral	3 Df, Qd	Not Reported
	Dafalgan	S	Oral	1000 Mg, Tid	Not Reported
	Diffu K	S	Oral	6 Df, Qd (3 Df Daily (2-1-0) 2x/Day (Bid))	Not Reported
	Xarelto	S	Oral	20 Mg, Qd	Not Reported
	Seroplex	S	Oral	1 Df, Qd	Not Reported
	Tavanic	S	Oral	250 Mg, Bid	Not Reported
	Valium	S	Oral	3 Df, Qd	Not Reported
	Diazepam	S	Oral	10 Mg, Tid	Not Reported
	Colchicine Opocalcium	S	Oral	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	14360707	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1001381		36 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling Face	Escitalopram			S	Unknown	5 Mg, Qd (1x Daags 1 Tablet)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	14615756	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-064260		74 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Accidental Overdose; Product Administration Error; Sopor	Clozapine			S	Oral			Not Reported
	Lorazepam			S	Oral			Accord
	Entact			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	14845118	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-042015		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Clonus; Confusional State; Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Nystagmus; Psychomotor Retardation; Suicide Attempt; Toxicity To Various Agents	Escitalopram Venlafaxine/Venlafaxine Hydrochloride Bromazepam Lormetazepam	S S S S	Oral Oral Oral Oral	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15722013	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2018-US-017928		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholelithiasis;	Xyrem			S	Oral	2.25 G, Bid		Jazz
Dehydration; Drug Ineffective;	Xyrem			S	Oral	Dose Adjustments		Jazz
Gastrointestinal Disorder;	Xyrem			S	Oral	3.75 G, Bid		Jazz
Gastrooesophageal Reflux Disease; Headache;	Zolpidem			S				Not Reported
Nausea; Viral Infection;	Escitalopram			S				Not Reported
Vomiting	Clonazepam			S				Not Reported
	Trazodone			S				Not Reported
	Amitriptyline Hcl			C				Not Reported
	Benadryl A			C				Not Reported
	Botox			C				Not Reported
	Iron			C				Not Reported
	Sumatriptan			C				Not Reported
	Vit D3			C				Not Reported
	Vit B12			C				Not Reported
	Tretinoin			C				Not Reported
	Seasonique			C				Not Reported
	Melatonin			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Ibuprofen			C				Not Reported
	Excedrin Migraine			C				Not Reported
	Allegra Allergy			C				Not Reported
	Ondansetron Hcl			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Methylphenidate			C				Not Reported
	Modafinil			C				Not Reported

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Topiramate	C	Not Reported
Sumatriptan Succinate	C	Not Reported
Cymbalta	C	Not Reported
Triamcinolone	C	Not Reported
Singulair	C	Not Reported
Norco	C	Not Reported
Ambien	C	Not Reported
Aleve	C	Not Reported
Amyvid	C	Not Reported
Hydrocodone/Apap	C	Not Reported
Nuvigil	C	Not Reported
Zolpidem Tartrate	C	Not Reported

Oral 10 Mg, Qd

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15804473	EXPEDITED (15-DAY)	HO		RO-ALLERGAN-1900656US		54 YR	Male	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Bronchitis; Chest	Quetiapine			S	Unknown	800 Mg, Qd		Not Reported
Discomfort; Chronic	Quetiapine			S	Unknown	300 Mg, Qd		Not Reported
Gastritis; Decreased	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
Appetite; Depressed	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
Mood; Depression;	Risperidone			S	Unknown	6 Mg, Qd		Not Reported
Depressive Symptom;	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
Dizziness; Drug	Doxepine			S	Unknown	100 Mg, Qd		Not Reported
Ineffective; Dyspnoea;	Olanzapine			S	Unknown	15 Mg, Qd		Not Reported
Fatigue; Feeling Guilty;								
Headache; Helplessness;								
Hypertension; Illness								
Anxiety Disorder;								
Insomnia; Libido								
Decreased; Memory								
Impairment; Obsessive-								
Compulsive Personality								
Disorder; Self Esteem								
Decreased; Somatic								
Symptom Disorder;								
Weight Decreased								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15820876	EXPEDITED (15-DAY)		HO	HR-JNJFOC-20190110264			Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance	Topiramate			S	Oral			Not Reported
	Propranolol			S	Unknown			Not Reported
	Propranolol			S	Unknown			Not Reported
	Ketoprofen			S	Unknown			Not Reported
	Helex			S	Unknown			Not Reported
	Elicea			S	Unknown			Not Reported
	Normabel			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Cipralext			S	Unknown			Not Reported
	Botox			S	Unknown			Not Reported
	Sumatriptan Sulfate			S	Unknown			Not Reported
	Knaxon			S	Unknown			Not Reported
	Erenumab			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15845176	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-000867		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Asthenia; Back Pain; Chest Pain; Chills; Confusional State; Decreased Appetite; Depression; Fatigue; Insomnia; Irritability; Libido Decreased; Memory Impairment; Somnolence; Suicidal Ideation; Thirst	Auro-Escitalopram Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo
	Atorvastatin Calcium			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15847701	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1902571US		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catatonia	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported	
	Alprazolam			S	Unknown	4 Mg, Qd (4 Separate Dosages Of 1 Mg)		Not Reported	
	Alprazolam			S	Unknown	1 Mg, Qd (4 Separate Dosages Of 0.25 Mg)		Not Reported	
	Losartan			C	Unknown			Not Reported	
	Rosuvastatin			C	Unknown			Not Reported	
	Metformin			C	Unknown	500 Mg, Bid		Not Reported	
	Sitagliptin			C	Unknown	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856161	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-196866		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Rash; Swelling Face	Cefalexin			S	Unknown	Unk		Ranbaxy	
	Cefalexin			S				Ranbaxy	
	Oseltamivir			S	Unknown	Unk		Not Reported	
	Oseltamivir			S				Not Reported	
	Mesalazine			S	Unknown	As Necessary		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Metronidazole			C	Unknown	Unk		Not Reported	

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856242	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002494		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856243	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1002493			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Baclofen			C				Not Reported	
	Cialis			C				Not Reported	
	Pregabalin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856245	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002497		35 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856744	EXPEDITED (15-DAY)		HO	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019019562			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Escitalopram Oxalate			S	Oral	10 Milligram, 24 Hourly		Macleods	
	Irbesartan/Hydrochlorothiazide			S	Oral	Unk		Macleods	
	Carbamazepine			S	Oral	50 Milligram, 24 Hourly,		Not Reported	

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Gabapentin			S		Oral		(200 Mg In The Morning A Quarter Of A Tablet)		Unk		Not Reported	
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23-Jan-2019	15856808	EXPEDITED (15-DAY)		DE		US- OSMOTICA_PHARMAC EUTICAL_US_LLC- POI0573201900037			23 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>		<u>Mfr</u>	
Completed Suicide	Methylphenidate Hydrochloride Extended-Release Tablets				S						Osmotica	
	Bupropion				S						Not Reported	
	Escitalopram				S						Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2019	15856809	EXPEDITED (15-DAY)		DE		US- OSMOTICA_PHARMAC EUTICAL_US_LLC- POI0573201900038			33 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>		<u>Mfr</u>	
Completed Suicide	Methylphenidate Hydrochloride Extended-Release Tablets				S						Osmotica	
	Propranolol				S						Not Reported	
	Escitalopram				S						Not Reported	
	Lamotrigine				S						Not Reported	
	Diazepam				S						Not Reported	
	Melatonin				S						Not Reported	
	Olanzapine				S						Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>		<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2019	15857080	EXPEDITED (15-DAY)		OT		DE-ASTRAZENECA- 2019SE07475			32 YR	Female	DEU	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>		<u>Mfr</u>	
Stillbirth	Quetiapine				S	Oral					Zeneca	
	Escitalopram				S	Oral					Not Reported	

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Presinol			S		Oral			Not Reported	
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23-Jan-2019	15857183	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-102681		36 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Off Label Use; Rash; Swelling Face	Escitalopram			S				Not Reported	
	Tazocin			S				Not Reported	
	Cefalexin			S				Not Reported	
	Ciprofloxacin			S				Not Reported	
	Oseltamivir/Oseltamivir			C				Not Reported	
	Phosphate								
	Ceftriaxone			S				Not Reported	
	Clindamycin			S				Not Reported	
	Benzympenicillin			S				Not Reported	
	Mesalazine			C				Not Reported	
	Metronidazole			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15859172	EXPEDITED (15-DAY)		OT	BE-TEVA-2019-BE-1002247		52 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Limb Discomfort; Syncope; Tremor	Escitalopram 10 Mg			S	Oral	5 Milligram Daily;		Ivax	
	L-Thyroxine Christiaens 25 Ug, Tablet			C	Oral	Monday -Tuesday - Friday : 25 Microgram/Day Wednesday -Saturday - Sunday : 2.25 Microgram/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15859310	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902769US		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Meningioma	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	

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	Oestrogel		S	Transdermal				Not Reported	
	Androcur		S	Oral				Not Reported	
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23-Jan-2019	15859315	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1902771US		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Psychomotor Skills Impaired; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Depamide			S	Oral	Unk		Not Reported	
	Zyprexa			S	Oral	Unk		Not Reported	
	Solian			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15860057	EXPEDITED (15-DAY)		DE	US-PHARMA_RESEARCH_SOFTWARE_SOLUTION-USA-POI058020		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Potassium Chloride For Oral Solution			S				Pharma Research Software Solution	
	Metoprolol			S				Not Reported	
	Amlodipine			S				Not Reported	
	Hydrochlorothiazide			S				Not Reported	
	Quetiapine			S				Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15860170	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1902926US		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Fall; Haematoma; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Inexium			S	Ophthalmic	1 Df, Qd		Not Reported	
	Lasilix			S	Oral	1 Df, Qd		Not Reported	

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Lipanthyl	S	Oral	1 Df, Qd	Not Reported
Xarelto	S	Oral	1 Df, Unk	Not Reported
Dafalgan	C	Unknown	Unk	Not Reported
Aranesp	C	Unknown	Unk	Not Reported
Cardensiel	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15860260	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1902708US		36 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Night Sweats; Off Label Use; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	Actual: 1/4 Of 5mg Tablet Once Daily.		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Diazepam			C	Unknown	Actual: Approx 20 Tablets Prescribed Every 2/3 Months.		Not Reported	
	Buscopan			C	Unknown	10 Mg, Prn		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15357950	EXPEDITED (15-DAY)		OT	PHHY2018CZ047147		58 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Clomipramine			S	Unknown	Unk Unk, Unknown		Novartis	
	Olanzapine			S	Unknown	Unk Ukn, Unknown		Not Reported	
	Olanzapine			S				Not Reported	
	Escitalopram			S	Unknown	Unk Ukn, Unknown		Not Reported	
	Citalopram			S	Unknown	Unk Ukn, Unknown		Not Reported	
	Aripiprazole			S	Unknown	Unk Ukn, Unknown		Not Reported	
	Mirtazapine			S	Oral	Unk Ukn, Unknown		Not Reported	
	Mirtazapine			S				Not Reported	
	Mirtazapine			S				Not Reported	

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Ziprasidone	S	Unknown	Unk Ukn, Unknown	Not Reported
Risperidone	S	Unknown	Unk Ukn, Unknown	Not Reported
Venlafaxine	S	Unknown	Unk Ukn, Unknown	Not Reported
Melperone	C	Unknown	Unk Ukn, Unknown	Not Reported
Tiapride	C	Unknown	Unk Ukn, Unknown	Not Reported
Haloperidol	C	Unknown	Unk Ukn, Unknown	Not Reported
Propofol	C	Unknown	Unk Ukn, Unknown	Not Reported
Memantine	C	Unknown	Unk Ukn, Unknown	Not Reported
Clonazepam	C	Unknown	Unk Ukn, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15612484	EXPEDITED (15-DAY)	HO		FR-009507513-1811FRA002682		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Thrombosis	Desloratadine			S	Oral	5 Milligram, 1 Per Day		Merck
	Methotrexate			S	Subcutaneous	20 Milligram, 1 Per Week		Not Reported
	Lisinopril			S	Oral	10 Milligram, 1 Per Day		Merck
	Prednisone			S	Oral	4 Milligram, 1 Per Day		Merck
	Cacit [Calcium Carbonate]			S	Oral	1 Dosage Form, 1 Per Day		Not Reported
	Codeine			S	Oral	2 Dosage Form, 1 Per Day		Not Reported
	Escitalopram			S	Oral	20 Milligram, 1 Per Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Per Week		Not Reported
	Acetaminophen			S	Oral	2 Dosage Form, 1 Per Day		Not Reported
	Risedronate Sodium			S	Oral	35 Milligram, 1 Per Week		Not Reported
	Speciafoldine			S	Oral	10 Milligram, 1 Per Week		Not Reported
	Uvedose			S	Oral	1 Dosage Form, 1 Per Trimester		Not Reported
	Valacyclovir Hydrochloride			S	Oral	1000 Milligram, Qd		Not Reported

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24-Jan-2019	15757434	EXPEDITED (15-DAY)		HO	FR-OTSUKA-2018_039661		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Mg, Qd		Otsuka	
	Nalmefene			S	Oral	1 Df, Qd		Not Reported	
	Seroplex			S	Unknown	20 Mg, Qd		Not Reported	
	Lexomil			C	Unknown	1 Df, Qd		Not Reported	
	Corgard			C	Unknown	80 Mg, Qd		Not Reported	
	Loxen (Nicardipine Hydrochloride)			C	Unknown	1 Df, Qd		Not Reported	
	Methadone			C	Unknown	80 Mg, Qd		Not Reported	
	Ventolin			C	Unknown	Unk		Not Reported	
	Kardegic			C	Unknown	1 Df, Qd		Not Reported	
	Theralene			C	Unknown	2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15861093	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1002945		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stillbirth	Quetiapine			S	Oral	25 Milligram Daily; 25 [Mg/D]		Teva	
	Escitalopram			S	Oral	20 Milligram Daily; 20 [Mg/D]		Ivax	
	Presinol			S	Oral	500 Milligram Daily; 500 [Mg/D (2x250)]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15861416	NON-EXPEDITED			US-APOTEX-2019AP005058		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dizziness; Gastrointestinal Disorder; Restlessness; Somnolence	Fluoxetine	S	Unknown	5 Mg, Unk	Apotex
	Fluoxetine	S			Apotex
	Sertraline	S	Unknown	12.5 Mg, Unk	Apotex
	Sertraline	S			Apotex
	Citalopram	S	Unknown	5 Mg, Unk	Apotex
	Citalopram	S			Apotex
	Escitalopram	S	Unknown	2.5 Mg, Unk	Apotex
	Escitalopram	S			Apotex
	Dextroamphetamine /00016601/	C	Unknown	25 Mg, Unk	Not Reported
	Dextroamphetamine /00016601/	C			Not Reported
	Methylphenidate	C	Unknown	5 Mg, Unk	Not Reported
	Methylphenidate	C			Not Reported

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24-Jan-2019	15862646	EXPEDITED (15-DAY)		DE	US-PERRIGO-19US000749		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Acetaminophen			S	Oral	Unknown, Unknown		Perrigo
	Escitalopram			S	Unknown	Unknown, Unknown		Not Reported
	Doxepin			S	Unknown	Unknown, Unknown		Not Reported
	Cough And Cold Preparations			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15863017	NON-EXPEDITED			US-TEVA-2018-US-994130			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder; Malaise	Escitalopram			S				Ivax
	Escitalopram			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15863179	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SE08060		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Kidney Injury; Fall; Haematoma; Hyponatraemia	Inexium	S	Oral	Not Reported
	Seroplex	S	Oral	Not Reported
	Furosemide	S	Oral	Not Reported
	Lipanthyl 200	S	Oral	Not Reported
	Rivaroxaban	S	Oral	Not Reported
	Cardensiel	C		Not Reported
	Aranesp	C		Not Reported
	Dafalgan	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15865323	NON-EXPEDITED			US-ACORDA- ACO_154566_2018		44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Ampyra			S	Oral	10 Milligram, Q 12 Hrs		Acorda
Abdominal Pain;	Lexapro			S	Unknown	Unk		Not Reported
Abdominal Pain Upper;	Tecfidera			S	Unknown	240 Milligram, Bid		Not Reported
Back Pain; Balance	Tecfidera			S	Unknown	240 Milligram, Qd		Not Reported
Disorder; Burning	Tecfidera			S	Unknown	240 Milligram, Bid		Not Reported
Sensation; Constipation;	Alli			C	Unknown	Unk		Not Reported
Decreased Appetite;	Aspirin			C	Unknown	Unk		Not Reported
Depression; Faeces								
Discoloured; Feeling								
Abnormal; Gastric								
Disorder; Headache;								
Insomnia; Muscular								
Weakness; Nausea; Neck								
Pain; Pruritus; Vitamin D								
Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15865391	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD- MAC2019019679			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis Infectious	Escitalopram Oxalate			S	Unknown	Unk		Macleods	

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Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling Face	Ceftriaxone	S	Unknown	Unk	Not Reported
	Ceftriaxone	S			Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Benzylpenicillin	S	Unknown	Unk	Not Reported
	Cephalexin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	S.O.S.	Not Reported
	Metronidazole	S			Not Reported
	Tazocin	S	Unknown	Unk	Not Reported
	Oseltamivir	C	Unknown	Unk	Macleods
	Mesalazine	C	Unknown	Unk, S.O.S.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	13071337	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2016M1057329		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Drug Ineffective; Drug Interaction; Feeling Of Despair; Insomnia; Intentional Product Misuse; Medication Error; Suicidal Ideation; Treatment Noncompliance	Alprazolam			S	Oral	1.5 Mg Total Qd		Not Reported
	Alprazolam			S		1 Mg, Unk		Not Reported
	Alprazolam			S		1.5 Unk		Not Reported
	Valproic Acid			S	Oral	300 Mg, Total Qd		Not Reported
	Valproic Acid			S		600 Unk		Not Reported
	Valproic Acid			S		300 Unk		Not Reported
	Venlafaxine			S	Oral	300 Mg, Total Qd		Not Reported
	Venlafaxine			S		300 Mg,Unk		Not Reported
	Escitalopram			S	Oral	20 Mg Total Qd		Not Reported
	Escitalopram			S		20 Unk		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Total Qd		Not Reported
	Clonazepam			S	Oral	0.5 Unk		Not Reported
	Quetiapine			S	Oral	200 Mg Total Qd		Not Reported
	Quetiapine			S	Oral	200 Mg,Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trazodone	S	Oral	75 Mg Total Qd	Not Reported
Trazodone	S		150 Unk	Not Reported
Trazodone	S		75 Mg,Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	13217393	NON-EXPEDITED		HO	US-ACORDA- ACO_121585_2016		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Back Pain;	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda
Condition Aggravated;	Tysabri			S	Intravenous (not	300 Mg (Infused Over An		Not Reported
Confusional State;					otherwise specified)	Hour), Monthly		
Disease Progression; Fall;	Lexapro			S	Unknown	Unk		Not Reported
Fall; Fatigue; Gait	Ibuprofen			S	Unknown	Unk		Not Reported
Disturbance; Incorrect								
Dosage Administered;								
Neurological Symptom;								
Urticaria; Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14765858	EXPEDITED (15-DAY)		HO, LT, OT	ES-ALLERGAN- 1821233US		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Behaviour	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
Disorder; Cardio-	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan
Respiratory Arrest;	Haloperidol			S	Unknown	Unk		Not Reported
Condition Aggravated;	Haloperidol			S	Unknown	2 Mg, Qd		Not Reported
Electrocardiogram Qt								
Prolonged; Myocardial								
Ischaemia; Off Label Use;								
Torsade De Pointes								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15243075	EXPEDITED (15-DAY)		HO	DE-ACCORD-070543		42 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Drug Level Decreased; Major Depression; Panic Attack; Prescribed Overdose	Escitalopram	S	Oral	Overdose: 30 Mg, Overdose: 40 Mg Also Received 40 Mg On Dec-2017	Not Reported
	Lorazepam	C			Not Reported
	Pangrol	C		Dose 2 Unk Unit	Not Reported
	Olanzapine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15747063	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1858362US		44 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Selincro			S	Oral	1 Df, Qd		Not Reported
	Abilify			S	Unknown	2 Mg, Unknown		Not Reported
	Lexomil			C	Unknown	1 Df, Unknown		Not Reported
	Corgard			C	Unknown	80 Mg, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			C	Unknown	1 Df, Qd		Not Reported
	Methadone			C	Unknown	80 Mg, Qd		Not Reported
	Ventolin			C	Unknown	Unk, Unknown		Not Reported
	Kardegic			C	Unknown	Unk, Qd		Not Reported
	Theralene			C	Unknown	2 Df, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15812097	EXPEDITED (15-DAY)		HO, OT	AU-BAUSCH-BL-2019-000630		36 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Hypersensitivity; Idiosyncratic Drug Reaction; Rash; Swelling	Clindamycin			S	Unknown			Not Reported
	Metronidazole			S	Unknown	As Required		Not Reported
	Metronidazole			S				Not Reported
	Ceftriaxone Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Face	Ceftriaxone Sodium	S			Not Reported
	Cephalexin	S	Unknown		Not Reported
	Cephalexin	S			Not Reported
	Escitalopram Oxalate	S	Unknown		Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Benzylpenicillin	S	Unknown		Not Reported
	Tazocin	S	Unknown		Not Reported
	Oseltamivir	C			Not Reported
	Oseltamivir	C			Not Reported
	Mesalazine	C		As Required	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15848916	EXPEDITED (15-DAY)		HO, OT	RO-JNJFOC-20190113479		54 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety;	Risperidone			S	Unknown			Not Reported	
Bronchitis; Chest	Mirtazapine			S	Unknown			Not Reported	
Discomfort; Chronic	Clonazepam			S	Unknown			Not Reported	
Gastritis; Condition	Escitalopram			S	Unknown			Not Reported	
Aggravated; Decreased	Doxepine			S	Unknown			Not Reported	
Appetite; Depressed	Olanzapine			S	Unknown			Not Reported	
Mood; Depression;	Duloxetine			S	Unknown			Not Reported	
Depression; Dizziness;	Quetiapine			S	Unknown			Not Reported	
Drug Ineffective;	Quetiapine			S	Unknown			Not Reported	
Dyspnoea; Fatigue;	Quetiapine			S	Unknown			Not Reported	
Feeling Guilty; Headache;	Quetiapine			S	Unknown			Not Reported	
Helplessness;	Quetiapine			S	Unknown			Not Reported	
Hypertension; Illness	Quetiapine			S	Unknown			Not Reported	
Anxiety Disorder;	Quetiapine			S	Unknown			Not Reported	
Insomnia; Libido	Quetiapine			S	Unknown			Not Reported	
Decreased; Loss Of									
Personal Independence In									
Daily Activities; Memory									
Impairment; Obsessive-									
Compulsive Personality									
Disorder; Self Esteem									
Decreased; Somatic									
Symptom Disorder;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment
Noncompliance; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15865740	EXPEDITED (15-DAY)		OT	DE-LUPIN PHARMACEUTICALS INC.-2019-00188		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Stillbirth	Quetiapine Fumarate			S	Oral	25 Mg, Qd		Lupin	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Presinol			S	Oral	250 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866881	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2019DE00077		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stillbirth	Escitalopram			S	Oral	20 Milligram, Qd, During First Trimester (0-35.3 Gestational Week)		Hetero	
	Quetiapine			S	Oral	25 Milligram, Qd, During First Trimester (0-35.3 Gestational Week)		Not Reported	
	Presinol			S	Oral	500 Milligram, Qd, During Third Trimester (33.4-35.3 Gestational Week)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866959	EXPEDITED (15-DAY)		HO, LT, OT	CZ-ACCORD-103475			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Electrocardiogram Qt Prolonged;	Clonazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

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Electrocardiogram Qt Shortened; Epilepsy; Gastrointestinal	Ibuprofen	S	Unknown	Not Reported
Hypermotility; Loss Of Consciousness; Poisoning	Levomepromazine	S	Oral	Not Reported
	Metoclopramide	S	Oral	Not Reported
	Melperone/Melperone Hydrochloride	S	Oral	Not Reported
	Olanzapine	S	Oral	Not Reported
	Venlafaxine/Venlafaxine Hydrochloride	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866993	EXPEDITED (15-DAY)		HO	FR-ACCORD-103253		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Urinary Retention	Escitalopram			S	Oral			Not Reported	
	Haldol			S	Oral	Strength:2 Mg/ML		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867108	EXPEDITED (15-DAY)		HO, LT, OT	IN-TORRENT-00002101		23 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Olanzapine			S		Nearly 4 Years		Unknown	
	Fluoxetine			S		Unknown		Unknown	
	Escitalopram			S				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867115	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013050		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

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Detailed Report

Exposure During Pregnancy; Stillbirth	Quetiapine	S	Oral	25 [Mg/D]	Unknown
	Escitalopram	S	Oral	20 [Mg/D]	Unknown
	Presinol	S	Oral	500 [Mg/D (2x250)]	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867582	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190130474		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Fall; Hyponatraemia; Subcutaneous Haematoma	Xarelto			S	Oral			Not Reported	
	Inexium			S	Ophthalmic			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Lasilix			S	Oral			Not Reported	
	Lipanthyl			S	Oral			Not Reported	
	Cardensiel			C	Unknown			Not Reported	
	Dafalgan			C	Unknown			Not Reported	
	Aranesp			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15868282	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019030420		91 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Gabapentin			S	Oral	Unk		Pfizer	
	Carbamazepine			S	Oral	50 Mg, 1x/Day (200mg In The Morning 1/4 Of The Tablet)		Not Reported	
	Irbesartan And Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15868316	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019030378			Male	HRV

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Alprazolam			S	Oral	Unk		Pfizer	
	Escitalopram			S	Oral	Unk		Not Reported	
	Caffetin [Caffeine;Codeine Phosphate Sesquihydrate;Paracetamol;Propyph			S	Oral	Unk		Not Reported	
	Klonazepam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15868460	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1002872		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Milligram Daily;		Not Reported	
	Seresta 50 Mg, Comprimé Sécable			S	Oral	100 Milligram Daily; 1/2cp-1/2cp-/1cp		Not Reported	
	Tercian 25 Mg, Comprimé Pelliculé Sécable			S	Oral	50 Milligram Daily; 1/2cp-1/2cp-/1cp/J		Not Reported	
	Zyprexa 5 Mg, Comprimé Enrobé			S	Oral	2 Dosage Forms Daily;		Not Reported	
	Dafalgan Codeine, Comprimé Pelliculé			S		3 Dosage Forms Daily;		Not Reported	
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Oxycontin Lp 40 Mg, Comprimé Pelliculé À Libération Prolongée			S	Oral	2 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15868731	EXPEDITED (15-DAY)		DE	US-GENUS_LIFESCIENCE S-USA-POI0580201900172		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Hydrocodone Bitartrate And Acetaminophen Oral Solution			S				Genus Lifesciences	

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	Escitalopram			S					Not Reported
	Acetaminophen With Oxycodone			S					Not Reported
	Alprazolam			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15869147	EXPEDITED (15-DAY)		OT	FR-NAPPMUNDI-GBR-2019-0063544		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Oxycontin Lp			S	Oral	2 Df, Daily (Strength 40mg)		Purdue	
	Seresta			S	Oral	100 Mg, Daily (1/2cp-1/2cp-/1cp)		Not Reported	
	Aripiprazole			S	Oral	10 Mg, Daily		Not Reported	
	Tercian /00759301/			S	Oral	50 Mg, Daily (1/2cp-1/2cp-/1cp/J)		Not Reported	
	Zyprexa			S	Oral	2 Df, Daily		Not Reported	
	Dafalgan Codeine			S	Unknown	3 Df, Daily		Not Reported	
	Seroplex			S	Oral	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2019	14413469	NON-EXPEDITED			US-TAKEDA-2016TEU001693		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Protonix			S	Unknown	Unk		Not Reported	
	Pantoprazole			S	Unknown	Unk		Not Reported	
	Trintellix			S	Unknown	Unk		Takeda	
	Vortioxetine			S	Unknown	Unk		Takeda	
	Lexapro			S	Unknown	Unk		Not Reported	
	Victoza			S	Unknown	Unk		Not Reported	
	Wellbutrin			S	Unknown	Unk		Not Reported	
	Elavil /00002202/			S	Unknown	Unk		Not Reported	

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Levaquin	S	Unknown	Unk	Not Reported
Lipitor	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Zithromax	S	Unknown	Unk	Not Reported
Dilantin /00017401/	S	Unknown	Unk	Not Reported
Valsartan	S	Unknown	Unk	Not Reported
Levomenol	S	Unknown	Unk	Not Reported
Bupropion	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Liraglutide	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2019	15871242	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019019742			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Stillbirth	Escitalopram Oxalate			S	Oral	20 Milligram, Qd,		Macleods
	Quetiapine			S	Oral	25 Milligram, Qd		Macleods
	Presinol			S	Oral	500 Milligram, Qd, 500 [Mg/D (2x250)]		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2019	15873420	NON-EXPEDITED			US-ACORDA- ACO_150530_2018			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Thirst	Ampyra			S	Unknown	Unk		Acorda
	Escitalopram			S	Unknown	Unk		Not Reported
	Oxybutynin			S	Unknown	Unk		Not Reported

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26-Jan-2019	15874316	NON-EXPEDITED			US-ACORDA- ACO_152055_2018			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Ampyra			S	Oral	10 Mg, Bid		Acorda
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	Unk		Not Reported
	Gilenya			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Neurontin			C	Unknown	Unk		Not Reported
	Pravastatin			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Vyvanse			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Copaxone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	10621762	NON-EXPEDITED			US-PFIZER INC- 2014331226		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Inderal			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Cefprozil			S		Unk		Not Reported

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	Lexapro	S		Unk		Not Reported
	Ketoconazole	S		Unk		Not Reported
	Niaspan	S		Unk		Not Reported
	Trileptal	S		Unk		Not Reported
	Oxytrol	S	Transdermal	Unk		Not Reported
	Risperdal	S		Unk		Not Reported
	Ambien	S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	12836416	EXPEDITED (15-DAY)		HO, LT	HU-PFIZER INC-2016468953		27 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Serotonin Syndrome; Suicide Attempt	Sertraline Hcl			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Moclobemid			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	12954971	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHO2016CH016594		81 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Bradycardia; Death; Dizziness; Dyspnoea; Dyspnoea; Dyspnoea; Ligament Rupture; Pneumonia	Valsartan			S	Oral	160 Mg, Bid		Novartis	
	Valsartan			S	Oral	80 Mg, Bid		Novartis	
	Valsartan			S	Oral	40 Mg, Bid		Novartis	
	Valsartan			S	Oral	Unk		Novartis	
	Jardiance			S	Oral	10 Mg, Qd		Not Reported	
	Seroquel			S	Oral	25 Mg, Qd		Not Reported	
	Cipralelex			S	Unknown	No Treatment		Not Reported	
	Cipralelex			S	Oral	10 Mg, Qd		Not Reported	
	Detrusitol			S	Oral	4 Mg, Qd		Not Reported	
	Torem			S	Oral	10 Mg, Qd		Not Reported	

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Torem	S	Oral	10 Mg, Qd	Not Reported
Aldactone	S	Oral	25 Mg, Qd	Not Reported
Aldactone	S	Oral	12.5 Mg, Qd	Not Reported
Januvia	C	Oral	100 Mg, Qd	Not Reported
Xarelto	C	Oral	20 Mg, Qd	Not Reported
Plavix	C	Unknown	75 Mg, Sid	Not Reported
Symbicort	C	Respiratory (inhalation)	2 Inha Appl,	Not Reported
Magnesiocard	C	Oral	243 Mg, Qd	Not Reported
Ramipril	C	Oral	1.25 Mg, Qd	Not Reported
Nasonex	C	Unknown	1 Appl Spray Qd	Not Reported
Bepanthen	C	Unknown	2 Appl	Not Reported
Spiriva	C	Respiratory (inhalation)	0.018 Mg, Qd	Not Reported
Pradif	C	Oral	400 Ug, Qd	Not Reported
Pantozol	C	Oral	40 Mg, Qd	Not Reported
Crestor	C	Oral	5 Mg, Qd	Not Reported
Movicol	C	Oral	13.25 G, Qd	Not Reported
Movicol	C	Oral	26.250 G, Unk	Not Reported
Movicol	C	Unknown	1 Df, Unk	Not Reported
Vi-De3	C	Oral	8 Gtt, Qd	Not Reported
Allopurinol	C	Oral	100 Mg, Qd	Not Reported
Cardioaspirin	C	Unknown	100 Mg, Sid	Not Reported
Acidum Folicum	C	Unknown	5 Mg, Unk	Not Reported
Atorvastatin	C	Unknown	40 Mg, Sid	Not Reported
Quetiapin	C	Unknown	12.5 Mg, Sid	Not Reported
Quetiapin	C	Unknown	100 Mg, Unk	Not Reported
Ferro Sanol	C	Unknown	200 Mg, Unk	Not Reported
Concor	C	Unknown	1.25 Mg, Sid	Not Reported
Allopur	C	Oral	100 Mg, Qd	Not Reported

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Magnesium			C		Oral		10 Mmol, Qd		Not Reported	
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28-Jan-2019	14658504	NON-EXPEDITED			US-PFIZER INC-2018114204			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer		
	Effexor Xr			S		Unk		Pfizer		
	Lexapro			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Jan-2019	15830558	EXPEDITED (15-DAY)		HO	RO-009507513-1901ROM001779		54 YR	Male	ROM	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Mirtazapine			S	Unknown	30 Milligram, Daily		Merck		
	Quetiapine Fumarate			S	Unknown	800 Milligram, Daily		Not Reported		
	Quetiapine Fumarate			S	Unknown	300 Milligram, Daily		Not Reported		
	Clonazepam			S	Unknown	0.5 Milligram, Daily		Not Reported		
	Risperidone			S	Unknown	6 Milligram, Daily		Not Reported		
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported		
	Doxepin Hydrochloride			S	Unknown	100 Milligram, Daily		Not Reported		
	Olanzapine			S	Unknown	15 Milligram, Daily		Not Reported		
	Duloxetine Hydrochloride			S	Unknown	60 Milligram, Daily		Not Reported		

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28-Jan-2019	15877035	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1003624			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15877613	EXPEDITED (15-DAY)		HO	FR-ZYDUS-032850			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Zydus Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15877861	EXPEDITED (15-DAY)		OT	US-SA-2019SA021529		92 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dyspnoea; Feeling Abnormal; Feeling Jittery; Gastroesophageal Reflux Disease; Haematuria; Insomnia; Unevaluable Event	Lasix			S		20 Mg, Qd		Sanofi	
	Warfarin Sodium			S	Oral	5 Mg, Qd		Not Reported	
	Warfarin Sodium			S	Oral	7.5 Unk		Not Reported	
	Docusate Sodium			S	Oral	Unk Unk, Qd		Sanofi	
	Caffeine			S	Oral	100 Mg, Qd		Not Reported	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Preservision Areds			S	Oral	2 Df, Qd		Not Reported	
	Pyridostigmine Bromide			S		60 Mg, Bid		Not Reported	

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Fludrocortisone	S	0.1 Mg, Qod	Not Reported
Midodrine	S	5 Mg, Tid	Not Reported
Northera	S	100 Mg, Tid	Not Reported

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28-Jan-2019	15878055	EXPEDITED (15-DAY)		HO, LT, OT	IN-CIPLA LTD.- 2019IN00541			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Escitalopram			S	Unknown	10 Mg, Unk		Invagen
	Olanzapine			S	Unknown	20 Mg, Unk, Nearly 4 Years		Not Reported
	Olanzapine			S	Unknown	20 Mg, Unk		Not Reported
	Olanzapine			S	Unknown	Unk, Cross Tapered With Risperidone		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878990	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-032957		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Respiratory Depression	Gabapentin			S	Oral	Neurontin 300: 1 Tablet With Breakfast, Lunch And Dinner		Not Reported
	Alprazolam			S	Oral	Trankimazin 1: 1 Tablet / Day 30 Minutes Before Bedtime		Not Reported
	Fentanyl			S	Transdermal	Durogesic: 1 Transdermal Patch Of 100 Microgrs. And Another 50 Microgrs. Every 72 Hours		Not Reported
	Morphine			S	Oral	Sevredol 10: 1 Tablet If Significant Pain Despite Treatment With Neurontin 300 And Hard		Not Reported

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Escitalopram	S	Oral	Not Reported
Aciclovir	C		Not Reported
Metamizole Sodium	C		Not Reported
Paracetamol	C		Not Reported
Allopurinol	C		Not Reported
Furosemide	C		Not Reported
Binocrit	C		Not Reported
Enoxaparin	C	Subcutaneous	Not Reported
Pantoprazole	C		Not Reported
Calcium	C		Not Reported
Carbonate/Colecalciferol			
Nystatin	C		Not Reported
Hydroxocobalamin/Pyridoxine	C		Not Reported
Hydrochloride/Thiamine			
Hydrochloride			
Fluticasone	C		Not Reported
Propionate/Salmeterol Xinafoate			
Megestrol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15879397	EXPEDITED (15-DAY)	DE		US-PERRIGO-19US001127		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Naproxen Sodium			S	Oral	Unk		Perrigo
	Amlodipine			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Zolpidem			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15879912	EXPEDITED (15-DAY)	DE, OT		FI-MYLANLABS-2017M1083064			Unknown	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Escitalopram			S	Unknown	Unk		Not Reported
Ventricular Fibrillation	Ciprofloxacin			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15879980	EXPEDITED (15-DAY)		OT	BE-ANIPHARMA-2019-BE-000002		70 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage	Clarithromycin Extended-Release (Non-Specific)			S				Ani	
	Rivaroxaban			S	Oral	15 Mg Daily		Not Reported	
	Diltiazem			S				Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880559	EXPEDITED (15-DAY)		DE	NO-JNJFOC-20190120730			Unknown	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Wrong Product Administered	Risperidone			S	Unknown			Not Reported	
	Haldol			S	Intramuscular			Not Reported	
	Vallergan			S	Unknown			Not Reported	
	Codeine Phosphate W/Paracetamol			S	Unknown			Not Reported	
	Oxazepam			S	Unknown			Not Reported	
	Zopiclone			S	Unknown			Not Reported	
	Cipralex			S	Unknown			Not Reported	
	Paracetamol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880952	EXPEDITED (15-DAY)		DE	US-PERRIGO-19US001018		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Potassium Chloride			S	Oral	Unk		Perrigo	
	Metoprolol			S	Oral	Unk		Not Reported	
	Amlodipine			S	Oral	Unk		Not Reported	

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		Hydrochlorothiazide		S	Oral	Unk			Not Reported
		Quetiapine		S	Oral	Unk			Not Reported
		Escitalopram		S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15881028	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1007138		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Zopiclone			S	Oral	7.5 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Risperdal			S	Oral	1 Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15881038	EXPEDITED (15-DAY)		HO, LT, OT	IN-ELI_LILLY_AND_COMP ANY-IN201901011059		23 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Intentional Product Misuse; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Olanzapine			S	Unknown	20 Mg, Unknown		Eli Lilly And Co	
	Olanzapine			S	Unknown	20 Mg, Unknown		Eli Lilly And Co	
	Escitalopram			S	Unknown	10 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15881305	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1007243		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Milligram, Total		Not Reported	
	Escitalopram			S	Oral	50 Milligram, Total		Not Reported	
	Tavor /00273201/			S	Oral	Unk		Mylan	

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28-Jan-2019	15983763	DIRECT		HO, LT				Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Dyspnoea; Suicidal Ideation	Methocarbamol			S	Oral		3 YR	Granules India	
	Prozac			S				Not Reported	
	Seroquel			S				Not Reported	
	Topamax			S				Not Reported	
	Paxil			S				Not Reported	
	Hydroxyzine			S				Not Reported	
	Naproxen			S				Not Reported	
	Lexapro			S				Not Reported	
	Adderall			S				Not Reported	
	Trazodone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	8653132	EXPEDITED (15-DAY)		DE, HO, OT	DK-FRI-1000025398		72 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Overdose; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd		Allergan	
	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported	
	Lithium Citrate			S	Oral	Actual: 1 Df Am And 1.5 Df Pm		Not Reported	
	Zeldox			S	Oral	40 Mg, Unk		Not Reported	
	Amlodipine Actavis			C	Unknown			Not Reported	
	Fragmin			C				Not Reported	
	Ferro Duretter			C	Unknown	100 Mg, Qd		Not Reported	
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported	
	Centyl Med Kaliumklorid			C		1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	13505206	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1716970US		50 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan	
	Tecfidera			S	Oral	1 Df, Qd		Not Reported	
	Epitomax			S	Oral	100 Mg, Bid		Not Reported	
	Levocarnil			S	Oral	30 MI, Qd		Not Reported	
	Procoralan			S	Oral	1 Df, Bid, 1-0-1		Not Reported	
	Trivastal			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15084214	EXPEDITED (15-DAY)		LT	FR-TEVA-2018-FR-918275		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral			Teva	
	Teralithe Lp 400 Mg, Comprimé			S	Oral			Not Reported	
	Sécable À Libération Prolongée								
	Seroplex 5 Mg, Comprimé Pelliculé			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15766587	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1859349US		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Intentional Overdose; Sluggishness	Escitalopram Oxalate Unk			S	Oral	30 MI, In Total (Overdose)		Allergan	
	Alprazolam			S	Oral	20 MI, In Total		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15793185	EXPEDITED (15-DAY)		HO	RO-ROCHE-2239869		54 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety;	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported	

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Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Mirtazapine Escitalopram Oxalate Risperidone Duloxetine Doxepine Quetiapine Fumarate Quetiapine Fumarate Olanzapine	S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	30 Mg, Qd 10 Mg 6 Mg, Qd 60 Mg, Qd 100 Mg, Qd 300 Mg, Qd 800 Mg, Qd 15 Mg, Qd	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15843001	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1902043US		52 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Limb Discomfort; Off Label Use; Syncope; Tremor	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	
	L-Thyroxine Christiaens 25 Mcg, Tabletten			C	Oral	Mo-Tu-Fr: 25 Mcg/Day We-Sa-Su: 2/25 Mcg/Day		Not Reported	
	Kerutabs			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15882998	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019019672			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram Oxalate	S	Oral	15 Milligram, Qd	Macleods
	Durogesic	S	Transdermal	150 Microgram, 72 Per Hour	Not Reported
	Neurontin	S	Oral	300 Milligram, 8 Per Hour	Not Reported
	Sevredol	S	Oral	10 Milligram, S.O.S.	Not Reported
	Trankimazin	S	Oral	1 Milligram, 24 Per Hour	Not Reported
	Pantoprazole	C	Unknown	Unk	Macleods
	Paracetamol	C	Unknown	Unk	Not Reported
	Borea	C	Unknown	Unk	Not Reported
	Binocrit	C	Subcutaneous	Unk	Not Reported
	Clexane	C	Subcutaneous	Unk	Not Reported
	Hidroxil	C	Unknown	Unk	Not Reported
	Mycostatin	C	Unknown	Unk	Not Reported
	Natecal D	C	Unknown	Unk	Not Reported
	Nolotil	C	Unknown	Unk	Not Reported
	Seguril	C	Unknown	Unk	Not Reported
	Seretide	C	Unknown	Unk	Not Reported
	Zovirax	C	Unknown	Unk	Not Reported
	Zyloric	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15883367	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100861		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Clonazepam			S	Oral	Unk, Unknown		Par
	Amlodipine			S	Oral	Unk, Unknown		Not Reported
	Metoprolol			S	Oral	Unk, Unknown		Not Reported
	Hydrochlorothiazide			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

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29-Jan-2019	15883394	EXPEDITED (15-DAY)		HO	DE-ACCORD-104083		20 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Mental Disorder; Orthostatic Intolerance; Product Prescribing Error	Escitalopram			S		15 Mg, Nk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15883462	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-004660			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Prescription Form Tampering	Quetiapine			S	Unknown	Non Renseignée		Aurobindo	
	Escitalopram			S	Unknown	Non Renseignée		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15884074	NON-EXPEDITED			US-APOTEX-2017AP023722			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heat Illness; Mydriasis; Vomiting	Paxil Tablets			S	Unknown	Unk		Apotex	
	Lexapro			S	Unknown	Unk		Not Reported	
	Zoloft			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885538	EXPEDITED (15-DAY)		HO	FR-TAKEDA-2019TUS003425		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Depression; Disorientation; Drug Ineffective; Haemorrhoid	Brintellix			S	Unknown	5 Milligram		Takeda	
	Brintellix			S	Oral	15 Milligram, Qd		Takeda	

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Operation; Malaise	Seroplex	S	Oral	Unk, Qd	Not Reported
	Alprazolam	C	Unknown	Unk	Not Reported

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29-Jan-2019	15885558	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2019-ES-1003508		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram 15 Efg Comprimido			S	Oral	15 Milligram Daily; Escitalopram 15 Efg: 1 Tablet/Day With Breakfast. During The Entry Into History		Ivax
	Neurontin 300			S	Oral	Neurontin 300:1 Tablet With Breakfast, Lunch And Dinner		Not Reported
	Trankimazin 1			S	Oral	1 Milligram Daily; Trankimazin 1:1 Tablet/Day 30 Minutes Before Bedtime.		Not Reported
	Durogesic			S	Transdermal	Durogesic: 1 Transdermal Patch Of 100 Microgram. And Another Of 50 Microgram. Every 72 Hours		Not Reported
	Sevredol 10 Comprimidos			S	Oral	Sevredol 10:1 Compressed If Major Pains Despite Treatment With Neurontin 300 And Durogesic 100 + 50.		Not Reported
	Zovirax 800 Mg Comprimidos Dispersables			C				Not Reported
	Nolotil			C				Not Reported
	Paracetamol 1gr. Comprimido			C				Not Reported
	Zyloric 100 Mg Comprimidos			C				Not Reported
	Seguril 40 Mg Comprimidos			C				Not Reported
	Binocrit 30.000 Ui/0,75 MI			C	Subcutaneous	30,000 Ui/0.75 MI Injectable Solution In A		Not Reported
	Solucion Inyectable En Una							

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Jeringa Precarga		Preloaded Syringe	
Clexane	C	Subcutaneous	Not Reported
Pantoprazol 20 Mg Comprimido	C		Not Reported
Natecal D	C		Not Reported
Mycostatin	C		Not Reported
Hidroxil B1-B6-B12	C		Not Reported
Comprimidos Recubiertos Con Pelicula			
Seretide Accuhaler 50	C	50 Micrograms/250 Micrograms/Inhalation, Inhalation Powder.	Not Reported
Microgramos/250			
Microgramos/Inhalacion, Polvo Pa			
Borea	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885602	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100751		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Tramadol			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885605	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100756		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Lamotrigine			S	Oral	Unk, Unknown		Par
	Diazepam			S	Oral	Unk, Unknown		Dava
	Olanzapine			S	Oral	Unk, Unknown		Par

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Escitalopram	S	Oral	Unk, Unknown	Not Reported
Methylphenidate	S	Oral	Unk, Unknown	Not Reported
Melatonin	S	Oral	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885611	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100762		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Quetiapine			S	Oral	Unk, Unknown		Not Reported
	Amlodipine			S	Oral	Unk, Unknown		Not Reported
	Primidone			S	Oral	Unk, Unknown		Not Reported
	Trazodone			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885616	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100759		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Propranolol Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Levetiracetam			S	Oral	Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Gabapentin			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885635	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1003318		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Haemorrhagic Stroke	Escitalopram	S	Oral	5 Milligram Daily;	Ivax
	Kardegic 160 Mg, Poudre Pour Solution Buvable En Sachet	S	Oral	1 Dosage Forms Daily;	Not Reported
	Inegy 10 Mg/40 Mg, Comprimé	C	Oral	1 Dosage Forms Daily;	Not Reported
	Spironolactone	C	Oral	75 Milligram Daily;	Not Reported
	Cardensiel 1,25 Mg, Comprimé Pelliculé	C	Oral	1 Dosage Forms Daily;	Not Reported
	Lasilix	C	Oral	60 Milligram Daily;	Not Reported
	Esomeprazole	C	Oral	20 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15885794	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS- 2019M1007633		34 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Interstitial Lung Disease	Mycophenolate Mofetil			S	Oral	Unk Unk,Bid		Not Reported
	Esomeprazole Mylan			S	Oral	20 Mg,Qd		Mylan
	Escitalopram			S	Oral	10 Mg,Bid		Not Reported
	Atorvastatin			S	Oral	10 Mg,Qd		Not Reported
	Triatec /00885601/			S	Oral	5 Mg,Qd		Mylan
	Stilnox			S	Oral	10 Mg,Qd		Mylan
	Theralene			S	Oral	5 Mg,Bid		Mylan
	Ixprim			S	Oral	Unk(Unk Unk,Unk,37,5 Mg / 325 Mg Coated Tablets)		Mylan
	Cortancyl			S	Oral	5 Mg,Bid		Mylan
	Seresta			C		Unk(Strength: 50 Mg)		Mylan
	Lasilix /00032601/			C		Unk(Strength: 40 Mg)		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15886228	EXPEDITED (15-DAY)		OT	GB-ALLERGAN- 1904006US		37 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Dizziness; Dry Skin;	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Unk	Allergan
Dyspnoea; Fatigue;	Amitriptyline	S	Oral	10 Mg, Unk	Not Reported
Hypoaesthesia; Nausea;	Calcium	C	Unknown	Unk	Not Reported
Paraesthesia; Urticaria	Zinc	C	Unknown	Unk	Not Reported
	Vitamin B Complex	C	Unknown	Unk	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15886368	EXPEDITED (15-DAY)		DE	US- GENUS_LIFESCIENCE S-USA- POI0580201900218		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Potassium Chloride Oral Solution			S				Genus Lifesciences	
	Metoprolol			S				Not Reported	
	Amlodipine			S				Not Reported	
	Hydrochlorothiazide			S				Not Reported	
	Quetiapine			S				Not Reported	
	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	14241831	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-106977		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Dafalgan			S	Oral	1000 Mg,3x/Day (Tid)		Bristol Myers Squibb	
	Metformin Hydrochloride			S	Oral	1000 Mg, Qd		Bristol Myers Squibb	
	Seroplex			S	Oral	1 Df, Once Daily (Qd)		Not Reported	
	Seroplex			S	Unknown			Not Reported	
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported	
	Mirtazapine			S	Unknown			Not Reported	
	Valium			S	Oral	10 Mg, Tid		Not Reported	

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Alprazolam	S	Oral	0.25 Mg, Tid	Not Reported
Alprazolam	S	Unknown		Not Reported
Bisoprolol Hemifumarate	S	Oral	1.25 Mg, Qd	Not Reported
Amlodipine	S	Oral	10 Mg, Once Daily (Qd)	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Not Reported
Irbesartan	S	Unknown		Not Reported
Diffu-K	S	Oral	6 Df, Qd	Not Reported
Pantoprazole	S	Oral	20 Mg, Qd	Not Reported
Pantoprazole	S	Unknown		Not Reported
Nefopam Hydrochloride	S	Oral	3 Mg, Qd	Not Reported
Nefopam Hydrochloride	S	Unknown		Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Tavanic	S	Oral	250 Mg, Bid	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Terbutaline Sulfate	S	Unknown		Not Reported
Furosemide	S	Oral	30 Mg, Bid	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15172325	EXPEDITED (15-DAY)		HO, LT	DE-MYLANLABS-2018M1052950		21 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Linezolid			S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days		Not Reported
	Escitalopram			S		Unk		Not Reported
	Esomeprazol /01479301/			S		40 Mg Unk		Mylan
	Levetiracetam			C		Daily Dose: 2 Df Dosage Form Every Days		Mylan

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Ivabradina	C	Daily Dose: 15 Mg Milligram(S) Every Days	Mylan
Cotrimoxazol	C	Intravenous (not otherwise specified) Daily Dose: 2 Df Dosage Form Every Days	Mylan
Naloxone Hydrochloride W/Tilidine Hydrochlori Scopolamin	C	10 Gtt Drops	Mylan
Baclofen	C	Unk	Mylan
Prednisolon /00016201/	C	10 Milligram	Mylan
Lorazepam	C	Daily Dose: 1 Mg Milligram(S) Every Days	Mylan
L-Thyroxin /00068002/	C	75 Microgram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15779981	EXPEDITED (15-DAY)		OT	CZ-ACCORD-062025		45 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Sertraline			S	Oral			Accord
	Escitalopram			S	Oral			Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15796625	NON-EXPEDITED			US-LUNDBECK- DKLU2058913			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea	Northera			S	Oral			Lundbeck
	Northera			S	Oral			Lundbeck
	Lexapro			S	Unknown			Forest
	Tegretol			C	Unknown			Not Reported
	Sodium Chloride			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15887476	EXPEDITED (15-DAY)		HO, LT, OT	IN-LUPIN PHARMACEUTICALS INC.-2019-00370		23 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Olanzapine			S	Unknown	20 Mg, Unk, (Nearly 4 Years)		Not Reported	
	Olanzapine			S	Unknown	20 Mg, Unk		Not Reported	
	Olanzapine			S				Not Reported	
	Fluoxetine			S	Unknown	20 Mg, Unk (Nearly 4 Years)		Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Fluoxetine			S				Not Reported	
	Escitalopram Oxalate			S	Unknown	10 Mg, Unk		Lupin	
	Escitalopram Oxalate			S				Lupin	
	Escitalopram Oxalate			S				Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15887617	EXPEDITED (15-DAY)		HO	DE-ACCORD-104172		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dyspepsia	Escitalopram			S		20 Mg, 1-0-0		Not Reported	
	Neupro			S	Transdermal	14 Mg, 1-0-0-0		Not Reported	
	Ibuprofen			S		Nk		Not Reported	
	Bornaprine/Bornaprine Hydrochloride			S		4 Mg, 1-0.5-1-0		Not Reported	
	Amantadine			C		100 Mg, 1-1-0-0		Not Reported	
	Amitriptyline			C		75 Mg, 0-0-0-1		Not Reported	
	Madopar Depot			C		100-25 Mg, 0-0-0-1		Not Reported	
	Madopar			C		100-25 Mg, 1.5-1.5-1.5-1.5		Not Reported	
	Madopar Lt			C		100-25 Mg, 1-0-0-0		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15887894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-003455		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stillbirth	Quetiapine			S	Oral	25 Milligram, Daily		Aurobindo	
	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo	
	Presinol			S	Oral	500 Milligram, Daily,500 [Mg/D (2x250)]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15888033	EXPEDITED (15-DAY)		HO	DE-ACCORD-104016		77 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Contusion; Fall; Syncope	Escitalopram			S	Unknown			Not Reported	
	Eferox			C		50 Ug, 1-0-0-0		Not Reported	
	Hct			C		12.5 Mg, 1-0-0-0		Not Reported	
	Metoprolol			C		47.5 Mg, 1-0-0-0		Not Reported	
	Ventolair			C		250 Microgram, 2-0-0-2		Not Reported	
	Metamizole Sodium			C		500 Mg, 1-1-1-0		Not Reported	
	Valsartan			C		80 Mg, 0.5-0-0-1		Not Reported	
	Ass 100			C		100 Mg, 0-1-0-0		Not Reported	
	Simvastatin			C		40 Mg, 0-0-0-1		Not Reported	
	Pantoprazole			C		20 Mg, 1-0-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15888805	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1003165			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Syncope	Austedo			S	Unknown	24 Milligram Daily; 24 Mg/Day		Teva	

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Lexapro			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891048	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1008795			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer	Escitalopram			S	Unknown	Low Dose, At Last 10-15 Mg Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891131	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1007924		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Somnolence; Toxicity To Various Agents	Ibuprofen			S	Oral	20 Dosage Form		Not Reported	
	Paroxetine			S	Oral	12 Dosage Form		Not Reported	
	Escitalopram			S	Oral	28 Dosage Form		Not Reported	
	Havlane			S	Oral	20 Dosage Form		Mylan	
	Dafalgan			S	Oral	8 Gram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891156	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1007875		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol			S	Oral	Unk,Inconnue		Not Reported	
	Seroplex			S	Oral	Inconnue		Mylan	
	Paracetamol			C	Oral	Unk,Inconnue		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891375	NON-EXPEDITED			US-ALLERGAN-1845917US		67 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Fatigue; Stupor	Viibryd			S	Oral	20 Mg, Qd		Allergan
	Viibryd			S	Oral	10 Mg, Qd		Allergan
	Lexapro			S	Unknown	Unk		Not Reported
	Valium			C	Oral	4 Mg, Qhs		Not Reported
	Vitamin B Complex			C		Unk		Not Reported
	Vitamin D2			C		Unk		Not Reported
	Prozac			C				Not Reported
	Paxil			C				Not Reported
	Unithroid			C		Unk		Not Reported
	Topamax			C		Unk		Not Reported
	Primidone			C		Unk		Not Reported
	Allegra			C		Unk		Not Reported
	Unspecified Blood Pressure Medication			C		Unk		Not Reported
	Plavix			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891956	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1904202US		69 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Depression; Disorientation; Drug Ineffective; Haemorrhoid Operation; Malaise	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Brintellix			S	Unknown	5 Mg, Unk		Not Reported
	Brintellix			S	Oral	15 Mg, Qd		Not Reported
	Alprazolam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	16005135	DIRECT		RI			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Dry Eye; Eye Discharge; Eye Pruritus; Eye Swelling; Retinal Vascular Occlusion	Lexapro	Y	S	Oral	Quantity:5 Mg Milligram(S);	Aurobindo
	Amlodipine Besylate		C			Not Reported
	Lorazepam		C			Not Reported
	Vitamin D3		C			Not Reported
	Miralax		C			Not Reported
	Aleve		C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	8236555	EXPEDITED (15-DAY)		DE, HO, OT	DK-TEVA-307344ISR		72 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Hypertrophy; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis	Mirtazapine			S	Oral	30 Milligram Daily;		Teva
	Litarex (Lithium Citrate)			S	Oral	Dose: 1+0+0+1.5, Styrke: 6 Mmol Li+		Not Reported
	Zeldox			S	Oral	80 Milligram Daily;		Not Reported
	Ciprallex			S	Oral	30 Milligram Daily;		Not Reported
	Ferro Duretter			C		100 Milligram Daily;		Not Reported
	Centyl Med Kaliumklorid			C		Dose 1 Pcs Daily. Start Date Is Unknown		Not Reported
	Alprazolam			C		.5 Milligram Daily; Start Date Is Unknown		Not Reported
	Fragmin			C				Not Reported
	Amlodipine Actavis			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	13574722	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2017M1030214		55 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Overdose	Lorazepam			S	Oral	20 Milligram, Total		Not Reported
	Escitalopram			S	Oral	140 Milligram, Total		Not Reported

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31-Jan-2019	14953070	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2018214154		88 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anxiety; Bradypnoea; Drug Interaction; Overdose; Toxicity To Various Agents	Temesta Expidet			S	Oral	0.5 Mg, As Needed		Pfizer	
	Nexium			S	Oral	20 Mg, Daily		Unknown	
	Cipralext /01588501/			S	Oral	20 Mg, Daily (In The Morning)		Not Reported	
	Cipralext /01588501/			S	Oral	15 Mg, 1x/Day		Not Reported	
	Omeprazole			S	Oral	20 Mg, Daily		Not Reported	
	Durogesic			S	Cutaneous	75 Ug/H		Not Reported	
	Durogesic			S	Cutaneous	50 Ug/H		Not Reported	
	Anexate			C		1 Mg, Unk (2 X 0.5 Mg)		Not Reported	
	Atarax /00058402/			C		Unk		Not Reported	
	Calcimagon D3			C		Unk		Not Reported	
	Clopidogrel			C		Unk		Not Reported	
	Movicol			C		Unk		Not Reported	
	Paracetamol			C		Unk, As Needed		Not Reported	
	Prednisone			C		Unk		Not Reported	
	Quetiapine Xr			C		Unk		Not Reported	
	Quetiapine			C		Unk		Not Reported	
	Clexane			C		Unk		Not Reported	
	Morphine			C		Unk		Not Reported	
	Morphine Hcl			C		Unk		Not Reported	
	Flector Ep			C		Unk, As Needed		Not Reported	
	Beloc Zok			C		Unk		Not Reported	
	Laxoberon			C		Unk, As Needed		Not Reported	
	Ondansetron			C		Unk		Not Reported	

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31-Jan-2019	15851116	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2019-FR-1002109		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Faeces; Feeling Hot; Hyperhidrosis; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Milligram Daily;		Teva	
	Selincro			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Seroplex			S	Unknown	20 Milligram Daily;		Not Reported	
	Ventolin			C	Unknown			Not Reported	
	Loxen [Nicardipine Hydrochloride]			C	Unknown	1 Dosage Forms Daily;		Not Reported	
	Lexomil			C	Unknown	1 Dosage Forms Daily;		Not Reported	
	Methadone			C	Unknown	80 Milligram Daily;		Not Reported	
	Kardegic			C	Unknown			Not Reported	
	Theralene			C	Unknown	2 Dosage Forms Daily;		Not Reported	
	Corgard			C	Unknown	80 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15894226	EXPEDITED (15-DAY)		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2019-00340		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Novel Labs	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported	
	Trazodone			S	Unknown	300 Mg, Qd (Nightly)		Not Reported	
	Trazodone			S	Unknown	150 Mg, Qd (Nightly)		Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	
	Azithromycin			C	Unknown	Unk		Not Reported	

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31-Jan-2019	15894374	EXPEDITED (15-DAY)		HO	IT-ACCORD-103842		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anhedonia; Insomnia; Labelled Drug-Drug Interaction Medication Error; Suicidal Ideation	Clonazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Trazodone/Trazodone Hydrochloride			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported	
	Valproic Acid			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15895061	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2019-00941		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Stillbirth	Quetiapine Fumarate			S	Oral	25 [Mg/D]		Alkem	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Presinol			S	Oral	500 [Mg/D (2x250)]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15895773	NON-EXPEDITED			US-APOTEX-2016AP014849			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hallucination; Pain	Paxil Cr Tablets			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Xanax			S	Unknown	Unk		Not Reported	

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Neurotin /01003001/	S	Unknown	Unk	Not Reported
Pregabalin	C	Oral	1 Df, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15895913	EXPEDITED (15-DAY)	HO		FR-JNJFOC-20190138184		92 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Haematoma	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Lovenox			S	Intramuscular	7000 Iu, Unk		Not Reported
	Spironolactone			C	Oral			Not Reported
	Alprazolam			C	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896202	EXPEDITED (15-DAY)	DE		US-ENDO PHARMACEUTICALS INC-2019-100905		23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Bupropion Hydrochloride			S	Oral	Unk, Unknown		Par
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Methylphenidate			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896749	EXPEDITED (15-DAY)	HO, OT		ES-PFIZER INC-2019035206		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Respiratory Depression	Neurontin			S	Oral	300 Mg, 3x/Day (1 Tablet With Breakfast, Dinner And Supper)		Pfizer

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Trankimazin	S	Oral	1 Mg, 1x/Day (Every 24 Hours, 1 Tablet A Day 30 Minutes Before Going To Bed)	Pfizer
Durogesic	S	Transdermal	150 Ug, Unk (1 Transdermal Patch Of 100 Ug And The Other Of 50 Ug Every 72 Hours)	Not Reported
Escitalopram	S	Oral	15 Mg, 1x/Day	Not Reported
Sevredol	S	Oral	10 Mg, As Needed (Sevredol 10: 1 Tablet In Case Of Severe Pains Despite The Treatment With Neuronti)	Not Reported
Zovirax	C			Not Reported
Nolotil [Metamizole Magnesium]	C			Not Reported
Paracetamol	C			Not Reported
Zyloric	C			Not Reported
Seguril	C			Not Reported
Binocrit	C	Subcutaneous		Not Reported
Clexane	C	Subcutaneous		Not Reported
Pantoprazole	C			Not Reported
Natecal D	C			Not Reported
Mycostatin	C			Not Reported
Hidroxil B12 B6 B1	C			Not Reported
Seretide Accuhaler	C			Not Reported
Borea	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896921	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2019M1008365		16 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Nausea	Escitalopram			S	Unknown	Increased Up To A Dose Of 20 Mg; Initial Dose Not Stated		Not Reported	
	Sertraline			S	Unknown			Not Reported	

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	Dexmedetomidine	S	Other	Over 10 Min, Followed By 0.5 Microg/Kg/Hour Dose	Not Reported				
	Dexmedetomidine	S	Other	Per Hour Dose	Not Reported				
	Clonazepam	C	Unknown		Mylan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	16012120	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Appearance	Lexapro			S				Not Reported	
Confusion; Product	Celexa			S				Not Reported	
Dispensing Error; Wrong	Lortab			S				Not Reported	
Product Administered	Percocet			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	16013459	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error	Escitalopram Oxalate			S				Not Reported	
	Citalopram Hydrobromide			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	11239692	NON-EXPEDITED		HO, OT	TR-LUPIN PHARMACEUTICALS INC.-2015-01108		71 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	11874246	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04128		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Priapism	Escitalopram		S	Unknown		Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	12325764	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2015-02170		43 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	300 Mg, Qd			Not Reported
	Fluoxetine			S	Unknown	Unk			Not Reported
	Escitalopram			S	Unknown	Unk			Lupin
	Lofepramine			S	Unknown	Unk			Not Reported
	Dosulepin			S	Unknown	Unk			Not Reported
	Citalopram			C	Unknown	20 Mg, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	14323556	NON-EXPEDITED		HO	DE-LUPIN PHARMACEUTICALS INC.-2017-07180		52 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Aripiprazole			S	Oral	10 Mg, Qd			Not Reported
	Aripiprazole			S	Oral	5 Mg, Qd			Not Reported
	Escitalopram			S	Oral	15 Mg, Qd			Lupin
	Escitalopram			S	Oral	20 Mg, Qd			Lupin
	Escitalopram			S	Oral	10 Mg, Qd			Lupin
	Candesartan			S	Oral	16 Mg, Qd			Not Reported
	Metformin			C	Oral	1500 Mg, Unk			Not Reported
	Acetylsalicylic Acid			C	Oral	100 Mg, Qd			Not Reported
	L-Thyroxin			C	Oral	100 Mcg, Qd			Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	14501952	NON-EXPEDITED			CA-LUPIN PHARMACEUTICALS INC.-2017-00646		20 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Insomnia	Zopiclone			S	Unknown	7.5 Mg, Qd At Bedtime		Not Reported	
	Zopiclone			S	Unknown	15 Mg, Qd At Bedtime		Not Reported	
	Zopiclone			S	Unknown	3.75 Mg, Qd At Bedtime		Not Reported	
	Escitalopram			S	Unknown	Unk		Lupin	
	Escitalopram			S	Unknown	20 Mg,Qd,Every Morning		Lupin	
	Mirtazapine			S	Unknown	Unk Unk,Unk,Unknown		Not Reported	
	Duloxetine			C	Unknown	Unk Unk,Unk,Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	14505140	NON-EXPEDITED			SG-LUPIN PHARMACEUTICALS INC.-2017-07618		65 YR	Female	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
	Metformin			C	Unknown	500 Mg, Tid		Not Reported	
	Atenolol			C	Unknown	25 Mg, Qd		Not Reported	
	Hydrochlorothiazide			C	Unknown	12.5 Mg, Qd		Not Reported	
	Lovastatin			C	Unknown	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	14597357	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-07507			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin	

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Escitalopram Oxalate Tablets
Usp, 20 Mg
Wellbutrin

S

Lupin

C

Oral

300 Mg, Qd

Not Reported

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01-Feb-2019	14976515	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1828737US		88 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anxiety; Bradypnoea	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Nexium			S	Oral	20 Mg, Qd		Not Reported
	Durogesic			S	Unknown	50 Mg, Q1hr		Not Reported
	Durogesic			S	Cutaneous	75 Mg, Q1hr		Not Reported
	Temesta [Lorazepam]			S	Oral	0.5 Mg, Unknown		Not Reported
	Anexate			C		1 Mg, Unk		Not Reported
	Atarax			C		Unk		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Movicol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Quetiapine Xr			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Clexane			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Morphine Hcl			C		Unk		Not Reported
	Flector			C		Unk		Not Reported
Beloc Zok			C		Unk		Not Reported	
Laxoberon			C		Unk		Not Reported	

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01-Feb-2019	15105323	NON-EXPEDITED		OT	IL-LUPIN PHARMACEUTICALS INC.-2018-04641		65 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S		10 Unk, Unk		Lupin	
	Escitalopram			S	Unknown	20 Mg, Qd		Lupin	
	Escitalopram			S		Gradually Increased		Lupin	
	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported	
	Alprazolam			C	Unknown	Double Dose		Not Reported	
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported	
	Levetiracetam			C	Unknown	1000 Mg, Qd		Not Reported	
	Omeprazole			C	Unknown	20 Mg, Qd		Not Reported	
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15193759	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03406		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Aura; Ejaculation Failure; Erectile Dysfunction; Loss Of Libido; Sexual Dysfunction; Treatment Noncompliance; Withdrawal Syndrome	Lamotrigine			S	Unknown	100 Mg, Tid		Not Reported	
	Lamotrigine			S				Not Reported	
	Escitalopram			S	Intracardiac	20 Mg, Bid		Lupin	
	Escitalopram			S				Lupin	
	Escitalopram			S				Lupin	
	Mirtazapine			S	Intracardiac	22.5 Mg, Qd (Every Night At Bed Time)		Not Reported	
	Mirtazapine			S				Not Reported	
	Mirtazapine			S				Not Reported	
	Enalapril Maleate			S	Unknown	20 Mg, Qd (Every Morning)		Not Reported	

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Lansoprazole	S	Unknown	30 Mg, Qd (Every Morning)	Not Reported
Alprazolam	S	Unknown	1 Mg, Prn (Thrice A Day - Prn)	Not Reported
Alprazolam	S			Not Reported
Alprazolam	S			Not Reported

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01-Feb-2019	15467209	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2018-01431		58 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	Unk		Lupin	
	Hydroxychloroquine			C	Unknown	Unk		Not Reported	
	Prednisolone			C	Oral	Unk		Not Reported	
	Insulin			C	Unknown	Combination Of Fast And Long Acting Insulin		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	

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01-Feb-2019	15674850	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-980381		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram Oxalate			S	Oral	10 Milligram Daily;		Ivax	
	Coumadin 5 Mg Comprese			S	Oral			Not Reported	
	Plavix			S	Oral	75 Milligram Daily;		Not Reported	
	Pregabalin			C	Unknown			Not Reported	
	Doxazosin			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Esomeprazole Sodium			C	Unknown			Not Reported	

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01-Feb-2019	15743775	NON-EXPEDITED		HO, OT	QA-LUPIN PHARMACEUTICALS INC.-2018-07519		49 YR	Male	QAT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Lupin	

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01-Feb-2019	15852240	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-001296			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Faeces;	Aripiprazole Tablets			S	Unknown	2 Milligram, Once A Day		Aurobindo	
Contraindicated Product	Seroplex			S	Unknown	20 Milligram, Once A Day		Not Reported	
Administered; Feeling Hot;	Selincro			S	Oral	1 Dosage Form, Once A Day		Not Reported	
Hyperhidrosis;									
Hypotension; Malaise;	Loxen [Nicardipine Hydrochloride]			C	Unknown	1 Dosage Form, Once A Day		Not Reported	
Oxygen Saturation Decreased; Product Use In Unapproved Indication;	Theralene			C	Unknown	2 Dosage Form, Once A Day		Not Reported	
Rash; Respiratory Distress									
	Corgard			C	Unknown	80 Milligram, Once A Day		Not Reported	
	Methadone			C	Unknown	80 Milligram, Once A Day		Not Reported	
	Lexomil			C	Unknown	1 Dosage Form, Once A Day		Not Reported	
	Kardegic			C	Unknown	Unk, Once A Day		Not Reported	
	Ventolin			C	Unknown	Unk		Not Reported	

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01-Feb-2019	15897959	EXPEDITED (15-DAY)		OT	DE-DRREDDYS- GER/GER/19/0107177		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Exposure During Pregnancy; Stillbirth	Quetiapine	S	Oral	25 [Mg/D]	Not Reported
	Escitalopram	S	Oral	20 [Mg/D]	Not Reported
	Presinol	S	Oral	500 [Mg/D (2x250)]	Not Reported

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01-Feb-2019	15897968	NON-EXPEDITED			IN-LUPIN LIMITED-2018-02638		20 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Acneiform	Escitalopram			S	Unknown	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897978	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2017-07453		73 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram Tablets			S	Unknown	10 Mg, Qd		Lupin	
	Escitalopram Tablets			S	Unknown	5 Mg, Qd		Lupin	
	Duolin /01033501/			C	Unknown	Unk		Not Reported	
	Budesonide			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897987	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04685		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Insomnia; Nausea; Torticollis	Citalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	5 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
	Escitalopram			S	Unknown	15 Mg, Qd		Lupin	
	Celecoxib			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	

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	Ibuprofen		C	Unknown	Unk			Not Reported	
	Tamsulosin		C	Unknown	Unk			Not Reported	
	Omeprazole		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897988	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2017-07544		54 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Escitalopram			S	Unknown	10 Mg, Unk		Lupin	
	Lorazepam			C	Unknown	2 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897989	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02709			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fear; Nightmare; Product Dose Omission	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd (Every Bedtime)		Lupin	
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01-Feb-2019	15897990	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00124		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Malaise; Product Dispensing Error; Wrong Product Administered	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin	
	Levothyroxine			S	Oral	Unk Unk, Qd		Not Reported	
	Levothyroxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897991	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-00897			Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adjustment Disorder; Bruxism; Drug Ineffective; Mental Disorder; Overweight	Citalopram			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	20 Mg, Qd		Lupin

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01-Feb-2019	15897992	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2017-07918		64 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dyspepsia; Nausea; Weight Decreased; Weight Increased	Venlafaxine			S	Unknown	75 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	150 Mg, Unk		Not Reported
	Venlafaxine			S	Unknown	225 Mg, Unk		Not Reported
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Lupin
	Escitalopram Oxalate			S	Unknown	20 Mg, Unk		Lupin
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	10 Mg, Unk		Not Reported
	Citalopram			S	Unknown	40 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	20 Mg, Unk		Not Reported
	Cipramil /00582602/			S	Unknown	40 Mg, Unk		Not Reported

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Cipramil /00582602/	S	Unknown	20 Mg, Unk	Not Reported
Cipramil /00582602/	S	Unknown	20 Mg, Unk	Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk	Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk	Not Reported
Cipramil /00582602/	S	Unknown	40 Mg, Unk	Not Reported
Cipramil /00582602/	S	Unknown	20 Mg, Unk	Not Reported
Cipralelex /01588501/	S	Unknown	20 Mg, Qd	Not Reported
Cipralelex /01588501/	S	Unknown	20 Mg, Unk	Not Reported
Cipralelex /01588501/	S	Unknown	20 Mg, Unk	Not Reported
Cipralelex /01588501/	S	Unknown	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897993	NON-EXPEDITED		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2018-00509		76 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure	Zytomil Tablets			S	Oral	10 Mg, Unk		Lupin
	Pearinda Tablets			S	Oral	4 Mg, Unk		Not Reported
	Carbilev			S	Oral	Unk, 25/100mg		Not Reported
	Latanoprost			S	Intraocular	50 Mcg, Unk		Not Reported
	Estro-Pause			S	Oral	1 Mg, Unk		Not Reported
	Adco-Retic			S	Oral	Unk, 5/50mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897994	NON-EXPEDITED			IN-LUPIN LIMITED- 2018-07598		34 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia	Stalopam Film C.Tabs 5 Mg			S	Oral	1 Df, Qd (At Night)		Lupin

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897995	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08153		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event; Wrong Product Administered	Escitalopram Oxalate Tablets Usp, 10 Mg Alprazolam			S	Unknown	Unk		Lupin	
				S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897997	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06870		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate Tablets Usp, 5 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15897998	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-01213			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Escitalopram			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898000	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2018-00423		21 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertrichosis; Weight Increased	Escitalopram Fluoxetine			S	Unknown	10 Mg, Qd		Lupin	
				S	Unknown	20 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898001	NON-EXPEDITED		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-02136		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Flecainide			S	Oral	Unk		Not Reported	
	Verapamil			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898002	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05560		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mydriasis; Vision Blurred	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	10 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898003	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-07679		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Drug Hypersensitivity; Sedation	Mirtazapine			S	Unknown	7.5 Mg, Qd (At Night; 2 Months Before The Patient Was Referred For Evaluation)		Not Reported	
	Mirtazapine			S	Unknown	15 Mg, Qd (At Night; 2 Months Before The Patient Was Referred For Evaluation)		Not Reported	
	Sertraline			S	Unknown	300 Mg, Qd		Not Reported	
	Sertraline			S	Unknown	300 Mg, Qd		Not Reported	
	Sertraline			S				Not Reported	

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		Escitalopram	S	Unknown	Unk			Lupin	
		Citalopram	S	Unknown	40 Mg, Qd			Not Reported	
		Sulfamethoxazole And Trimethoprim	S	Unknown	Unk			Not Reported	
		Lamotrigine	C	Unknown	100 Mg, Qd			Not Reported	
		Venlafaxine	C	Unknown	375 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898004	NON-EXPEDITED			DE-LUPIN PHARMACEUTICALS INC.-2018-01613		27 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Nausea; Palpitations; Pyrexia; Vomiting	Escitalopram			S	Unknown	Unk		Lupin	
	Naratriptan			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898005	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2018-07583		23 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898006	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08028			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Hot Flush; Insomnia	Escitalopram Oxalate			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898007	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02251		16 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Food Allergy; Vomiting	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	Unk Unk, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898008	NON-EXPEDITED		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01860		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Paracetamol			S	Oral	Unk		Not Reported	
	Ethanol			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Cocaine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898009	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05218			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus Generalised; Rash; Urticaria	Escitalopram			S	Unknown	Unk		Lupin	
	Escitalopram			S	Unknown	Unk		Lupin	
	Bupropion Hcl XI			S	Unknown	150 Mg, Qd		Not Reported	
	Metoprolol			S		25 Mg, Unk		Not Reported	
	Metoprolol			S	Unknown	50 Mg, Unk		Not Reported	
	Zoloft			S				Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Flonase /00908302/			C	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	

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	Loratadine	C	Unknown	Unk	Not Reported
	Baby Aspirin	C	Unknown	Unk	Not Reported
	B Complex /00322001/	C	Unknown	Unk	Not Reported
	Vitamin D 3	C		Unk	Not Reported
	Fish Oil	C	Unknown	Unk	Not Reported
	Multivitamins /00116001/	C	Unknown	Unk	Not Reported
	Calcium Citrate	C	Unknown	Unk	Not Reported
	Miralax	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898049	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2019IN00798			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusional Disorder, Erotomanic Type	Escitalopram			S	Unknown	10 Mg, Per Day		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898185	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-004364		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Milligram, Daily		Aurobindo	
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported	
	Inegy			C	Oral	1 Dosage Form, Daily		Not Reported	
	Spironolactone			C	Oral	75 Milligram, Daily		Not Reported	
	Cardensiel			C	Oral	1 Dosage Form, Daily		Not Reported	
	Lasilix			C	Oral	60 Milligram, Daily		Not Reported	
	Esomeprazole			C	Oral	20 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898209	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-004039			Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898693	EXPEDITED (15-DAY)		OT	SE-ACCORD-105011		27 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Erectile Dysfunction	Escitalopram			S	Oral	Tablet		Not Reported	
	Lithionit			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898695	EXPEDITED (15-DAY)		HO	SE-ACCORD-105020		45 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block	Escitalopram			S	Oral			Not Reported	
	Desloratadine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898746	EXPEDITED (15-DAY)		HO, LT, OT	US-DRREDDYS-USA/USA/18/0105953		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898957	EXPEDITED (15-DAY)		HO, LT, OT	IN-MACLEODS PHARMACEUTICALS US LTD-			Unknown	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Self-Medication; Sleep Disorder; Tongue Biting	Escitalopram Oxalate			S	Unknown	10 Milligram		Macleods
	Olanzapine			S	Unknown	20 Milligram, Nearly 4 Years		Macleods
	Olanzapine			S	Unknown	20 Milligram		Macleods
	Fluoxetine			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	20 Milligram, Nearly 4 Years		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15899108	EXPEDITED (15-DAY)		HO, LT, OT	IN-HETERO CORPORATE-HET2019IN00094		23 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Cerebral Atrophy; Confusional State; Crying; Discomfort; Dysphoria; Postictal State; Seizure; Sleep Disorder; Tongue Biting	Escitalopram			S	Unknown	10 Milligram		Hetero
	Olanzapine			S	Unknown	20 Milligram		Not Reported
	Olanzapine			S		Nearly 4 Years		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15899110	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-003887		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral	10 Milligram, Once A Day		Aurobindo
	Seresta			S	Oral	100 Milligram, Once A Day		Not Reported
	Tercian			S	Oral	50 Milligram, Once A Day		Not Reported

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Zyprexa	S	Oral	2 Dosage Form, Once A Day	Not Reported
Dafalgan Codeine	S	Unknown	3 Dosage Form, Once A Day	Not Reported
Seroplex	S	Oral	1 Dosage Form, Once A Day	Not Reported
Oxycontin Lp	S	Oral	2 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15900954	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1904614US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Prescription Form Tampering	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Quetiapine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15901179	EXPEDITED (15-DAY)		HO	US-LANNETT COMPANY, INC.-US-2019LAN000105		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Epidermal Necrolysis	Escitalopram Oxalate			S	Unknown	Unk		Lannett	
	Lamotrigine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2019	15600119	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-053863		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	14 Dosage Form, In Total		Aurobindo	
	Lorazepam			S	Oral	40 Milligram, In Total		Aurobindo	
	Aripiprazole			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2019	15902869	EXPEDITED (15-DAY)		CA	DE-ACCORD-104411		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Pulmonary Artery Stenosis Congenital	Escitalopram			S	Transplacental	10 Mg/D		Not Reported	
	Sertraline			C	Transplacental	150 Mg/D		Not Reported	
	Quetiapine/Quetiapine Fumarate			C	Transplacental	25 Mg/D		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2019	15903106	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2019-004471			Unknown	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Weight Decreased	Duloxetine			S	Unknown	60 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Mirtazapine			S	Unknown	30 Milligram, Once A Day		Aurobindo	
	Olanzapine			S	Unknown	15 Milligram, Once A Day		Aurobindo	
	Clonazepam			S	Unknown	0.5 Milligram, Once A Day		Not Reported	
	Doxepin			S	Unknown	100 Milligram, Once A Day		Not Reported	
	Quetiapine			S	Unknown	300 Milligram, Once A Day		Not Reported	
	Quetiapine			S	Unknown	800 Milligram		Not Reported	
	Risperidone			S	Unknown	6 Milligram, Once A Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903625	EXPEDITED (15-DAY)		DS	GB-ACCORD-105178		33 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Jaw	Escitalopram			S	Oral			Not Reported	
	Lansoprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903635	EXPEDITED (15-DAY)		OT	PL-ACCORD-104941			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Myalgia;	Escitalopram			S				Not Reported	
Ventricular Arrhythmia	Rhodiola Rosea			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903636	EXPEDITED (15-DAY)		OT	PL-ACCORD-104943			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram			S				Not Reported	
Haemorrhage	Ginkgo Biloba/Ginkgo Biloba			S				Not Reported	
	Extract/Ginkgo Biloba Leaf								
	Extract								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903637	EXPEDITED (15-DAY)		OT	PL-ACCORD-104942			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram			S				Not Reported	
Serotonin Syndrome	Mirtazapine			S				Not Reported	
	Ginseng Nos			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903638	EXPEDITED (15-DAY)		OT	PL-ACCORD-104944			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage	Escitalopram Ginkgo Biloba/Ginkgo Biloba Extract/Ginkgo Biloba Leaf Extract			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15903639	EXPEDITED (15-DAY)		OT	PL-ACCORD-104945			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage	Escitalopram Ginkgo Biloba/Ginkgo Biloba Extract/Ginkgo Biloba Leaf Extract			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15906135	DIRECT		OT			32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Opiates Positive	Lexapro Generic Iron	Y		S C				Unknown Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	14961029	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA- 2018SE68831		88 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anxiety; Bradypnoea; Depression; Drug Interaction; Fall; Movement Disorder;	Nexium Omeprazole Cipraxel			S S S	Oral Oral Oral			Astrazeneca Not Reported Not Reported	

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Overdose; Pain; Toxicity To Various Agents	Ciprallex	S	Oral		Not Reported
	Durogesic	S	Cutaneous		Not Reported
	Durogesic	S	Cutaneous	50.0ug Unknown	Not Reported
	Temesta Expidet	S	Oral	0.5mg Unknown	Not Reported
	Anexate	C		0.5mg	Not Reported
	Atarax	C			Not Reported
	Calcimagon D3	C			Not Reported
	Clopidogrel	C			Not Reported
	Movicol	C			Not Reported
	Paracetamol	C			Not Reported
	Prednisone	C			Not Reported
	Quetiapine	C			Not Reported
	Quetiapine	C			Not Reported
	Clexane	C			Not Reported
	Morphine	C			Not Reported
	Morphine Hydrochloride	C			Not Reported
	Flector	C		As Required	Not Reported
	Beloc Zok	C			Not Reported
	Laxoberon	C			Not Reported
	Ondansetron	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15362727	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2018M1065842		34 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Dizziness; Mental Impairment	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Brintellix			S	Unknown	10 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15719103	EXPEDITED (15-DAY)		OT	CZ-APOTEX-2018AP026746		58 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Citalopram			S	Unknown	Series Of Citalopram Infusions		Apotex

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Risperidone	S	Unknown	Unk Unk,Unk	Apotex
Olanzapine	S	Unknown	Unk Unk,Unk	Apotex
Aripiprazole	S	Unknown	Unk	Apotex
Venlafaxine	S	Unknown	Unk Unk,Unk	Apotex
Escitalopram	S	Unknown	Unk Unk,Unk	Apotex
Mirtazapine	S	Oral	Unk Unk,Unk	Not Reported
Clomipramine	S	Unknown		Not Reported
Ziprasidone	S	Unknown	Unk	Not Reported
Tiapride	C	Unknown	Unk	Not Reported
Memantine	C	Unknown		Not Reported
Clonazepam	C	Unknown	Unk	Not Reported
Melperone	C	Unknown		Not Reported
Propofol	C	Unknown	Unk	Not Reported
Haloperidol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15904268	EXPEDITED (15-DAY)		HO	FR-AMGEN- FRASP2019014467		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Purpura; Rash Pruritic	Xgeva			S	Subcutaneous	120 Mg, Unk		Amgen
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Qd		Not Reported
	Aromasine			C	Oral	25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15905254	EXPEDITED (15-DAY)		OT	BR-TORRENT- 00004844		59 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema;	Espran			S	Oral	1 Tablet Daily		Unknown
Hypersensitivity; Off Label	Rosucor			S				Unknown

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Use; Pigmentation Disorder; Poor Quality Product Administered; Product Odour Abnormal; Product Taste Abnormal; Pruritus	Synthroid 10 Mg	C	Oral	1 Tablet Daily	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15907754	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100792		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Doxepin Hydrochloride			S	Oral	Unk, Unknown		Par
	Hydroxyzine Hydrochloride			S	Oral	Unk, Unknown		Vintage
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Ethanol			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15907759	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100777		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Doxepin Hydrochloride			S	Oral	Unk, Unknown		Par
	Acetaminophen			S	Oral	Unk, Unknown		Not Reported
	Escitalopram			S	Oral	Unk, Unknown		Not Reported
	Cough And Cold Preparation			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15908474	EXPEDITED (15-DAY)		HO	FR-ALLERGAN- 1904675US		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Purpura; Rash Pruritic	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Alprazolam			S	Oral	0.25 Mg, Qd		Not Reported

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	Xgeva	S	Subcutaneous	120 Mg, Single		Not Reported			
	Aromasine	C	Oral	25 Mg, Qd		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15908703	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1904806US		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Eliquis			S	Oral	2 Df, Qd		Not Reported	
	Digoxine			C	Unknown	Unk		Not Reported	
	Loxen L P			C	Unknown	Unk		Not Reported	
	Lopressor			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15909032	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1904812US		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan	
	Tetanus Vaccine			C	Transplacental	Unk Unk, Single		Not Reported	
	L-Thyroxin			C	Transplacental	50 Mg, Qd		Not Reported	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15909035	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1904815US		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pregnancy; Premature Labour	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Tetanus Vaccine			C	Intramuscular	Unk Unk, Unknown		Not Reported	

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L-Thyroxin	C	Oral	50 Mg, Qd	Not Reported
Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15913285	NON-EXPEDITED			US-PFIZER INC- 2019048906		23 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Pristiq			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Citalopram			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Influenza Virus Vaccine			S		Unk		Not Reported
	Xyzal			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	14490645	NON-EXPEDITED		DE, OT	US-LUPIN (EUROPE) LIMITED-2018-00094		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Gun Shot Wound	Escitalopram Oxalate Tablets Usp, 20 Mg			S	Oral	20 Mg, Qd		Lupin
	Luvox Sr			S	Oral	150 Mg, Qd		Not Reported
	Clonidine			C	Unknown	Prn (As Needed)		Not Reported
	Trazodone			C	Unknown	Prn (As Needed)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15917066	EXPEDITED (15-DAY)		HO	DE-ACCORD-105524		79 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine	S	Oral	100 Mg, 0-0-0-1, Tablet	Not Reported
	Ciprallex	S	Oral	Strength :10 Mg, 1-0-0-0, Tablet	Not Reported
	Valproic Acid	S	Oral	500 Mg, 0-0-0-1, Tablet	Not Reported
	Levothyroxine	C	Oral	75 Microgram, 1-0-0-0, Tablet	Not Reported
	Toraseamide	C	Oral	10 Mg, 1-0-0-0, Tablet	Not Reported
	Felodipine	C	Oral	10 Mg, 1-0-0-0, Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15917174	EXPEDITED (15-DAY)		OT	DE-ACCORD-105349		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotonia Neonatal; Myoclonus; Small For Dates Baby	Escitalopram			S	Transplacental	10 Mg/D		Not Reported	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	0.8 Mg/D		Not Reported	
	Vaccine Flu			C	Transplacental			Not Reported	
	Levothyroxine			C	Transplacental	100 /Mcgd / Initial 75mcg/D, Dosage Increase To 100mcg/D From Week 34+2		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15917656	EXPEDITED (15-DAY)		HO, OT	JP-AMEL-2018-07817AA		70 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thirst	Sulpiride			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Lupin	
	Ddavn			C	Unknown	5 Mcg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15918204	EXPEDITED (15-DAY)		OT	IN-TORRENT-00002112		23 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusional Disorder, Erotomanic Type; Grandiosity; Judgement Impaired	Escitalopram			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15918831	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2019M1009321		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Hypotension; Suicide Attempt	Paracetamol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Alprazolam			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Mylan	
	Ibuprofene			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15920480	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-101053		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Venlafaxine Hydrochloride			S	Oral	Unk Unknown, Unknown		Par	
	Escitalopram			S	Oral	Unk Unknown, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15920891	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2019-100989		13 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Hydrocodone Bitartrate,			S	Oral	Unk, Unknown		Vintage	
	Acetaminophen			S	Oral	Unk, Unknown		Vintage	
	Oxycodone Hydrochloride, Acetaminophen			S	Oral	Unk, Unknown		Dava	
	Alprazolam			S	Oral	Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	Unk, Unknown			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15921144	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2019M1008157		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Trazodone			S	Unknown	At Night (Nightly); High-Dose		Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	14938562	EXPEDITED (15-DAY)		HO, OT	CH-JNJFOC- 20180532750		88 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anxiety; Bradypnoea; Decreased Appetite; Drug Interaction; Toxicity To Various Agents	Durogesic			S	Cutaneous			Not Reported	
	Durogesic			S	Cutaneous			Not Reported	
	Cipralext			S	Oral			Not Reported	
	Cipralext			S	Oral			Not Reported	
	Omeprazole			S	Oral			Not Reported	
	Nexium			S	Oral			Not Reported	
	Temesta [Lorazepam]			S	Oral			Not Reported	
	Morphine Hcl			S	Unknown			Not Reported	

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Morphine	S	Unknown	Not Reported
Paracetamol	C	Unknown	Not Reported
Calcimagon D3	C	Unknown	Not Reported
Clopidogrel	C	Unknown	Not Reported
Movicol	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Quetiapine Xr	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported
Clexane	C	Unknown	Not Reported
Diclofenac Epolamine	C	Unknown	Not Reported
Beloc Zok	C	Unknown	Not Reported
Laxoberon	C	Unknown	Not Reported
Anexate	C	Unknown	Not Reported
Atarax	C	Unknown	Not Reported
Ondansetron	C	Unknown	Not Reported
Diclofenac Epolamine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	14966922	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2018-022632			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anhedonia; Asthenia; Chest Pain; Decreased Appetite; Depressed Mood; Drug Ineffective; Drug Intolerance; Gastritis; Palpitations; Parkinsonism; Psychiatric Symptom; Sleep Disorder	Escitalopram			S	Unknown	10 Mg, Unk		Aurobindo
	Mirtazapine			S	Unknown	15 Milligram,Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Sertraline			C	Unknown	Unk		Not Reported
	Bupropion Hydrochloride			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15470968	NON-EXPEDITED			US-TEVA-2018-US-960589			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15923508	EXPEDITED (15-DAY)		HO	FR-ACCORD-105801		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Escitalopram			S	Oral			Not Reported	
	Atacand			S	Oral			Not Reported	
	Plegriby			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15923980	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019GSK017081			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Meniscus Injury; Meniscus Removal	Lamictal			S		Unk		Glaxosmithkline	
	Lamictal			S				Glaxosmithkline	
	Lamictal			S				Glaxosmithkline	
	Levoxyl			S		Unk		Not Reported	
	Lexapro			S				Not Reported	
	Lexapro			S				Not Reported	
	Lexapro			S				Not Reported	
	Armour Thyroid			C		Unk		Not Reported	
	Effexor			C		Unk		Not Reported	
	Effexor			C				Not Reported	
	Effexor			C				Not Reported	
	Venlafaxine			C		150 Mg, Qd		Not Reported	
	Venlafaxine			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15924595	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-010846			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb	
	Carbidopa And Levodopa			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Prevacid			S	Unknown	Unk		Not Reported	
	Prozac			S	Unknown	Unk		Not Reported	
	Lyrica			C	Unknown	200 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15926441	NON-EXPEDITED			US-MYLANLABS- 2019M1006039		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Agitation; Irritability	Emsam (Selegiline Transdermal System)			S	Transdermal	Unk		Mylan	
	Lexapro			S	Oral	20 Milligram, Qd		Mylan	
	Amlodipine			C		Unk		Mylan	
	Metoprolol			C		50 Milligram, Bid		Mylan	
	Trazodone			C		25 Milligram, Prn		Mylan	
	Omeprazole			C		20 Milligram, Bid		Mylan	
	Flovent			C		110 Microgram, Bid		Mylan	
	Zofran /00955301/			C		4-8 Mg, Prn		Mylan	
	Insulin			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15927655	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT- 00013207		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram	S	Transplacental	10 [Mg/D (5)]	Unknown
	Skinoren	C	Transplacental	Unknown	Unknown
	Folsure	C	Transplacental	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15927660	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013236		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Tetanus Vaccine			C	Transplacental	Unknown		Unknown	
	Escitalopram			S	Transplacental	5 [Mg/D]		Unknown	
	L-Thyroxin			C	Transplacental	50 [G/D]		Unknown	
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15927672	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013208			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15928998	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1010410		26 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Interaction; Dyskinesia; Hyperhidrosis; Muscle Tightness; Musculoskeletal Stiffness; Myalgia; Serotonin Syndrome	Escitalopram			S	Oral	10 Milligram, Qd (1 Keer Per Dag 1 Tablet)		Not Reported	
	Sumatriptan			S	Oral	Bij Migraine 1 Tablet, Herhaal Zo Nodig 2 Keer Per Dag, Wacht Meer Dan 2 Uur Na De Vorige Tablet.		Not Reported	

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Loperamide	C	2 Milligram (Zo Nodig 6 Keer Per Dag 1 Capsule)	Mylan
Imodium	C	2 Milligram, Qd (1dd1)	Mylan
Colestyramine	C	4 Gram, Bid (2dd1)	Mylan
Oxazepam	C	10 Milligram (Zo Nodig 1 Keer Per Dag 1 Tablet)	Mylan
Psylliumvezels	C	2 Keer Per Dag Zo Nodig 1 Zakje	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15929791	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1905127US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	13362853	EXPEDITED (15-DAY)		DE, HO	FR-CELGENEUS-FRA-2017032245		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Revlimid			S	Oral	25 Milligram		Celgene
	Zyloric			S	Oral	300 Milligram		Not Reported
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported
	Augmentin			S	Oral	3 Gram		Not Reported
	Ciprofloxacin			S	Oral	1000 Milligram		Not Reported
	Sodium Pamidronate			S	Intravenous drip	30 Milligram		Not Reported
	Seroplex			S	Oral	1 Dosage Forms		Not Reported
	Bactrim			C	Oral	400 Milligram		Not Reported
	Bactrim			C	Oral			Not Reported
	Lyrica			C	Oral	50 Milligram		Not Reported

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Lyrica	C	Oral		Not Reported
Seresta	C	Oral	10 Milligram	Not Reported
Seresta	C	Oral		Not Reported
Mianserine	C	Oral	30 Milligram	Not Reported
Mianserine	C	Oral		Not Reported
Zelitrex	C	Oral	1000 Milligram	Not Reported
Zelitrex	C	Oral		Not Reported
Lovenox	C	Subcutaneous	14000 Iu (International Unit)	Not Reported
Lovenox	C	Subcutaneous		Not Reported
Durogesic	C	Unknown		Not Reported
Gaviscon	C	Unknown		Not Reported
Previscan	C	Unknown	15 Milligram	Not Reported
Paracetamol	C	Unknown		Not Reported
Movicol	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Tamiflu	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	14302133	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2017-45878			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Alprazolam			S	Oral	0.75 Milligram, Daily, 0.25 Mg, 3x/Day (Tid)		Aurobindo	
	Amlodipine Capsule, Hard			S	Oral	10 Mg, Once Daily (Qd)		Aurobindo	
	Bisoprolol			S	Oral	1.25 Milligram, Once A Day, 1.25 Mg, Qd		Aurobindo	
	Mirtazapine			S	Oral	15 Mg, Once Daily (Qd)		Aurobindo	
	Furosemide			S	Oral	30 Mg Daily (2-1-0), 2x/Day (Bid)		Not Reported	
	Furosemide			S	Oral	Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	S	Oral	Unk Unk, Once A Day	Not Reported
Irbesartan	S	Oral	300 Milligram, Once A Day, 300 Mg, Qd	Aurobindo
Metformin Film-Coated Tablet	S	Oral	1000 Milligram, Once A Day, 500 Mg, 2x/Day (Bid)	Aurobindo
Pantoprazole	S	Oral	20 Mg, Qd	Aurobindo
Terbutaline	S		1 Dosage Form, Daily, 1 Df, Qd	Not Reported
Dafalgan	S	Oral	1000 Mg, 3x/Day (Tid)	Not Reported
Nefopam Hydrochloride	S	Oral	3 Df, Unk	Not Reported
Nefopam Hydrochloride	S	Oral	3 Mg, Qd	Not Reported
Diffu K	S	Oral	6 Df, Qd, 6 Df, Qd (3 Df Daily (2-1-0) 2x/Day (Bid))	Not Reported
Colchicine Opocalium	S	Oral	1 Mg, Once Daily (Qd)	Not Reported
Xarelto	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Seroplex	S	Oral	1 Df, Once Daily (Qd)	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day (Bid)	Not Reported
Tavanic	S	Oral	500 Milligram, Once A Day, 250 Mg, Bid	Not Reported
Valium	S	Oral	3 Dosage Form, Daily, 10 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	14379249	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001929			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Alprazolam			S	Oral	0.75 Mg, Qd		Aurobindo	
	Amlodipine			S	Oral	10 Mg, Qd		Aurobindo	
	Bisoprolol			S	Oral	1.25 Mg, Qd		Aurobindo	
	Diazepam			S	Oral	30 Mg, Qd		Not Reported	
	Furosemide			S	Oral	30 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	S	Oral	2 Unk, Qd (1)	Not Reported
Furosemide	S	Oral	1 Unk, Once A Day, 2 Ot, Qd	Not Reported
Irbesartan	S	Oral	300 Mg, Qd	Aurobindo
Irbesartan	S	Oral	300 Mg, Qd	Aurobindo
Metformin	S	Oral	1000 Mg, Qd	Aurobindo
Mirtazapine	S	Oral	15 Mg, Qd	Aurobindo
Pantoprazole	S	Oral	20 Mg, Qd	Aurobindo
Terbutaline	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Diffu K	S	Oral	6 Df, Qd	Not Reported
Xarelto	S	Oral	20 Mg, Qd	Not Reported
Dafalgan	S	Oral	3000 Mg, Qd	Not Reported
Colchicine Opocalcium	S	Oral	1 Mg, Qd	Not Reported
Nefopam	S	Oral	3 Df, Qd	Not Reported
Seroplex	S	Oral	1 Df, Qd	Not Reported
Tavanic	S	Oral	500 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15930338	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-033250		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Drug Interaction; Frequent Bowel Movements; Myoclonus; Serotonin Syndrome; Symptom Masked; Tremor	Escitalopram			S	Unknown			Zydus Pharm	
	Linezolid			S	Unknown			Zydus Pharm	
	Trazodone			S	Unknown			Zydus Pharm	
	Trazodone			S	Unknown			Zydus Pharm	
	Clonazepam			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			C	Unknown			Not Reported	
	Amikacin			C	Unknown			Not Reported	
	Ceftaroline			C	Unknown			Not Reported	

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Vancomycin	C	Unknown	Not Reported
Metronidazole	C	Unknown	Not Reported
Cefepime	C	Unknown	Not Reported
Ceftriaxone	C	Unknown	Not Reported
Azithromycin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15931107	DIRECT	Y					Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Panic Disorder;	Escitalopram			S				Not Reported
Tachyphrenia	Sertraline			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15931336	EXPEDITED (15-DAY)		HO	US-SA-2019SA034998		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation;	Lasix			S	Unknown	40 Mg, Qod		Sanofi
Hypotension; Presyncope;	Metoprolol Tartrate			S	Unknown	25 Mg, Bid		Not Reported
Sinus Tachycardia	Escitalopram Oxalate			S	Oral	10 Mg, Qd In Morning		Not Reported
	Rosuvastatin Calcium			S	Oral	10 Mg, Qd		Not Reported
	Senna Alexandrina			S	Oral	8.6 Mg, Bid		Not Reported
	Cabazitaxel			S	Unknown	Unk		Sanofi
	Carboplatin			S	Unknown	Unk		Not Reported
	Methylphenidate			S	Unknown	10 Mg, Twice Daily Prn		Not Reported
	Eliquis			S	Oral	5 Mg, Bid		Not Reported
	Norco			S	Oral	10 Mg, Q8h Prn		Not Reported
	Norco			S	Unknown	Q8 Prn		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15931461	EXPEDITED (15-DAY)		DS	FI-ACCORD-104226		37 YR	Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Aphasia; Cushingoid; Derealisation; Dizziness; Drug Withdrawal Syndrome; Dysarthria; Dysgraphia; Dyspnoea; Erythema; Face Oedema; Facial Pain; Headache; Hyperhidrosis; Insomnia; Mydriasis; Oedema; Polyuria; Pyrexia; Sympathomimetic Effect; Tremor; Vision Blurred	Escitalopram Voxra Triptyl			S S C	Oral	450,Mg,Daily		Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15931984	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA- 2019SE18381		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Seroquel			S	Oral	6.0g Once/Single Administration		Zeneca
	Escitalopram Oxalate			S	Oral	3920.0mg Once/Single Administration		Not Reported
	Felison			S	Oral	900.0mg Once/Single Administration		Not Reported
	Tavor (Lorazepam)			S	Oral	50.0mg Once/Single Administration		Not Reported
	Zoloft			S	Oral	6.0g Once/Single Administration		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15933258	EXPEDITED (15-DAY)		HO	US-VALIDUS PHARMACEUTICALS LLC-US- 2019VAL000028		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Hypotension; Presyncope; Sinus Tachycardia	Lasix			S	Unknown	40 Mg, Qod		Validus	
	Lopressor			S	Unknown	25 Mg, Bid		Validus	
	Lexapro			S	Oral	10 Mg, In Morning		Not Reported	
	Norco			S	Oral	10 Mg, Every 8 Hours, Prn		Not Reported	
	Norco			S		Q 8, Prn		Not Reported	
	Eliquis			S	Oral	5 Mg, Bid		Not Reported	
	Crestor			S	Oral	10 Mg, Qd		Not Reported	
	Senna /00142201/			S	Oral	8.6 Mg, Bid		Not Reported	
	Methylphenidate			S		10 Mg, Bid (Prn)		Not Reported	
	Cabazitaxel			S		Unk		Not Reported	
	Carboplatin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934524	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS- 2019M1011088		59 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Abuse; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Moaning	Alprazolam			S	Oral	Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Trilafon /00023401/			S	Oral	Unk		Mylan	
	Ramipril			C	Oral	2.5 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934889	EXPEDITED (15-DAY)		HO	FR-ASCEND THERAPEUTICS- 2062319		44 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Meningioma	Estrogel			S	Transdermal			Ascend	
	Androcur (Cyproterone Acetate)			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934912	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1905271US		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Loss	Escitalopram Oxalate Unk			S	Oral	10 Mg, Qd		Allergan	
	Prolia			S	Subcutaneous	60 Mg, Q6mo		Not Reported	
	Calcimagon D3			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	13953995	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-ACCORD-058259		50 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Loss Of Consciousness; Suicide Attempt; Tinnitus; Tinnitus	Escitalopram			S	Oral	Doctor Switched The Patient From Sertraline To Escitalopram		Accord	
	Tramadol/Tramadol Hydrochloride			S	Oral	Tramadol In Combination With Meloxicam For About Two Years Ago		Accord	
	Sertraline			S	Oral	Morning Dose Of 50 Mg		Accord	
	Bisoprolol			S	Unknown			Accord	
	Clarithromycin/Clarithromycin Lactobionate			S	Oral	Two 10 Day Cycles.		Accord	
	Trosicam			S	Oral	Tramadol In Combination With Meloxicam, For About Two Years Ago		Not Reported	
	Atorvastatin			S		Unk (Bedtime)		Not Reported	
Perindopril/Perindopril Erbumine			S	Oral			Not Reported		

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Zolpidem	S	Oral	10 Mg At Bedtime	Not Reported
Doxepin	S	Oral	25 Mg Overnight	Not Reported
Atorvastatin	C			Not Reported
Perindopril/Perindopril Erbumine	C			Not Reported
Movalis	S		Tramadol In Combination With Meloxicam, For About Two Years Ago	Not Reported
Polisen	S	Oral	10 Mg At Bedtime	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15935891	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-ACCORD-104977		37 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation; Withdrawal Syndrome	Escitalopram			S	Oral			Not Reported
	Adcal-D3			C				Not Reported
	Metformin			C				Not Reported
	Generics Uk Nifedipine			C				Not Reported
	Pregabalin			C				Not Reported
	Nefopam			C				Not Reported
	Tiotropium			C				Not Reported
	Sodium Picosulfate			C				Not Reported
	Cetirizine			C				Not Reported
	Naproxen			C				Not Reported
	Diazepam			C				Not Reported
	Cassia (Senna Alexandrina)			C				Not Reported
	Methotrexate			C				Not Reported
	Budesonide/Formoterol			C				Not Reported
	Fumarate							
	Lansoprazole			C				Not Reported
	Meptazinol			C				Not Reported
	Quetiapine			C				Not Reported
	Temazepam			C				Not Reported
	Montelukast			C				Not Reported
	Pyridoxine			C				Not Reported
	Folic Acid			C				Not Reported
	Escitalopram			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936040	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-006319			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Alprazolam			S	Oral	0.25 Milligram, Once A Day		Aurobindo	
	Xgeva			S	Subcutaneous	120 Milligram, In Total		Not Reported	
	Aromasine			C	Oral	25 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936067	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-006196			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Sluggishness	Alprazolam			S	Oral	20 Milliliter, In Total		Aurobindo	
	Escitalopram Oxalate			S	Oral	30 Milliliter, In Total		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936252	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1008720		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Alprazolam			S	Oral	.25 Milligram Daily;		Actavis	
	Xgeva 120 Mg, Solution Injectable			S	Subcutaneous			Not Reported	
	Aromasine 25 Mg, Comprimé			C	Oral	25 Milligram Daily;		Not Reported	
	Enrobé								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936643	EXPEDITED (15-DAY)		OT	PL-PRINSTON PHARMACEUTICAL			Unknown	POL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Prinston Pharmaceutical Not Reported
	Ginseng			S	Unknown			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15937064	EXPEDITED (15-DAY)		HO	BE-ACCORD-104489		25 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Lactation Disorder; Maternal Exposure During Pregnancy	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15937109	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX- 2019AP007214		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Respiratory Depression	Escitalopram			S	Oral	15 Mg, Qd		Apotex
	Neurontin			S	Oral	300 Mg, Tid		Not Reported
	Trankimazin			S	Oral	1 Mg, Qd		Not Reported
	Durogesic			S	Transdermal	150 Mg, 72 Hours		Not Reported
	Sevredol			S	Oral	10 Mg, 1 Necessary		Not Reported
	Zovirax /00587301/			C	Unknown			Not Reported
	Nolotil /00473101/			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Zyloric			C	Unknown			Not Reported

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Seguril	C	Unknown	Not Reported
Binocrit	C	Subcutaneous	Not Reported
Clexane	C	Subcutaneous	Not Reported
Pantoprazol /01263201/	C	Unknown	Not Reported
Natecal D	C	Unknown	Not Reported
Mycostatin	C	Unknown	Not Reported
Hidroxil B12 B6 B1	C	Unknown	Not Reported
Seretide Accuhaler	C	Unknown	Not Reported
Borea	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15937391	EXPEDITED (15-DAY)		HO	BR-TORRENT-00004851		58 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Gastrointestinal Disorder	Espran			S	Oral	Unknown		Torrent	
	Lorax//Lorazepam			C	Oral	2 Tablets Daily		Unknown	
	Dormonid			C	Unknown	Unknown, She Used It Once		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15939783	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1905600US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15939808	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1905587US		68 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Food Intolerance;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Unk		Allergan	

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Gastrointestinal Pain;
Migraine; Nausea;
Nervous System Disorder;
Serotonin Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15940612	EXPEDITED (15-DAY)		HO, LT	NL-MYLANLABS-2019M1011240		69 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Qd (1 X Per Dag 1 Stuk)		Not Reported	
	Hydrochlorothiazide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15941206	EXPEDITED (15-DAY)		OT	CA-OTSUKA-2019_003295		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Product Use In Unapproved Indication; Salivary Hypersecretion; Vomiting	Abilify			S	Oral	5 Mg (In The Morning)		Otsuka	
	Abilify			S				Otsuka	
	Escitalopram Oxalate			S	Oral	20 Mg (In The Evening)		Not Reported	
	Escitalopram Oxalate			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15941637	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2019	15917147	EXPEDITED (15-DAY)		HO	IT-ACCORD-105519		49 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Minias			S	Oral	Strength : 2.5 Mg / ML, Oral Drops, Solution		Not Reported
	Paroxetine			S	Oral	Strength : 20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2019	14764255	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2017PL101604		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope; Tachycardia	Metoprolol Succinate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd, Before Sleep		Novartis
	Escitalopram			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported
	Cyproheptadine			S	Unknown	16 Mg, Unk		Not Reported
	Venlafaxine			S	Oral	150 Mg In The Morning, In The Afternoon		Not Reported
	Moclobemide			S	Oral	150 Mg, In Afternoon		Not Reported
	Trazodone			S	Oral	50 Mg, At Night		Not Reported
	Sertraline			S	Oral	50 Mg, At Night		Not Reported
	Moklar			S	Unknown	150 Mg, Qd		Not Reported
	Sotalol			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Ginkgo Biloba Extract			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15944239	EXPEDITED (15-DAY)			FR-UCBSA-2019004502		48 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Thrombocytopenia	Keppra	S	Oral	1500 Mg Daily	Ucb
	Seroplex	S	Oral	20 Mg Daily	Not Reported
	Seroplex	S			Not Reported
	Dantrium	C		25 Mg	Not Reported
	Lovenox	C		Unk	Not Reported
	Lioresal	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15945677	EXPEDITED (15-DAY)		OT	IN-ACCORD-105722		23 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusional Disorder, Erotomanic Type	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15946502	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1011513		73 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Gait Disturbance	Quetiapine			S	Oral	150 Milligram, Qd		Not Reported	
	Lorans			S	Oral	1 Dosage Form, Qd		Mylan	
	Carbolithium			S	Oral	1.5 Dosage Form, Qd		Mylan	
	Cipralext /01588501/			S	Oral	0.5 Dosage Form, Qd		Mylan	
	Lorans			S	Oral	1 Dosage Form, Qd		Mylan	
	Motilium /00498201/			C		Unk		Mylan	
	Omeprazen /00661201/			C		Unk		Mylan	
	Metformina Teva			C		Unk		Mylan	
	Eskim			C		Unk		Mylan	
	Totalip			C		Unk		Mylan	
	Nicetile			C		Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15950112	NON-EXPEDITED			US-TAKEDA-2019TUS004873			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Trintellix			S	Oral	Unk		Takeda	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15950509	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1011314		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Skin Eruption	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported	
	Stresam			S	Oral	3 Dosage Form, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	13343976	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1709923US		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Gastrointestinal Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Augmentin			S	Oral	1 G, Tid		Not Reported	
	Ciprofloxacin			S	Oral	500 Mg, Qd		Not Reported	
	Dexamethasone			S	Oral	40 Mg, Qweek		Not Reported	
	Disodium Pamidronate			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported	
	Revlimid			S	Oral	25 Mg, Qd		Not Reported	
	Zyloric			S	Oral	300 Mg, Qd		Not Reported	
	Previscan			C	Unknown	15 Mg, Qd		Not Reported	
	Previscan			C		Unk		Not Reported	
	Bactrim			C	Oral	Unk		Not Reported	

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Bactrim	C	Oral	400 Mg, Q Week	Not Reported
Durogesic	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	20 Mg, Unk	Not Reported
Gaviscon	C	Unknown	Unk	Not Reported
Lovenox	C	Subcutaneous	Unk	Not Reported
Lovenox	C	Subcutaneous	7000 Iu, Bid	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Lyrica	C	Oral	25 Mg, Bid	Not Reported
Mianserine	C	Oral	Unk	Not Reported
Mianserine	C	Oral	30 Mg, Qd	Not Reported
Movicol	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Seresta	C	Oral	Unk	Not Reported
Seresta	C	Oral	10 Mg, Qd	Not Reported
Tamiflu	C	Unknown	Unk	Not Reported
Zelitrex	C	Oral	500 Mg, Bid	Not Reported
Zelitrex	C	Oral	500 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	14207004	EXPEDITED (15-DAY)		HO, OT	ES-LUPIN PHARMACEUTICALS INC.-2017-06633		68 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram Oxalate			S	Oral	5 Mg, Qd (At Breakfast, For Several Years)		Lupin
	Emconcor			C	Oral	1.25 Mg, Bid (At Breakfast And Dinner, Every 12 Hours)		Not Reported
	Simvastatina Cinfa			C	Oral	20 Mg, Qd (At Dinner)		Not Reported
	Hibor (Bemiparin Sodium)			C	Subcutaneous	3500 Iu Anti-Xa/0.2 MI Solution For Injection In Pre-Filled Syringe; In The		Not Reported

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Evening

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	14282047	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2017524123		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Alprazolam			S	Oral	0.25 Mg, 3x/Day		Pfizer
	Alprazolam			S	Oral	0.75 Mg, 3x/Day		Pfizer
	Alprazolam			S		0.75 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Oral	10 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Pfizer
	Metformin			S	Oral	500 Mg, 2x/Day		Not Reported
	Metformin			S	Oral	1000 Mg, 1x/Day/Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	30 Mg, 1x/Day		Not Reported
	Furosemide			S	Oral	2 Df, 1x/Day		Not Reported
	Irbesartan			S	Oral	300 Mg, 1x/Day		Not Reported
	Irbesartan			S		500 Mg, 2x/Day		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day		Not Reported
	Dafalgan			S		6 Df, Daily		Not Reported
	Dafalgan			S	Oral	1000 Mg, 3x/Day		Not Reported
	Nefopam			S	Oral	1 Df, 3x/Day		Not Reported
	Nefopam			S	Oral	3 Df, 3x/Day		Not Reported
	Nefopam			S	Oral	3 Ug, 1x/Day		Not Reported
	Nefopam			S		3 Df, 1x/Day		Not Reported
	Diffu K			S	Oral	3 Df (2-1-0), 2x/Day		Not Reported
	Diffu K			S	Oral	6 Df, 1x/Day/Qd		Not Reported
	Colchicine Opocalcium			S	Oral	1 Mg, 1x/Day		Not Reported
	Colchicine Opocalcium			S	Oral	1 Df, 1x/Day/Qd		Not Reported

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Xarelto	S	Oral	20 Mg, 1x/Day	Not Reported
Xarelto	S		1 Df, Unk	Not Reported
Xarelto	S		1 Df, 1x/Day	Not Reported
Seroplex	S	Oral	1 Df, 1x/Day	Not Reported
Tavanic	S	Oral	250 Mg, 2x/Day	Not Reported
Tavanic	S	Oral	500 Mg, Daily	Not Reported
Tavanic	S	Oral	2 Df, 1x/Day	Not Reported
Diazepam	S	Oral	10 Mg, 3x/Day (If Needed)	Not Reported
Diazepam	S	Oral	30 Mg, 1x/Day/Qd	Not Reported
Bisoprolol Fumarate	S	Oral	1.25 Mg, 1x/Day	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Df, 1x/Day	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	1 Ug, Unk	Not Reported
Valium	S	Oral	10 Mg, 3x/Day, If Needed	Not Reported
Valium	S	Oral	3 Ug, 1x/Day/Qd	Not Reported
Valium	S		3 Df, Daily	Not Reported
Nefopam Hydrochloride	S	Oral	3 Ug, 1x/Day/Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15580025	EXPEDITED (15-DAY)		HO, OT	PHHY2018AT144314			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation; Alcoholism; Apraxia; Behaviour Disorder; Cognitive Disorder; Dementia; Dementia With Lewy Bodies; Depression; Drug Ineffective; Dysphoria; Hallucination, Visual; Insomnia; Korsakoff'S Syndrome;	Rivastigmine			S	Transdermal	Unk (Transdermales Pflaster 4,6mg/24h)		Novartis
	Rivastigmine			S	Transdermal	4.6 Mg, Qd		Novartis
	Quetiapine			S	Oral	25 Mg, Qd		Not Reported
	Quetiapine			S	Oral	100 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	1000 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported

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Mania; Muscle Rigidity;	Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
Parkinsonism;	Escitalopram	S	Unknown	3 Mg, Qd	Not Reported
Restlessness; Sleep	Risperidone	S	Unknown	3 Mg, Qd	Not Reported
Disorder; Tremor; Urinary	Risperidone	S	Unknown	1 Mg, Unk	Not Reported
Incontinence	Naltrexone	S	Unknown	Unk	Not Reported
	Risperdal	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown	Unk	Not Reported
	Piracetam	S	Unknown	1200 Mg, Unk	Not Reported
	Cerebrolysin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Oral	25 Mg, Bid	Not Reported
	Oxazepam	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15613742	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1085728		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Esomeprazole			S	Oral	40 Mg, Qd		Not Reported
Hemianopia;	Esidrex			S	Oral	0.5 Df, Qd		Mylan
Hyponatraemia; Language	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
Disorder	Procoralan			C		Unk		Mylan
	Aspirin /00002701/			C		Unk		Mylan
	Seresta			C		Breackable		Mylan
	Dafalgan			C		Unk		Mylan
	Pravastatine /00880401/			C		Unk		Mylan
	Mediatusyl /00631801/			C		Unk		Mylan
	Ramipril			C		Unk		Mylan
	Acebutolol /00405702/			C		Unk		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15779198	NON-EXPEDITED			US-PFIZER INC-2018534559		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15805244	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019009533		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Sluggishness	Alprazolam			S	Oral	20 MI, Single		Pfizer	
	Escitalopram Oxalate			S	Oral	30 MI, Single		Not Reported	
	Omeprazole			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15815207	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-101426		46 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Gases Abnormal; Drug Abuse; Muscle Rigidity; Sopor; Suicide Attempt	Escitalopram			S	Oral			Not Reported	
	Lexotan			S	Oral			Not Reported	
	Venlafaxine			S	Oral			Not Reported	
	Lamictal			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15838200	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL184404		52 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram	S	Unknown	Unk	Not Reported
	Omeprazole	S	Unknown	20 Mg, In The Morning, Fasting	Novartis
	Tramadol Hydrochloride	S	Unknown	100 Mg, Bid (Sustained Release)	Not Reported
	Metamizole	S	Unknown	Unk	Not Reported
	Ketoprofen	S	Unknown		Not Reported
	Alprazolam	S	Unknown		Not Reported
	Buprenorphine	S	Unknown	35 Ug, Unk (Per Hour Every 4 Days)	Not Reported
	Valproic Acid	C	Unknown		Not Reported
	Betamethason	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Zoledronic Acid	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Metoclopramide	C	Unknown	30 Mg, Qd	Not Reported
	Effentora	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15904470	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-105266		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage; Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Not Reported
	Indapamide			S	Oral			Not Reported
	Lactulose			C				Not Reported
	Perindopril/Perindopril Erbumine			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15917899	NON-EXPEDITED			US-PFIZER INC-2019048861		71 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Chest Pain; Drug Ineffective For Unapproved Indication	Gabapentin			S		400 Mg, 3x/Day		Pfizer
	Gabapentin			S				Pfizer
	Buspirone			S		Unk		Not Reported
	Buspirone			S				Not Reported
	Lexapro			S		Unk		Not Reported
	Lexapro			S				Not Reported
	Lamotrigine			S		Unk		Not Reported
	Lamotrigine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15944840	DIRECT		DS, OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tremor; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Accord
	Atenolol			C				Not Reported
	Brilinta			C				Not Reported
	Aspirin			C				Not Reported
	Celebrex			C				Not Reported
	Multivitamin			C				Not Reported
	Fish Oil			C				Not Reported
	Co Q10			C				Not Reported
	Potassium			C				Not Reported
	Glucosamine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15947303	EXPEDITED (15-DAY)		DS, OT	FR-AUROBINDO-AUR-APL-2019-006726			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Eliquis			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported

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	Loxen L P		C	Unknown	Unk				Not Reported
	Lopressor		C	Unknown	Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15948026	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-006578			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram Film-Coated Tablets			S	Oral	3920 Milligram, Total		Aurobindo	
	Felison			S	Oral	900 Milligram, Total		Not Reported	
	Seroquel			S	Oral	6 Gram, In Total		Not Reported	
	Tavor (Lorazepam)			S	Oral	50 Milligram, Total		Not Reported	
	Zoloft			S	Oral	6 Gram, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15948259	NON-EXPEDITED			US-TEVA-2019-US-998906			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Escitalopram Oxalate			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15948515	EXPEDITED (15-DAY)		CA	DE-ACCORD-106609		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Megaureter; Foetal Exposure During Pregnancy; Pelvic Kidney; Renal Dysplasia	Escitalopram			S	Transplacental	15 (Mg/D) / Until Gestational Week 34 3/7: 15 Mg, Then 10 Mg/D		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15948581	EXPEDITED (15-DAY)		HO	FR-ACCORD-106653		85 YR	Female	FRA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Balance Disorder; Depressed Level Of Consciousness; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion; Vertigo	Escitalopram			S	Oral			Not Reported	
	Aldactazine			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948584	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-106507		86 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Haemorrhage Intracranial	Escitalopram			S	Oral			Not Reported	
	Duoplavin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948875	EXPEDITED (15-DAY)		HO	IT-ACCORD-106640		31 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Impaired Gastric Emptying; Vomiting	Escitalopram			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949215	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-012443		< 1 DAY	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Premature Baby	Nulojix			S	Transplacental	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb	
	Nulojix			S	Transmammary	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb	
	Envarsus			S	Transplacental	Unk		Not Reported	

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	Imuran /00001501/	S	Transplacental	Unk		Not Reported
	Prednisone	S	Transplacental	Unk		Not Reported
	Miacalcin	S	Transplacental	Unk		Not Reported
	Zantac	S	Transplacental	Unk		Not Reported
	Imitrex /01044801/	S	Transplacental	Unk		Not Reported
	Lexapro	S	Transplacental	Unk		Not Reported
	Phenergan /00033001/	S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15949306	EXPEDITED (15-DAY)		OT	IN-MACLEODS PHARMACEUTICALS US LTD- MAC2019020040			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusional Disorder, Erotomanic Type	Escitalopram 10 Mg Film Coated Tablet			S	Oral	10 Milligram, Qd		Macleods	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15949451	EXPEDITED (15-DAY)		HO	PHHY2019IT030225		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral	500 Mg, Unk (Total)		Not Reported	
	Lorazepam			S	Oral	250 Mg, Unk (Total)		Novartis	
	Escitalopram Oxalate			S	Oral	100 Mg, Unk (Total)		Not Reported	
	Trittico			S	Oral	10 Mg, Unk (Total)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15951952	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS- 2019M1012138		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma- Glutamyltransferase	Escitalopram			S	Oral	Unk		Not Reported	

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Increased; Miosis; Prothrombin Time Shortened; Suicide Attempt; Tachycardia; Vomiting	Dafalgan Codeine	S	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15951983	EXPEDITED (15-DAY)		OT	NL-MYLANLABS- 2019M1012159		61 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthyroidism	Escitalopram			S	Oral	10 Milligram, Qd (1dd)		Not Reported	
	Ptu			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15952816	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019054837		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura; Rash Pruritic	Alprazolam			S	Oral	0.25 Mg, 1x/Day		Pfizer	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Xgeva			S	Subcutaneous	120 Mg, Single		Not Reported	
	Aromasine			C	Oral	25 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15953528	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2019- 003874		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	In Total		Not Reported	
	Quetiapine Fumarate			S	Oral	In Total		Not Reported	
	Escitalopram Oxalate			S	Oral	In Total		Not Reported	
	Trittico			S	Oral	In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15954292	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1011857		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Metoprolol			S	Transplacental	Unk Unk, Qd (71.25 [Mg/D]/ 47.5-0-23.75 Mg/D)		Not Reported
	Amitriptyline			S	Transplacental	37.5 Milligram, Qd (37.5 [Mg/D])		Not Reported
	Cipralex /01588502/			S	Transplacental	5 [Mg/D]		Mylan
	Paracetamol			C	Transplacental	Unk Unk, Qd (2000 [Mg/D]/ 1-2 G/D If Required)		Mylan
	Clexane			C	Transplacental	Unk Unk, Qd (120 [Mg/D (-40)]/ Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D)		Mylan
	Ibuprofen			C	Transplacental	600 Milligram, Qd (600 [Mg/D]/ If Required)		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	14241423	EXPEDITED (15-DAY)		HO	FR-ROCHE-2031433		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)			Not Reported
	Dafalgan			S	Oral			Not Reported
	Dafalgan			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Xarelto			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported

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Amlodipine Besilate	S	Oral		Not Reported
Irbesartan	S	Oral		Not Reported
Irbesartan	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Nefopam Hydrochloride	S	Oral		Not Reported
Bisoprolol Hemifumarate	S	Oral		Not Reported
Diffu K	S	Oral	3 Df Daily (2-1-0), Bid	Not Reported
Valium	S	Oral		Not Reported
Valium	S	Oral		Not Reported
Valium	S	Oral		Not Reported
Mirtazapine	S	Oral		Not Reported
Furosemide	S	Oral	30 Mg Daily (2-1-0), 2 Times A Day	Not Reported
Furosemide	S	Oral	2 Ot, Qd	Not Reported
Tavanic	S	Oral		Not Reported
Metformin Hydrochloride	S	Oral		Not Reported
Colchicine Opocalcium	S	Oral		Not Reported
Alprazolam	S	Oral		Not Reported
Alprazolam	S	Oral	0.75 Mg Three Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15883058	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2019-003018			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death;	Mirtazapine Film-Coated Tablet			S	Oral	Unk		Aurobindo
Agitation; Delirium;	Venlafaxine			S	Unknown	Unk		Aurobindo
Dissociative Amnesia;	Seroplex			S	Unknown	Unk, Pkgid=Unknown		Not Reported
Drug Intolerance;	Lysanxia			S	Unknown	Unk		Not Reported
Psychotic Disorder;	Norset			S	Oral	Unk		Not Reported
Suicidal Ideation;								
Withdrawal Syndrome								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15932468	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1007529		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Frequent Bowel Movements; Serotonin Syndrome; Symptom Masked	Linezolid			S	Unknown			Teva	
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax	
	Trazodone			S	Unknown	300 Milligram Daily; At Night (Nightly); High-Dose		Actavis	
	Trazodone			S	Unknown	150 Milligram Daily; At Night		Actavis	
	Clonazepam			S	Unknown			Teva	
	Piperacillin/Tazobactam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15954759	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007211			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram, Daily (5 [Mg/D])		Aurobindo	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental	Unk		Not Reported	
	L-Thyroxin			C	Transplacental	50 Microgram, Daily (50 [Mg/D])		Not Reported	
	Tetanus Vaccine			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15954870	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2019-007342			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin	S	Oral	500 Milligram, Once A Day (1000 Milligram)	Aurobindo
	Dexamethasone	S	Oral	40 Milligram Once In A Week (5.7143 Milligram)	Not Reported
	Revlimid	S	Oral	25 Milligram (28 Day)	Not Reported
	Augmentin	S	Oral	1 Gram, Once A Day (3 Gram)	Not Reported
	Pamidronate Disodium	S	Intravenous drip	30 Milligram, Once A Day	Not Reported
	Zyloric	S	Oral	300 Milligram, Once A Day	Not Reported
	Seroplex	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Zelitrex	C	Oral	Unk	Not Reported
	Zelitrex	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Zelitrex	C	Oral	500 Milligram, Once A Day(1000 Milligram)	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Oral	25 Milligram, Once A Day (50 Milligram)	Not Reported
	Durogesic	C	Unknown	Unk	Not Reported
	Gaviscon	C	Unknown	Unk	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Lovenox	C	Subcutaneous	Unk	Not Reported
	Lovenox	C	Subcutaneous	7000 International Unit, Once A Day (14000 Iu (International Unit))	Not Reported
	Bactrim	C	Oral	400 Milligram Once In A Week	Not Reported
	Bactrim	C	Oral	Unk	Not Reported
	Seresta	C	Oral	Unk	Not Reported
	Seresta	C	Oral	10 Milligram, Once A Day	Not Reported

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Mianserine	C	Oral	30 Milligram, Once A Day	Not Reported
Mianserine	C	Oral	Unk	Not Reported
Furosemide	C	Unknown	20 Milligram, Unk	Not Reported
Previscan	C	Unknown	15 Milligram, Once A Day	Not Reported
Tamiflu	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15954893	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007406			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram 5 Mg			S	Unknown	5 Milligram, Once A Day		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15955348	EXPEDITED (15-DAY)		HO	GB-TORRENT-00020313		56 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyarrhythmia; Circulatory Collapse	Elleste-Solo			C	Transdermal			Unknown	
	Escitalopram Oxalate			S	Oral			Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15955858	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-00067			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyrexia	Blinded Escitalopram			S				Not Reported	
	Blinded Aripiprazole			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15955941	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1905931US		1 DAY	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd; 0. - 5.5. Gestational Week		Allergan	
	Skinoren			C	Transplacental	Preconceptional		Not Reported	
	Folsaure			C	Transplacental	4.4. - 5.3. Gestational Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15956823	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1012013		90 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Delirium; Fall; Post Procedural Haemorrhage; Traumatic Haemorrhage	Escitalopram			S	Unknown	15 Milligram, Qd (15 Mg, Per Day)		Not Reported	
	Eliquis			S	Unknown	Unk		Mylan	
	Eliquis			S	Unknown	10 Milligram, Qd (5 Mg, Bid)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15956935	EXPEDITED (15-DAY)		HO, LT, OT	RO-ALLERGAN-1906116US		51 YR	Female	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Overdose; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk Unk, Unknown (Overdose)		Allergan	
	Phenobarbital/Valerian Dry Hydroalcoholic Extract			S	Oral	Unk, Unknown (Overdose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15956949	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1906102US		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Balance Disorder; Deep Vein	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S				Allergan	

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Thrombosis; Dizziness; Headache; Ligament Rupture; Migraine; Paraesthesia; Pulmonary Embolism; Vision Blurred	Neurontin Neurontin Klonopin Klonopin	S S C C	Oral Oral	300 Mg, Tid 1 Mg, Qd	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14297008	EXPEDITED (15-DAY)		DS, HO	BE- GLAXOSMITHKLINE- BE2017GSK056316		41 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Exposure During Pregnancy; Exposure During Pregnancy; Unintended Pregnancy	Nucala			S	Subcutaneous	100 Mg, Unk		Glaxosmithkline
	Relvar Ellipta			S		Unk Unk, Qd		Glaxosmithkline
	Sipralexa			S		10 Mg, Z, Tablet		Glaxosmithkline
	Avamys			S		Unk Unk, Bid		Glaxosmithkline
	Flixotide			S		250 ?G, Bid		Glaxosmithkline
	Ventolin			S	Unknown	100 ?G, Unk		Glaxosmithkline
	Xanthium (Theophylline)			S		20 Mg, Qd		Glaxosmithkline
	Levocetirizine			S		5 Mg, Qd		Glaxosmithkline
	Seretide			S	Unknown	Unk		Glaxosmithkline
	Fluticasone Furoate			S		Unk		Glaxosmithkline
	Xyzall			S		5 Mg, Qd		Glaxosmithkline
	D-Cure			S	Unknown	25 Kiu, Unk		Not Reported
	Pantomed (Pantoprazole)			S	Unknown	20 Mg, Qd		Not Reported
	Vilanterol Trifenatate			S	Unknown	Unk Unk, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14567226	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-AUROBINDO-AUR- APL-2018-009821			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac	Metoprolol			S	Unknown	Unk		Aurobindo
	Sertraline			S	Oral	50 Mg, At Night		Aurobindo

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Disorder; Contraindicated	Ivabradine	S	Unknown	Unk	Not Reported
Product Administered;	Escitalopram	S	Unknown	Unk	Aurobindo
Drug Ineffective; Drug	Cyproheptadine	S	Oral	16 Milligram	Not Reported
Interaction;	Venlafaxine	S	Unknown	150 Milligram, Once A Day	Not Reported
Electrocardiogram Qt	Zolpidem	S	Oral	10 Mg, At Bedtime, Before	Not Reported
Prolonged; Fatigue; Initial				Sleep	
Insomnia; Insomnia;	Trazodone	S	Unknown	Unk	Not Reported
Ischaemic Stroke; Middle	Moklar	S	Unknown	150 Milligram, Once A	Not Reported
Insomnia; Palpitations;				Day, Hs	
Syncope	Sotalol	C	Unknown	Unk	Not Reported
	Warfarin	C	Unknown	Unk	Not Reported
	Ginkgo Biloba Extract	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14597629	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01580		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Lupin	
	Escitalopram			S	Oral	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14603027	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01639		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Bupropion			S	Oral	Unk		Lupin	
	Amlodipine			S	Oral	Unk		Lupin	
	Escitalopram			S	Oral	Unk		Lupin	
	Losartan			S	Oral	Unk		Lupin	
	Salicylates Nos			S	Oral	Unk		Not Reported	

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Levothyroxine	S	Oral	Unk	Not Reported
Ethanol	S	Oral	Unk	Not Reported

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14-Feb-2019	14603039	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01640		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin
	Gabapentin			S	Oral	Unk		Lupin
	Ibuprofen			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14603427	EXPEDITED (15-DAY)		OT	ZA-LUPIN (EUROPE) LIMITED-2018-01555			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Visual Impairment	Zytomil Tablets			S	Oral	20 Mg, Unk		Lupin
	Theophylline			S	Oral	200 Mg, Unk		Not Reported
	Estrofem /00045401/			S	Oral	1 Mg, Unk		Not Reported
	Forvent			S	Oral	18 1/2 1/2G, Unk		Not Reported
	Dulera			S	Oral	Unk, 200/5 Mg		Not Reported
	Bio-Nifedipine			S	Oral	5 Mg, Unk		Not Reported
	Bayer Aspirin Cardio			S	Oral	100 Mg, Unk		Not Reported
	Purgoxin			S	Oral	0.25 Mg, Unk		Not Reported
	Betacor /00008501/			S	Oral	5 Mg, Unk		Not Reported
	Adco-Bisocor			S	Oral	5 Mg, Unk		Not Reported
	Trepiline /00002201/			S	Oral	25 Mg, Unk		Not Reported
Puresis			S	Oral	40 Mg, Unk		Not Reported	

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Foxair			S		Oral		Unk, 50/500 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Feb-2019	14603428	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01518		31 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin		
	Escitalopram			S	Respiratory (inhalation)	Unk		Lupin		
	Ethanol			S	Oral	Unk		Not Reported		
	Ethanol			S	Respiratory (inhalation)	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Feb-2019	14607395	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01663		43 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Amitriptyline			S	Oral	Unk		Not Reported		
	Escitalopram			S	Oral	Unk		Lupin		
	Lorazepam			S	Oral	Unk		Lupin		
	Lithium			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Feb-2019	14613085	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01657		55 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide	Bupropion			S	Oral	Unk		Lupin		
	Escitalopram			S	Oral	Unk		Lupin		
	Venlafaxine			S	Oral	Unk		Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14616567	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01753		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Lamotrigine			S	Oral	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14617065	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01719		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	
	Diphenhydramine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14617341	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01801		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Fluoxetine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Lupin	
	Risperidone			S	Oral	Unk		Not Reported	
	Diphenhydramine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14625161	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-01821		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Escitalopram			S	Oral	Unk		Lupin	

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Escitalopram	S	Respiratory (inhalation)	Unk	Lupin
Lamotrigine	S	Oral	Unk	Lupin
Lamotrigine	S	Respiratory (inhalation)	Unk	Lupin
Mirtazapine	S	Oral	Unk	Not Reported
Mirtazapine	S	Respiratory (inhalation)	Unk	Not Reported
Cyclobenzaprine	S	Oral	Unk	Not Reported
Cyclobenzaprine	S	Respiratory (inhalation)	Unk	Not Reported
Buspirone	S	Oral	Unk	Not Reported
Buspirone	S	Respiratory (inhalation)	Unk	Not Reported
Clonazepam	S	Oral	Unk	Not Reported
Clonazepam	S	Respiratory (inhalation)	Unk	Not Reported
Propranolol	S	Oral	Unk	Not Reported
Propranolol	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14731467	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-AUROBINDO-AUR-APL-2017-44076			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Anomaly; Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine Film-Coated Tablet			S	Transplacental	5 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantomed (Dexpanthenol)			S	Transplacental	Unk		Not Reported
	Mepolizumab			S	Transplacental	100 Milligram		Not Reported
	D-Cure			S	Transplacental	25 Kilo-International Unit		Not Reported
	Flixotide			S	Transplacental	500 Microgram, Two		Not Reported

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				Times A Day	
Flixotide	S	Transplacental	250 Ug, Bid		Not Reported
Flixotide	S	Transplacental	250 Ug, Bid		Not Reported
Avamys	S	Transplacental	Unk Unk, Bid		Not Reported
Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd		Not Reported
Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd		Not Reported
Xanthium (Theophylline)	S	Transplacental	200 Mg, Qd		Not Reported
Ventolin	S	Transplacental	100 Ug, Unk		Not Reported
Relvar	S	Transplacental	Unk, Qd		Not Reported
Seretide	S	Transplacental	Unk		Not Reported
Fluticasone Furoate	S	Transplacental	Unk Unk, Qd (1)		Not Reported
Vilanterol Trifenatate	S	Transplacental	Unk		Not Reported
Nucala	S	Transplacental	100 Mg, Unk		Not Reported
Xyzall	S	Unknown	5 Mg, Qd		Not Reported
Sipralexa	S	Transplacental	10 Mg, Z		Not Reported
Theophylline	S	Unknown	Unk		Not Reported
Theophylline	S		Unk ()		Not Reported
Theophylline	S		Unk ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	14790649	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2018M1025389		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Sildenafil			S		Unk		Not Reported
	Spironolactone			S		Unk		Mylan
	Phenobarbital			S		Unk		Mylan
	Varivax (Varicella Zoster Virus Vaccine Live)			S	Intramuscular	1 Df, Unk		Mylan
	Topiramate			S	Unknown	Unk		Mylan
	Synagis			S	Intramuscular	150mg		Mylan

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Exodus /01588502/

S

Unk

Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15959004	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-007420			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)], 0. - 5.5. Gestational Week		Aurobindo
	Skinoren			C	Transplacental	Trimester: Preconceptional		Not Reported
	Folic Acid			C	Transplacental	4.4. - 5.3. Gestational Week		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15959052	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-007596			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram Film-Coated Tablets			S	Oral	5 Milligram,Starting Dose 5mg		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15959507	EXPEDITED (15-DAY)		HO	FR-ACCORD-106342		42 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Disinhibition; Suicidal Ideation	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15959595	EXPEDITED (15-DAY)		OT	SE-ACCORD-107423		85 YR	Female	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ecchymosis; Erythema	Escitalopram			S	Oral			Not Reported	
	Zopiklon			C				Not Reported	
	Kalcipos-D			C				Not Reported	
	Aclasta			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15960726	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE- HET2019DE00145		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 Mg, Qd		Hetero	
	Skinoren			C	Transplacental	Unk		Not Reported	
	Folsäure			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15960919	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2019DE00146		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram, Qd		Hetero	
	Tetanus Vaccine			C	Transplacental	Unk		Not Reported	
	L-Thyroxin			C	Transplacental	50 Microgram, Qd		Not Reported	
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15961183	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019020077			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During	Escitalopram			S	Transplacental	Unk, 10 [Mg/D (5)], 1 {Trimester}, 0-5.5.		Macleods	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Transposition Of The Great Vessels	Skinoren	C	Transplacental	Gestational Week Unk, Trimester: Preconceptional	Not Reported
	Folsaure	C	Transplacental	Unk, 4.4-5.3. Gestational Week, 1 {Trimester}	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15961486	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1010044		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram Oxalate			S	Oral			Ivax	
	Felison 30 Mg Capsule Rigide			S	Oral			Not Reported	
	Seroquel 100 Mg Comprese Rivestite Con Film			S	Oral			Not Reported	
	Tavor 2,5 Mg Comprese			S	Oral			Not Reported	
	Zoloft Comprese Rivestite Con Film 100 Mg			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15961833	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE22480		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral	500.0mg Unknown		Not Reported	
	Escitalopram Oxalate			S	Oral	100.0mg Unknown		Not Reported	
	Lorazepam			S	Oral	250.0mg Unknown		Not Reported	
	Trittico			S	Oral	10.0df Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15962057	NON-EXPEDITED			US-009507513-1902USA000588		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Remeron			S	Oral	30 Milligram		Merck	

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Sertraline Hydrochloride	S	Oral	150 Milligram	Not Reported
Ativan	S		1 Milligram	Not Reported
Lexapro	S		20 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15962342	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1906329US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	9737411	EXPEDITED (15-DAY)		DE, LT, OT	NO-ASTRAZENECA-2013SE88323		20 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Seroquel			S	Oral			Zeneca	
Completed Suicide;	Ciprallex			S	Unknown			Not Reported	
Drowning; Intentional Self-Injury; Medication Error; Overdose; Sedation; Unevaluable Event	Rivotril			S	Unknown			Not Reported	
	Vival			S	Unknown			Not Reported	
	Remeron			S	Unknown			Not Reported	
	Catapresan			S	Unknown	50.0mg Unknown		Not Reported	
	Imovane			S	Oral			Not Reported	
	Oxynorm			S	Oral	5 To 10mg		Not Reported	
	Oxynorm			S	Oral	5 To 10mg		Not Reported	
	Oxynorm			S	Oral	10.0mg Unknown		Not Reported	
	Oxynorm			S	Oral	10.0mg Unknown		Not Reported	
	Lamictal			S	Unknown	100.0mg Unknown		Not Reported	
	Nozinan			S	Unknown			Not Reported	
	Pinex Forte			S	Oral	Strength: 500/30 Mg And Pandeine		Not Reported	
	Nobligan			S	Oral	200.0mg Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nobligan	S	Oral	50, 200mg Unknown	Not Reported
Sobril	S	Oral		Not Reported
Sarotex	S	Oral		Not Reported
Truxal	S	Oral	600 To 1200mg	Not Reported
Cipramil [Citalopram Hydrobromide]	S	Oral		Not Reported
Orfiril	S	Unknown	1200.0mg Unknown	Not Reported
Atarax	S	Unknown		Not Reported
Morphine	C			Not Reported
Diamorphine	C			Not Reported
Cyanocobalamin	C			Not Reported
Codeine Phosphate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	14668063	EXPEDITED (15-DAY)		DE, HO, OT	DE-AUROBINDO-AUR-APL-2018-016247			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Oxygen Saturation Decreased; Pain; Pneumonia; Respiratory Failure	Topiramate			S	Unknown	Unk		Aurobindo
	Sildenafil			S	Unknown	Unk		Aurobindo
	Phenobarbital			S	Unknown	Unk		Not Reported
	Spironolactone			S	Unknown	Unk		Not Reported
	Exodus (Escitalopram Oxalate)			S	Unknown	Unk		Not Reported
	Synagis			S	Intramuscular	150 Mg, Unk		Not Reported
	Varivax			S	Intramuscular	1 Dosage Form		Not Reported
	Water			C	Unknown	4 Unk, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15744038	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-096972		73 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Drug Interaction	Escitalopram Oxalato (2858ob)			S	Oral			Not Reported

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Amiodarone Hydrochloride (392ch)			S	Oral		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15801906	NON-EXPEDITED			US-ALKERMES INC.- ALK-2019-000035			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Psychotic Symptom	Aristada			S	Intramuscular	1064 Mg, Qmo		Alkermes	
	Aristada			S	Intramuscular	1064 Mg, Q8wk		Alkermes	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15893872	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2019ZA00683			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhoids	Lexamil			S	Oral	10 Milligram, Qd		Invagen	
	Co-Tareg			C	Oral	1 Dosage Form, Qd, Tablet		Not Reported	
	Aspavor			C	Oral	1 Dosage Form, Qd, Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15964648	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019020078			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram Oxalate			S	Unknown	5 Milligram, Qd		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15966059	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2019-007658			Unknown	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Milligram		Aurobindo	
	Quetiapine			S	Oral	500 Milligram		Aurobindo	
	Escitalopram			S	Oral	100 Milligram		Aurobindo	
	Trittico			S	Oral	10 Dosage Form		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15966581	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1011404			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram 5 Mg			S		5 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15967079	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019063530		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Nuchal Rigidity; Overdose; Suicide Attempt	Tavor (Lorazepam)			S	Oral	50 Mg, Single		Pfizer	
	Zoloft			S	Oral	6 G, Single		Pfizer	
	Escitalopram Oxalate			S	Oral	3920 Mg, Single		Not Reported	
	Felison			S	Oral	900 Mg, Single		Not Reported	
	Seroquel			S	Oral	6 G, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15967733	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1013192		24 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Prescribed Overdose	Escitalopram			S	Oral	30 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	

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Escitalopram	S	Oral	10 Milligram, Qd(Overdose: 30 Milligram Daily)	Not Reported
Diazepam	C	Oral	5 Milligram, Qd	Mylan
Diazepam	C	Oral	10 Milligram, Qd	Mylan
Pantozol /01263204/	C	Oral	20 Milligram, Qd	Mylan
Pantozol /01263204/	C	Oral	40 Milligram, Qd	Mylan
Prothipendyl	C	Oral	80 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15969018	EXPEDITED (15-DAY)		DE, OT	CH- GLAXOSMITHKLINE- CH2019025266		47 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Brain Oedema; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea; Encephalopathy; Multiple Organ Dysfunction Syndrome; Oropharyngeal Pain; Pyrexia	Ventolin			S	Respiratory (inhalation)	As Necessary		Glaxosmithkline	
	Dafalgan			S	Oral	As Necessary		Glaxosmithkline	
	Clarithromycin			S	Oral	500 Mg, Unk		Not Reported	
	Piperacillin + Tazobactam			S	Intravenous drip	4500 Mg, Unk		Not Reported	
	Haloperidol			S	Oral	5 Mg, Unk		Not Reported	
	Metfin			S	Oral	500 Mg, Unk		Not Reported	
	Betmiga			S	Oral	50 Mg, Qd		Not Reported	
	Clopin (Clozapine)			S	Oral	Started At 25 Mg/D The 04.12.2018 And Increased Up To 300 Mg/D The 20.12.2018		Not Reported	
	Clopin (Clozapine)			S	Oral	300 Mg, Unk		Not Reported	
	Cipralext			S	Oral	10 Mg, Unk		Not Reported	
	Inderal			S	Oral	40 Mg, Unk		Not Reported	
	Temesta [Lorazepam]			S	Oral	As Necessary		Not Reported	
	Eltroxin			C	Oral	75 ?G, Qd		Glaxosmithkline	
	Atorvastatine			C	Oral	20 Mg, Qd		Glaxosmithkline	

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Zolpidem	C	Oral	As Necessary	Not Reported
Tranxilium	C	Oral	40 Mg, Qd	Not Reported
Calcium D3 (Calcium Carbonate+Colecalciferol)	C	Oral	1 Df, Unk	Not Reported
Duspatalin Retard	C	Oral	400 Mg, Unk	Not Reported
Symbicort	C	Respiratory (inhalation)	2 Inhalations/Days	Not Reported
Spasmo-Urgenin Neo	C	Oral	40 Mg, Unk	Not Reported
Cerazette	C	Oral	0.075 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15969565	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1011603		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Milligram Daily; 5 [Mg/D]		Ivax
	Tetanus Vaccine			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental	50 Microgram Daily; 50 [Mg/D]		Not Reported
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide]			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15970180	EXPEDITED (15-DAY)		HO	GB-ALLERGAN-1906608US		56 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyarrhythmia; Circulatory Collapse	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Elleste-Solo			C	Transdermal	80 Mg, Qd (24 Hrs)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	15935585	EXPEDITED (15-DAY)		HO	IT-ACCORD-106317		21 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Aripiprazole			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Zitromax			S	Oral	Strength: 500 Mg		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	Strength: 25 Mg		Not Reported	
	Alprazolam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	15972618	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2019-FR-1012020		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	500 Milligram Daily; 1000 Milligram		Not Reported	
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Augmentin			S	Oral	1 Gram Daily; 3 Gram		Not Reported	
	Sodium Pamidronate			S	Intravenous drip	30 Milligram Daily;		Not Reported	
	Zyloric			S	Oral	300 Milligram Daily; 300 Milligram		Not Reported	
	Seroplex			S	Oral	1 Dosage Forms Daily; 1 Dosage Forms		Not Reported	
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported	
	Revlimid			S	Oral	25 Milligram		Not Reported	
	Paracetamol			C	Unknown			Not Reported	
	Zelitrex			C	Oral			Not Reported	
	Lyrica			C	Oral			Not Reported	
	Durogesic			C	Unknown			Not Reported	
	Gaviscon			C	Unknown			Not Reported	
	Movicol			C	Unknown			Not Reported	
	Lyrica			C	Oral	25 Milligram Daily; 50		Not Reported	

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Lovenox	C	Subcutaneous	Milligram	Not Reported
Bactrim	C	Oral	400 Milligram	Not Reported
Seresta	C	Oral		Not Reported
Lovenox	C	Subcutaneous	7000 lu (International Unit) Daily; 14000 lu (International Unit)	Not Reported
Mianserine	C	Oral	30 Milligram Daily; 30 Milligram	Not Reported
Tamiflu	C	Unknown		Not Reported
Zelitrex 500 Mg, Comprimé	C	Oral	1 Dosage Forms Daily;	Not Reported
Enrobé	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Zelitrex	C	Oral	500 Milligram Daily; 1000 Milligram	Not Reported
Mianserine	C	Oral		Not Reported
Seresta	C	Oral	10 Milligram Daily; 10 Milligram	Not Reported
Bactrim	C	Oral		Not Reported
Previscan	C	Unknown	15 Milligram Daily; 15 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	15972640	EXPEDITED (15-DAY)		OT	DE-HETERO CORPORATE- HET2019DE00147		68 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	5 Milligram		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2019	15573407	EXPEDITED (15-DAY)		OT	US-DEXPHARM-20180828		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Escitalopram			S		Daily Dose: 40 Mg Milligram(S) Every Days		Not Reported	
	Mirtazapine			S		Every Night At Bedtime		Not Reported	
	Alprazolam			S		When Necessary		Not Reported	
	Lamotrigine			S		Daily Dose: 300 Mg Milligram(S) Every Days		Not Reported	
	Enalapril			S		Every Morning		Not Reported	
	Lansoprazole			S		Every Morning		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2019	15979486	DIRECT		OT			55 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Feeling Abnormal; Lethargy	Escitalopram			S	Oral	Quantity:1 Tablet(S);	12 YR	Torrent	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2019	15979705	DIRECT					58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Feeling Jittery; Headache; Nausea; Nausea; Nervousness; Restlessness	Escitalopram Oxalate Generic For Lexapro			S	Oral	Quantity:30 Tablet(S);		Accord	
	Estradiol			C				Not Reported	
	Progesterone			C				Not Reported	
	Benedryl			C				Not Reported	
	Multi Vitamin, Vitamin D3			C				Not Reported	
	Magnesium			C				Not Reported	
	Flaxseed Oil,			C				Not Reported	

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Garlic	C	Not Reported
Vitamin B Complex	C	Not Reported
Primrose Oil	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15545910	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1079566		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Alprazolam			S		0.75 Mg, Qd, 0.25 Mg, 3x/Day (Tid)		Not Reported
	Bisoprolol			S	Oral	1.25 Mg, Once Daily (Qd)		Not Reported
	Furosemide			S	Oral	30 Milligram, Bid (2-1-0), 2x/Day (Bid)		Not Reported
	Furosemide			S	Oral	2 Unk, Qd		Not Reported
	Terbutaline			S	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Irbesartan			S		300 Mg, Once Daily Qd		Not Reported
	Mirtazapine			S	Oral	15 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Metformin			S		500 Mg, Bid (1000 Mg Qd)		Not Reported
	Xarelto			S	Oral	20 Mg, Qd (1 Df Qd)		Mylan
	Nefopam			S	Oral	3 Df, Qd, 1 Df, 3x/Day (1 Df, Tid)		Mylan
	Valium			S	Oral	10 Mg, Qd, 3x/Day (Tid) (3 Df Qd)		Mylan
	Diffu-K			S	Oral	6 Df, Qd, 3 Df Daily (2-1-0) 2x/Day (Bid)		Mylan
	Dafalgan			S	Oral	3000 Mg, Qd, 1000 Mg, 3x/Day (Tid) (6 Df, Qd)		Mylan
	Tavanic			S	Oral	250 Mg, Bid (2 Df Qd)		Mylan
	Seroplex			S	Oral	1 Df, Once Daily Qd		Mylan

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	Colchicine Opocalcium	S	Oral	1 Mg, Daily Once Qd (1 Df Qd)		Mylan			
	Metformine Pfizer	S		500 Mg, Bid		Mylan			
	Diazepam	S	Oral	10 Mg, Tid (3 Df Qd)		Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15936680	EXPEDITED (15-DAY)		HO	ZA-LUPIN PHARMACEUTICALS INC.-2019-00673			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain	Flexocam 7,5 Mg			S	Oral	7.5 Milligram		Lupin	
	Lexamil			S	Oral	10 Milligram		Not Reported	
	Tramazac Co			S	Oral	37.5/325mg		Not Reported	
	Zopax			S	Oral	0.25 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15974629	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-1011767		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)]		Ivax	
	Skinoren			C	Transplacental			Not Reported	
	Folsaure			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976225	NON-EXPEDITED			US-PFIZER INC-2019060446		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Floxin [Ofloxacin]			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Requip			S		Unk		Not Reported	

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Zyprexa			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15977390	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1014139		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence	Escitalopram			S	Oral	Non Renseign�e		Not Reported	
	Diazepam			S	Oral	Non Renseign�e		Mylan	
	Imovane			S	Oral	7.5 Milligram, Qd		Mylan	
	Theralene			S	Oral	20 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	14382284	EXPEDITED (15-DAY)		HO, OT	AT-PFIZER INC-2018013512		47 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder; Condition Aggravated; Paraesthesia; Serotonin Syndrome	Escitalopram Oxalate			S	Oral	5 Mg, 1x/Day		Not Reported	
	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported	
	Alprazolam			S	Unknown	0.5 Mg, 1x/Day		Pfizer	
	Alprazolam			S	Unknown	1 Mg, Unk		Pfizer	
	Seropram (Citalopram Hydrobromide)			S	Intravenous drip	20 Mg, 1x/Day		Not Reported	
	Temesta [Lorazepam]			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15454724	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-APOTEX-2018AP021203		62 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Contraindicated Product Administered;	Venlafaxine			S	Oral	150 Mg, Qd, In The Morning		Apotex	
	Venlafaxine			S	Unknown	150 Mg, Qd, In The Afternoon		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope; Syncope	Zolpidem	S	Oral	10 Mg, Qd, At Bedtime	Apotex
	Zolpidem	S	Unknown	10 Mg Before A Sleep	Apotex
	Sertraline	S	Oral	50 Mg, At Night	Apotex
	Sertraline	S	Unknown	50 Mg Milligram(S) Every Days	Apotex
	Escitalopram	S	Unknown		Apotex
	Moclobemide	S	Oral	150 Mg, Qd, In Afternoon	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Moklar	S	Unknown	150 Mg Milligram(S) Every Days	Not Reported
	Cyproheptadine	S	Oral		Not Reported
	Trazodone	S	Unknown		Not Reported
	Ivabradine	S	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Ginkgo Biloba Extract	C	Unknown	Unk	Not Reported
	Warfarin	C	Unknown	Unk	Not Reported
	Sotalol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15978415	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1013012		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine Fumarate			S	Oral			Teva
	Lorazepam			S	Oral			Actavis
	Escitalopram Oxalate			S	Oral			Ivax
	Trittico 150 Mg Compresse A Rilascio Prolungato			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15978906	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL		74 YR	Male	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

INDUSTRIES LTD-
2019RR-199516

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	1000 Milligram		Ranbaxy
	Seroplex 10 Mg, Comprime			S	Oral	1 Dosage Form, Daily		Not Reported
	Pellicule Secable							
	Augmentin			S	Oral	3 Gram		Not Reported
	Sodium Pamidronate			S	Intravenous drip	30 Milligram		Not Reported
	Zyloric			S	Oral	300 Milligram		Not Reported
	Seroplex			S	Oral	1 Dosage Forms		Not Reported
	Dexamethasone Oral			S	Oral	5.7143 Milligram		Not Reported
	Revlimid			S	Oral	25 Milligram		Not Reported
	Paracetamol			C	Unknown	()		Not Reported
	Zelitrex			C	Oral	()		Not Reported
	Zelitrex			C	Oral	1000 Milligram		Not Reported
	Lyrica			C	Oral	()		Not Reported
	Lyrica			C	Oral	50 Milligram		Not Reported
	Durogesic			C	Unknown	()		Not Reported
	Gaviscon			C	Unknown	()		Not Reported
	Movicol			C	Unknown	()		Not Reported
	Lovenox			C	Subcutaneous	()		Not Reported
	Lovenox			C	Subcutaneous	14000 Iu (International Unit)		Not Reported
	Bactrim			C	Oral	400 Milligram		Not Reported
	Bactrim			C	Oral	()		Not Reported
	Seresta			C	Oral	()		Not Reported
	Seresta			C	Oral	10 Milligram		Not Reported
	Mianserine			C	Oral	30 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mianserine	C	Oral	()	Not Reported
Tamiflu	C	Unknown	()	Not Reported
Zelitrex 500 Mg, Comprime	C	Oral	1 Dosage Form, Daily	Not Reported
Enrobe				
Furosemide	C	Unknown	20 Milligram	Not Reported
Previscan	C	Unknown	15 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15979913	EXPEDITED (15-DAY)		DE, HO, OT	FR-ZYDUS-033545		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Norset			S	Oral	Unk ()		Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			S	Unknown			Zydu Pharm
	Seroplex			S	Unknown	Unk ()		Not Reported
	Lysanxia			S	Unknown	Unk ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15980348	EXPEDITED (15-DAY)		HO	IT-APOTEX-2019AP008025		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Psychomotor Skills Impaired	Quetiapine			S	Oral	500 Mg, Unk (In Total)		Apotex
	Lorazepam			S	Oral	250 Mg, In Total		Not Reported
	Escitalopram Oxalate			S	Oral	100 Mg, In Total		Not Reported
	Trittico			S	Oral	10 Df, Unk (In Total)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15980821	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1770585US		32 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia;	Escitalopram Oxalate Unk			S	Oral	5 Mg, Qd		Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Extrapyramidal Disorder;	Trimipramin	S	Oral	75 Mg, Qd	Not Reported
Muscle Twitching;	Trimipramin	S	Oral	25 Mg, Qd	Not Reported
Restlessness					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15980822	EXPEDITED (15-DAY)		OT	BE-ALLERGAN-1906774US		22 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bladder Obstruction;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
Product Use In	Abilify Maintena			S	Unknown	400 Mg, Unk		Not Reported
Unapproved Indication								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15981017	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1015420		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown			Not Reported
	Kratom			S	Oral			Mylan
	Kratom			S	Unknown			Mylan
	Valsartan			C	Unknown			Mylan
	Metoprolol Tartrate			C	Unknown			Mylan
	Clonazepam			C	Unknown			Mylan
	Fexofenadine			C	Unknown			Mylan
	Acetaminophen			C	Unknown	Restricted Use To The Recommended 3000 Mg Per Day Limit		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15983002	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1906785US		62 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Escitalopram Oxalate - Bp			S	Unknown			Allergan
Haemorrhagic Diathesis;	Escitalopram Oxalate - Bp			S				Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injection Site	Fluanxol Depot	C	Unknown	Not Reported
Haemorrhage; Product Use In Unapproved Indication	Nebivolol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15984687	DIRECT		HO			7 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Personality Change; Tibia Fracture; Trismus	Concerta 18 Mg			S	Oral	Quantity:1 Capsule(S);		Alza
	Lexapro			S	Oral	Quantity:1 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15823501	EXPEDITED (15-DAY)		HO	PHHY2018CO197794			Male	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Ascites; Cardiac Failure; Fluid Retention; General Physical Health Deterioration; Urethral Stenosis; Viral Infection; Vomiting	Entresto			S	Oral	200 Mg (97 Mg Sacubitril/103 Mg Valsartan), Q12h		Not Reported
	Carvedilol			S	Unknown	2 Df, Q12h		Novartis
	Bosentan			S	Unknown	125 Mg, Q12h		Not Reported
	Escitalopram			S	Unknown	Unk Unk, Qd		Not Reported
	Atorvastatin			S	Unknown	10 Mg, Qd		Not Reported
	Omeprazole			C	Oral	Unk Unk, Qd		Not Reported
	Nifedipine			C	Oral	60 Mg, Q12h		Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported
	Sevelamer			C	Unknown	2 Df, Qd		Not Reported
	B Complex			C	Unknown	Unk, Qd		Not Reported
	Folic Acid			C	Unknown	5 Df, Qd		Not Reported
	Bupropion			C	Unknown	Unk Unk, Qd		Not Reported
	Levomepromazine			C	Unknown	10 Ot, Qhs (10 Drios) (At Night)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clonidine	C	Oral	2 Df, Q8h (150 Mg)	Not Reported
Trazodone	C	Unknown		Not Reported
Varenicline	C	Unknown	1 Mg, Qd	Not Reported
Iron	C	Unknown		Not Reported
Bisacodyl	C	Unknown	Unk Unk, Qd	Not Reported
Allopurinol	C	Unknown	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15855702	EXPEDITED (15-DAY)	HO		FR-ALLERGAN-1902712US		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Abnormal; Intentional Overdose; Miosis; Off Label Use; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	14 Df, Single (In Total Overdose: 14 Dosage Forms)		Allergan
	Paroxetine			S	Oral	28 Df, Single (In Total)		Not Reported
	Prazepam			S	Oral	20 Df, Single (In Total)		Not Reported
	Cocaine			S	Unknown	0.5 G, Unknown		Not Reported
	Tercian			S	Oral	16 Df, Single (In Total)		Not Reported
	Atarax			S	Oral	10 Df, Single (In Total)		Not Reported
	Valium			S	Oral	3 Df, Single (In Total)		Not Reported
	Alcool			S	Oral	Unk, Unknown		Not Reported
	Diazepam			S	Oral	8 Df, Single (In Total)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15882008	EXPEDITED (15-DAY)	DE, HO, OT		FR-PFIZER INC-2019035267		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder;	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Norset			S	Oral	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

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Suicidal Ideation; Withdrawal Syndrome	Lysanxia	S	Unknown	Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15983295	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-199622		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Milligram, In Total		Sun
	Escitalopram			S	Oral	100 Milligram, In Total		Not Reported
	Quetiapine Fumarate			S	Oral	500 Milligram, In Total		Not Reported
	Trittico 150 Mg Compresse A Rilascio Prolungato			S	Oral	10 Dosage Form, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984200	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE- 1012302		68 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	Startdos 5mg		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984495	EXPEDITED (15-DAY)		LT	NO-ALLERGAN- 1906992US		54 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Drug Interaction; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	20 Mg Tablet: 1/2 Tablet Per Day.		Allergan
	Tambocor			S	Oral	100 Mg, Q12h		Not Reported
	Selo-Zok			C	Oral	50 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984666	EXPEDITED (15-DAY)		DE, HO, OT	CH-ASTELLAS-2019US006040		47 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Brain Oedema; Cardiac Arrest; Cough; Dyspnoea; Eschar; Hypoxic-Ischaemic Encephalopathy; Multiple Organ Dysfunction Syndrome; Oropharyngeal Pain; Psychomotor Hyperactivity; Pyrexia	Betmiga			S	Oral			Astellas
	Clopin Eco			S	Oral			Not Reported
	Clopin Eco			S	Oral			Not Reported
	Cipralex /01588502/			S	Oral			Not Reported
	Temesta /00273201/			S	Oral	2.5 Mg, As Needed (Maximum 2 Per Day On Hand)		Not Reported
	Temesta /00273201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Inderal			S	Oral	40 Mg, Once Daily (Usual Treatment For Several Years)		Not Reported
	Metfin			S	Oral			Not Reported
	Ventolin /00139502/			S	Other	100 Mg, (On Hand Maximum 4 Per Day) As Needed		Not Reported
	Dafalgan			S	Oral	1 G, (3 Per Day On Hand) As Needed		Not Reported
	Clarithromycin			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Piperacillin Tazobactam Pa			S	Intravenous drip	Unk Unk, Unknown Freq.		Not Reported
	Haloperidol			S	Oral			Not Reported
	Tranxilium			C	Oral			Not Reported
	Zolpidem			C	Oral	10 Mg, (On Hand) Once Daily		Not Reported
	Atorvastatine /01326101/			C	Oral			Not Reported
	Eltroxin			C	Oral			Not Reported
	Calcium Sandoz D			C	Oral	1 Df, (Calcium 500 Mg, Cholecalciferol 440 Iu) Unknown Freq.		Not Reported

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Duspatalin /00139402/	C	Oral		Not Reported
Symbicort Forte	C	Other	2 Df, (Inhalations) (Budesonide 200 Microg, Formoterol 6 Microg) Once Daily	Not Reported
Spasmo-Urgenin Neo	C	Oral		Not Reported
Cerazette /00754001/	C	Oral	0.075 Mg, Once Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984700	EXPEDITED (15-DAY)	CA		DE-ALLERGAN-1906998US		< 1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Unk		Allergan	
	L-Thyroxin			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Not Reported	
	Femibion [Calcium Phosphate Dibasic\Ferrous Succinate\Magnesium Hydroxide] Progesteran			C	Transplacental	0.8 Mg, Qd		Not Reported	
				C	Transplacental	Actual: 600 [Mg/D (3 X 200 Mg/D)]		Not Reported	
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Not Reported	
	Progynova			C	Transplacental	3 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984747	EXPEDITED (15-DAY)	CA		NL-ALLERGAN-1906804US			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15985679	DIRECT					35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate 20mg Tab			S	Oral	Quantity:135 Tablet(S);Other Frequency:1.5 Tab Per Day;	10 YR	Accord	
	Lamictal 100 Mg Tab			C				Not Reported	
	Losartan 100 Mg Tabs			C				Not Reported	
	Amlodipine 10 Mg			C				Not Reported	
	Zantac 150			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15985820	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1906960US		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Hydrochlorothiazide Unk			S	Oral	12.5 Mg, Qd		Allergan	
	Metoprolol			C	Unknown	147.5 Mg, Qd		Not Reported	
	Kardegic			C	Oral	75 Mg, Qd		Not Reported	
	Felodipine			C	Unknown	5 Mg, Qd		Not Reported	
	Lexomil			C	Oral	4 Df, Qd		Not Reported	
	Colecalciferol			C	Unknown	100000 Iu, Biw		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15985854	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00013348			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital	L-Thyroxin			C	Transplacental	112 [G/D (Bis 75 G/D)]		Unknown	
Hydronephrosis; Foetal Exposure During	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Unknown	

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Pregnancy	Progestan	C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]	Unknown
	Escitalopram	S	Transplacental	20 [Mg/D]	Unknown
	Dekristol	C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Unknown
	Progynova	C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	12082727	EXPEDITED (15-DAY)		HO, OT	TW-LUPIN PHARMACEUTICALS INC.-2016-00644		46 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Quetiapine			S	Unknown	100 Milligram, Qd		Lupin	
	Quetiapine			S	Unknown	Increased To 150 Milligram, Qd		Lupin	
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin	
	Escitalopram			S				Lupin	
	Lithium			S	Unknown	600 Milligram, Qd		Not Reported	
	Lithium			S				Not Reported	
	Sertraline			C	Unknown	Unk		Not Reported	
	Aripiprazole			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15947262	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2019-00731		23 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion; Delusional Disorder, Erotomanic Type; Grandiosity; Judgement Impaired; Mental Disorder; Weight Increased	Escitalopram Tablets			S		10 Milligram, Qd		Lupin	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Haloperidol			S	Unknown	5 Milligram, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15977323	EXPEDITED (15-DAY)		HO	PT-ALLERGAN-1906602US		50 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Lymphoma	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan	
	Bromazepam			S	Unknown	Unk, Unknown		Not Reported	
	Oral Contraceptive Nos			S	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988466	EXPEDITED (15-DAY)		HO	IT-ACCORD-108225		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Sopor; Therapy Change	Escitalopram			S	Oral			Not Reported	
	Anafranil			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988654	EXPEDITED (15-DAY)		DS	FI-ACCORD-107985		73 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hypoaesthesia; Musculoskeletal Pain; Myalgia; Pain In Extremity; Paraesthesia; Sleep Disorder	Escitalopram			S	Oral	10,Mg,Daily		Not Reported	
	Cohemin Depot			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988657	EXPEDITED (15-DAY)		OT	IT-ACCORD-108600		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor; Suicidal Ideation	Escitalopram			S	Oral			Not Reported	

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Olanzapine	S	Oral	Not Reported
Tavor (Lorazepam)	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988717	EXPEDITED (15-DAY)		OT	US-ZYDUS-034032		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chromaturia; Decreased Appetite; Drug-Induced Liver Injury; Dysuria; Fatigue; Hepatic Steatosis; Hyperbilirubinaemia; Jaundice; Malaise; Micturition Urgency; Pollakiuria; Potentiating Drug Interaction; Pruritus; Pyrexia; Vomiting	Escitalopram			S	Unknown			Zydus Pharm
	Kratom			S	Unknown	Powder Form		Not Reported
	Valsartan			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported
	Kratom			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988880	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2019-008779			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Aurobindo
	Elleste-Solo			C	Transdermal	80 Microgram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15991256	EXPEDITED (15-DAY)		HO	PHHY2018CO153935		81 YR	Male	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Prescribed Underdose; Renal Disorder; Wrong Technique In Product Usage Process	Entresto			S	Oral	(Half A Day)0.5 Df (50 Mg), Qd		Novartis
	Entresto			S	Oral	1df (50 Mg) , Qd		Novartis

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Carvedilol	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Human Insulink	C	Unknown		Not Reported
Tiotropium Bromide	C	Unknown		Not Reported
Salmeterol	C	Unknown		Not Reported
Levothyroxine	C	Unknown		Not Reported
Omeprazole	C	Unknown		Not Reported
Apixaban	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Spironolactone	C	Unknown		Not Reported
Metildigoxin	C	Unknown		Not Reported
Insuline Glargine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15992768	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1907195US		23 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Logorrhoea; Off Label Use; Seizure; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Valium			S	Oral	Unk		Not Reported
	Lithium			S	Oral	1.2 G, Qd		Not Reported
	Tercian			S	Oral	250 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15994564	DIRECT		DS			36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Decreased	Lexapro			S	Oral		15 YR	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	9184821	EXPEDITED (15-DAY)		DE, LT	NO-ROCHE-1203940		20 YR	Female	NOR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drowning; Intentional Self- Injury; Medication Error; Overdose; Sedation	Rivotril			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Oxynorm			S	Unknown	Strength: 5 Mg- 10 Mg		Not Reported
	Lamictal			S	Unknown	Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Cipralext			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Hydroxyzine Hydrochloride			S	Unknown			Not Reported
	Truxal			S	Unknown	Unk		Not Reported
	Remeron			S	Unknown			Not Reported
	Sobril			S	Unknown	Unk		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	Unk		Not Reported
	Catapresan			S	Unknown	Strength 25 Mg, 50 Mg		Not Reported
	Levomepromazine Maleate			S	Unknown			Not Reported
	Sarotex			S	Unknown			Not Reported
	Atarax (Hydroxyzine Hydrochloride)			S	Unknown			Not Reported
	Vival (Diazepam)			S	Unknown			Not Reported
	Nobligan			S	Unknown	Strength: 50 Mg -200 Mg, Unk		Not Reported
	Orfiril			S	Unknown	Strength: 600 Mg -1200 Mg		Not Reported
	Pinex Forte			S	Unknown	Strength: 500/30 Mg And Pandeine		Not Reported
	Imovane			S	Oral			Not Reported
	Seroquel			S	Unknown			Not Reported
	Nozinan			S	Unknown			Not Reported
	Cyanocobalamin			C	Unknown	Unk		Not Reported
	Forte			C	Unknown	Unk		Not Reported

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		Diamorphine	C	Unknown	Unk			Not Reported	
		Codeine Phosphate	C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	11376828	EXPEDITED (15-DAY)		HO	FR-FRI-1000078942		20 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Focal Dyscognitive Seizures; Hypoglycaemia; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15993322	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009074			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo	
	Ginkgo Biloba			S	Unknown	Unk		Not Reported	
	Ginkgo Biloba			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15993323	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009077			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo	
	Ginkgo Biloba			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15993325	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-009072			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Herbal Interaction; Myalgia; Ventricular	Escitalopram			S	Unknown	Unk		Aurobindo	

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Arrhythmia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15995491	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-1907327US		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety; Decreased Appetite; Depression; Dizziness; Drug Dependence; Hypotension; Irritability; Pruritus; Psychiatric Symptom; Somnolence; Tachycardia; Tinnitus; Withdrawal Syndrome; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	½ Tablet Or ¾ Tablet In The Morning		Allergan
	Escitalopram Oxalate - Bp Orfida			S C	Oral	Unk		Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15995503	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1907085US		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Mass; Chest Pain; Depression; Drug Ineffective; Hot Flush; Monoplegia; Nerve Injury; Pain	Lexapro			S	Unknown			Allergan
	Effexor Xr			S	Unknown	75 Mg, Qd		Not Reported
	Effexor Xr			S				Not Reported
	Hormones Patch			S	Unknown			Not Reported
	Ritalin			C	Unknown	20 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15995805	EXPEDITED (15-DAY)		DE, HO, OT	CH-ALLERGAN-1906964US		47 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd (Usual Long Term Treatment)		Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oropharyngeal Pain; Product Use In Unapproved Indication; Pyrexia	Ventolin	S	Respiratory (inhalation)	100 Mg, Prn (100 Micrograms In Reserve, Maximum 4x/Day; As Necessary)	Not Reported
	Clarithromycin	S	Oral	500 Mg, Bid	Not Reported
	Piperacillin & Tazobactam	S	Intravenous drip	4500 Mg, Tid	Not Reported
	Haloperidol	S	Oral	5 Mg, Bid	Not Reported
	Clopin Eco	S	Oral	300 Mg, Qd	Not Reported
	Clopin Eco	S	Oral	25 Mg, Qd	Not Reported
	Temesta [Lorazepam]	S	Oral	2.5 Mg, Prn (2.5 Mg Maximum 2x J En Serve Depuis Au Moins Mai 2018; As Necessary)	Not Reported
	Inderal	S	Oral	40 Mg, Qd (Usual Treatment Since Several Years)	Not Reported
	Metfin	S	Oral	500 Mg, Qd	Not Reported
	Betmiga	S	Oral	50 Mg, Qd	Not Reported
	Dafalgan	S	Oral	1 G, Prn (1 G Maximum 3x/Day In Reserve; As Necessary)	Not Reported
	Tranxilium	C	Oral	40 Mg, Qd	Not Reported
	Zolpidem	C	Oral	10 Mg, Prn (10 Mg/Day In Reserve At Least Since 26.11.2018; As Necessary)	Not Reported
	Atorvastatine	C	Oral	20 Mg, Qd	Not Reported
	Eltroxin	C	Oral	75 Mg, Qd	Not Reported
	Calcium Sandoz D	C	Oral	1 Df, Qd	Not Reported
	Duspatalin	C	Oral	400 Mg, Qd	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Df, Qd (2 Inhalations/Day)	Not Reported
	Spasmo-Urgenin Neo	C	Oral	40 Mg, Qd	Not Reported

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Cerazette			C	Oral	0.075 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15996581	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro 20mg			S				Not Reported	
	Trazodone 50mg			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15996937	EXPEDITED (15-DAY)		DE	CH-JNJFOC-20190215504		47 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Cardiac Arrest; Cough; Dyspnoea; Inappropriate Schedule Of Product Administration; Off Label Use; Oropharyngeal Pain; Pyrexia	Haloperidol			S	Oral			Not Reported	
	Temesta [Lorazepam]			S	Oral	As Necessary		Not Reported	
	Inderal			S	Oral			Not Reported	
	Metfin			S	Oral			Not Reported	
	Ventolin			S	Respiratory (inhalation)	As Necessary		Not Reported	
	Betmiga			S	Oral			Not Reported	
	Dafalgan			S	Oral	As Necessary		Not Reported	
	Clarithromycin			S	Oral			Not Reported	
	Piperacilline/Tazobactam			S	Intravenous drip			Not Reported	
	Clopin Eco			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Tranxilium			C	Oral			Not Reported	
	Zolpidem			C	Oral	As Necessary		Not Reported	
	Atorvastatin			C	Oral			Not Reported	
	Eltroxin			C	Oral			Not Reported	
	Duspatalin			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Symbicort	C	Respiratory (inhalation)	Not Reported
Spasmo-Urgenin Neo	C	Oral	Not Reported
Cerazette	C	Oral	Not Reported
Calcium Sandoz + Vitamin D3	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15997460	NON-EXPEDITED			US-BAUSCH-BL-2019-004387			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Ativan			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Pamelor			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	16122312	DIRECT					62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Irritable Bowel Syndrome	Lexapro Escitalopram			S	Oral	Quantity:20 Mg Milligram(S);		Aurobindo	
	Tofranil			C				Not Reported	
	Losartan			C				Not Reported	
	Toulaz			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Chlorella			C				Not Reported	
	Minerals			C				Not Reported	
	Cbd Oil			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15883296	EXPEDITED (15-DAY)		HO, LT	DE-ACCORD-103666		21 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Escitalopram	S		Strength: 5 Mg Milligram(S)	Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium	S			Not Reported
	Linezolid	S	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Levetiracetam	C		Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Ivabradine/Ivabradine Hydrochloride	C		Daily Dose: 15 Mg Milligram(S) Every Days	Not Reported
	Sulfamethoxazole/Trimethoprim	C	Intravenous (not otherwise specified)	Daily Dose: 2 Df Dosage Form Every Days	Not Reported
	Naloxone Hydrochloride/Tilidine Hydrochloride	C			Not Reported
	Scopolamin	C			Not Reported
	Baclofen	C			Not Reported
	Prednisolone	C		Strength: 10 Mg Milligram(S)	Not Reported
	Lorazepam	C		Daily Dose: 1 Mg Milligram(S) Every Days	Not Reported
	L-Thyroxin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15998171	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-108483		37 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Aripiprazole			S	Unknown	5 Milligram Daily;		Not Reported
Haematoma;	Escitalopram			S	Unknown	15 Milligram Daily;		Not Reported
Haemorrhage;						Reduced To 15 Mg/Day		
Menorrhagia; Respiratory Tract Infection; Sleep Disorder	Risperidone			S	Unknown	0.5 Mg		Not Reported
	Atorvastatin			C	Unknown	Evening Dose Of 100 Mg		Not Reported
	Pregabalin			C		100 Milligram Daily, Evening Dose Of 100 Mg		Not Reported
	Promethazine			C	Unknown			Not Reported

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Opipramol/Opipramol Hydrochloride	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Risperidone	S	Unknown	0.5 Mg	Not Reported
Escitalopram	S	Unknown	20 Milligram Daily; In A Morning Target Dose Of 20 Mg	Not Reported
Escitalopram	S	Unknown	20 Milligram Daily; Increased To A Dose Of 20 Mg Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15998180	EXPEDITED (15-DAY)		HO	FR-ACCORD-108961		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autonomic Nervous System Imbalance; Malaise; Orthostatic Hypotension	Escitalopram			S	Oral			Not Reported
	Zopiclone			S	Oral			Not Reported
	Risperdal			S	Oral	Strength: 1 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15998519	EXPEDITED (15-DAY)		HO	IT-ACCORD-108908		73 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Gait Disturbance	Quetiapine			S	Oral			Not Reported
	Lorans			S	Oral	Strength:1mg		Not Reported
	Carbolithium			S	Oral	Strength:150 Mg		Not Reported
	Cipralex			S	Oral	Strength:10mg		Not Reported
	Motilium			C		Strength:10 Mg		Not Reported
	Metformina Teva			C		Strength:500 Mg		Not Reported
	Omeprazen			C		Strength:20mg		Not Reported

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Eskim	C	Strength: 1000 Mg	Not Reported
Totalip	C	Strength:20 Mg	Not Reported
Nicetile	C	Strength: 500mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15998659	EXPEDITED (15-DAY)	HO, LT		NL-ACCORD-108852		69 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Hyponatraemia	Escitalopram			S		1 X Per Day 1 Piece		Not Reported	
	Hydrochlorothiazide			S		25 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15998923	EXPEDITED (15-DAY)	OT		DE-ACCORD-108884		76 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Rash	Escitalopram			S	Oral			Not Reported	
	Candesartan			C		Taking For Months		Not Reported	
	Eliquis			C	Oral	Taking For Months		Not Reported	
	Estradiol			C	Oral	Dose Not Changed		Not Reported	
	Novalgine (Metamizole Sodium)			C	Oral	Taking For Months		Not Reported	
	Amlodipine			C		Taking For Months		Not Reported	
	Sulfasalazine			C	Oral	Taking For Months		Not Reported	
	Concor			C	Oral	Taking For Months		Not Reported	
	Kalinor			C	Oral	Taking For Months		Not Reported	
	Sulfamethoxazole/Trimethoprim			C	Oral	Taking For Months		Not Reported	
	Vigantoletten			C	Subcutaneous	Taking For Months		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2019	16007766	EXPEDITED (15-DAY)	OT		HR-APOTEX-2019AP008097		17 YR	Male	HRV

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Somnolence; Suicide Attempt	Olanzapine			S	Oral	20 Mg, Unk		Apotex	
	Aspirin /00002701/			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Ibuprofen			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	14800420	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2018M1026541		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Lichen Planus	Verapamil			S	Oral	240 Milligram		Not Reported	
	Atorvastatin			S	Oral	20 Milligram		Not Reported	
	Esomeprazole			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Macrogol			S	Oral	Unk		Not Reported	
	Perindopril			S	Oral	2 Milligram		Not Reported	
	Aldactone /00006201/			S	Oral	Unk		Mylan	
	Esidrex			S	Oral	25 Milligram		Mylan	
	Kardegic			S	Oral	Unk		Mylan	
	Seroplex			S	Oral	Unk		Mylan	
	Teralithe			S	Oral	Unk		Mylan	
	Xeroquel			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	15986782	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC- 2019065613		47 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Cardiac Arrest; Cough; Drug Interaction; Dyspnoea;	Temesta [Lorazepam]			S	Oral	2.5 Mg, Maximum Twice Daily In Reserve As Necessary		Pfizer	

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Haemoglobin Decreased; Oropharyngeal Pain; Po2 Decreased; Pyrexia	Piperacillin/Tazobactam	S	Intravenous drip	4500 Mg, 3x/Day	Unknown
	Clopin Eco	S	Oral	25 Mg, 1x/Day	Not Reported
	Clopin Eco	S	Oral	300 Mg, 1x/Day	Not Reported
	Cipralex [Escitalopram Oxalate]	S	Oral	10 Mg, 1x/Day	Not Reported
	Inderal	S	Oral	40 Mg, 1x/Day	Not Reported
	Metfin	S	Oral	500 Mg, 1x/Day	Not Reported
	Ventolin [Salbutamol Sulfate]	S	Respiratory (inhalation)	100 Ug, Maximum In Reserve Four Times Daily As Necessary	Not Reported
	Betmiga	S	Oral	50 Mg, 1x/Day	Not Reported
	Dafalgan	S	Oral	1g, Maximum Thrice Daily In Reserve As Necessary	Not Reported
	Clarithromycin	S	Oral	500 Mg, 2x/Day	Not Reported
	Haloperidol	S	Oral	5 Mg, 2x/Day	Not Reported
	Tranxilium	C	Oral	40 Mg, 1x/Day	Not Reported
	Zolpidem	C	Oral	10 Mg, Once Daily In Reserve As Necessary	Not Reported
	Atorvastatin	C	Oral	20 Mg, 1x/Day	Not Reported
	Eltroxin	C	Oral	75 Ug, 1x/Day	Not Reported
	Calcium Sandoz + Witamin D3	C	Oral	1 Df = 1tablet (500mg/440 lu), 1x/Day	Not Reported
	Duspatalin [Mebeverine Hydrochloride]	C	Oral	400 Mg, 1x/Day	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Inhalations Once Daily (Budesonide 200 Microg, Formoterol 6 Microg)	Not Reported
	Spasmo-Urgenin Neo	C	Oral	40 Mg, 1x/Day	Not Reported
	Cerazette [Desogestrel]	C	Oral	0.075 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	15999578	EXPEDITED (15-DAY)		HO	FR- GLAXOSMITHKLINE- FR2019030170			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Withdrawal Syndrome	Lamictal			S	Transplacental	400 Mci, Qd		Glaxosmithkline	
	Seroplex			S	Transplacental	20 Mg, Qd		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16000010	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1907115US		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder With Mixed Anxiety And Depressed Mood; Anxiety; Atrial Septal Defect; Concussion; Depressed Mood; Ehlers-Danlos Syndrome; Hypermobility Syndrome; Loss Of Consciousness; Migraine With Aura; Myofascial Pain Syndrome; Postural Orthostatic Tachycardia Syndrome; Sleep Apnoea Syndrome	Lexapro			S	Oral	5 Mg, Unk		Allergan	
	Ester-C [Calcium Ascorbate]			S	Oral	Unk		Not Reported	
	Calcium			S	Oral			Not Reported	
	Zyrtec			S	Oral			Not Reported	
	Liposomal Ubiquinol			S	Oral			Not Reported	
	Cyanocobalamin			S	Oral	1000 Mg, Unk		Not Reported	
	Diclofenac			S	Topical	Unk		Not Reported	
	Epinephrine			S	Unknown	0.3 Mg/0.3 MI Injection		Not Reported	
	Ferrous Sulfate			S	Oral	325 Mg Total Salt (65 Mg Elemental)		Not Reported	
	Lactobac			S	Oral	40/Bifido 3/S. Thermop		Not Reported	
	Melatonin			S	Oral	Unk		Not Reported	
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported	
	Multivitamin			S	Oral	Unk		Not Reported	
	Omega 3 Fatty Acids			S	Oral	Unk		Not Reported	
	Ondansetron			S	Oral	4 Mg, Unk		Not Reported	
Lyrice			S	Oral	350 Mg, Unk		Not Reported		
Buffered Salt			S	Oral			Not Reported		
Sodium Chloride 0.9%			S	Intravenous (not otherwise specified)	Unk		Not Reported		

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16000492	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1015446		24 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	30 Milligram, Qd		Not Reported	
	Diazepam			C	Oral	5 Milligram, Qd		Mylan	
	Diazepam			C	Oral	10 Milligram, Qd		Mylan	
	Pantozol /01263204/			C		20 Milligram, Qd		Mylan	
	Pantozol /01263204/			C		40 Milligram, Qd		Mylan	
	Prothipendyl			C	Oral	80 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16000558	EXPEDITED (15-DAY)		HO	GB-TEVA-2019-GB-1015038		56 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyarrhythmia; Circulatory Collapse	Escitalopram Oxalate			S	Oral			Ivax	
	Elleste-Solo			C	Transdermal	80 Microgram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001413	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1907505US		57 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic	Escitalopram Oxalate - Bp			S	Unknown	5mg Uppttrappades Till 20 Mg		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Duloxetine			S	Unknown	30 Mg Uppttrappat Till 60 Mg		Not Reported	
	Duloxetine			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001415	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1907522US		33 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Intentional Overdose; Intentional Self-Injury	Escitalopram Oxalate - Bp			S	Oral	12-20 St Cipralex 10 Mg		Allergan	
	Cocillana-Etyfin			S	Oral	125 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001431	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1907525US		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Crestor			S	Unknown	Unk		Not Reported	
	Previscan (Fluindione)			S	Oral	Unk		Allergan	
	Plavix			S	Oral	Unk		Not Reported	
	Cordarone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001783	EXPEDITED (15-DAY)		DS, OT	US-ALLERGAN-1907313US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Attention Deficit/Hyperactivity Disorder; Developmental Delay; Failure To Thrive; Intellectual Disability; Physical Disability; Premature Baby	Lexapro			S	Transplacental	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16002033	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2019SUN000732			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bipolar Disorder; Brain Injury; Crying; Depression; Frequent Bowel Movements; Galactorrhoea; Hyperhidrosis; Hypomania; Intentional Product Use Issue; Intentional Self-Injury; Mania; Suicide Attempt; Tremor	Latuda			S	Oral	Unk		Sunovion
	Lexapro			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	300 Mg, Qd		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Tegretol			C				Not Reported
	Effexor			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16002938	NON-EXPEDITED			US-SA-2019SA050657			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Leflunomide			S				Sanofi
	Omeprazole			S		Unk		Not Reported
	Rosuvastatin			S				Not Reported
	Progesterone			S				Not Reported
	Estradiol			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Metformin			S		Unk		Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16003404	EXPEDITED (15-DAY)		OT	US-TORRENT-00007685		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis	Escitalopram			S		Unknown		Unknown
	Diazepam			C		Unknown		Unknown
	Lorazepam			C		Unknown		Unknown

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Zolpidem	C	Unknown	Unknown
Fexofenadine	C	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16004021	EXPEDITED (15-DAY)	CA		DE-ACCORD-109136		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Amitriptyline			S	Transplacental			Accord
	Cipralelex			S	Transplacental			Not Reported
	Metoprolol			S	Transplacental	71.25 Mg/D, 47.5-0-23.75 Mg/D		Not Reported
	Paracetamol			C	Transplacental	2000mg/D,1-2 G/D If Required		Not Reported
	Clexane			C	Transplacental	120mg/D (-40),Initial 40mg/D, Dosage Increase To 2 X 60 Mg/D		Not Reported
	Ibuprofen			C	Transplacental	600mg/D,If Required		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16004050	EXPEDITED (15-DAY)	LT		FR-ACCORD-109117		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma- Glutamyltransferase Increased; Miosis; Prothrombin Time Shortened; Suicide Attempt; Tachycardia; Vomiting	Escitalopram			S	Oral			Not Reported
	Dafalgan Codeine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16004081	EXPEDITED (15-DAY)	HO		IT-ACCORD-108639		59 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Crying; Electrocardiogram	Escitalopram	S						Not Reported
Qt Prolonged; Moaning	Alprazolam	S	Oral					Not Reported
	Trilafon	S	Oral					Not Reported
	Ramipril	C	Oral					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16127940	DIRECT	Y	OT			30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Product Substitution Issue	Escitalopram 10mg			S	Oral			Accord

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	9729873	EXPEDITED (15-DAY)		DE, LT, OT	NO-009507513-1312NOR001133		20 YR	Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Fatigue Syndrome; Completed Suicide; Drowning; Intentional Self-Injury; Jaw Fracture; Medication Error; Multiple Fractures; Overdose; Sedation; Unevaluable Event	Remeron			S	Unknown	Unk		Merck
	Pinex Forte			S	Unknown	300/30 Mg And Pandeine		Not Reported
	Sarotex			S	Unknown	Unk		Not Reported
	Cipramil (Citalopram Hydrobromide)			S	Unknown	Unk		Not Reported
	Orfiril			S	Unknown	1200 Mg, Unk		Not Reported
	Tramadol Hydrochloride			S	Unknown	50, 200mg		Not Reported
	Catapresan			S	Unknown	50 Mg, Unk		Not Reported
	Imovane			S	Oral	Unk		Not Reported
	Atarax (Hydroxyzine Hydrochloride)			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	100 Mg, Unk Strength: 25 Mg, 50 Mg, 100 Mg		Not Reported
	Vival			S	Unknown	Unk		Not Reported
	Nozinan			S	Unknown	Unk		Not Reported
	Oxynorm			S	Unknown	10 Mg, Unk; Strength: 5		Not Reported

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Oxynorm	S		Mg-10 Mg	Not Reported
Nobligan	S	Unknown	200 Mg, Qd (Also Reported As Unk); Strength: 50 Mg-200 Mg	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Rivotril	S	Unknown	Unk	Not Reported
Cipralex	S	Unknown	Unk	Not Reported
Sobril	S	Unknown	Unk	Not Reported
Truxal (Chlorprothixene Hydrochloride)	S	Unknown	600 To 1200mg	Not Reported
Hydroxyzine Hydrochloride	S	Unknown	Unk	Not Reported
Levomepromazine Maleate	S	Unknown		Not Reported
Diazepam	S	Unknown		Not Reported
Diacetylmorphine	C	Unknown	Unk	Not Reported
Cyanocobalamin	C	Unknown	According To Mah Product Name Is "Forte"	Not Reported
Nozinan	C		Unk	Not Reported
Codeine Phosphate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	15753702	EXPEDITED (15-DAY)		DE, HO, OT	DE-ACCORD-097178		1 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Flatulence; Immobile; Pain; Pneumonia; Respiratory Failure	Spironolactone			S				Accord
	Sildenafil/Sildenafil Citrate			S				Not Reported
	Topiramate			S	Unknown			Accord
	Phenobarbital			S				Not Reported
	Varivax			S	Intramuscular	1 Df		Not Reported
	Synagis			S	Intramuscular			Not Reported
	Exodus (Escitalopram Oxalate)			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	15991406	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2019077396		58 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatriuria	Pantozol			S	Unknown	Unk		Pfizer	
	Cipralex [Escitalopram Oxalate]			S	Unknown	Unk		Not Reported	
	Co Valsartan [Hydrochlorothiazide;Valsartan]			S	Unknown	Unk		Not Reported	
	Meto Zerok			C	Unknown	Unk		Not Reported	
	Prednison Galepharm			C	Unknown	Unk		Not Reported	
	Ecofenac			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16003794	EXPEDITED (15-DAY)		HO	FR-ACCORD-108629		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Skin Eruption	Escitalopram			S	Oral			Not Reported	
	Stresam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004456	EXPEDITED (15-DAY)		HO	DE-ACCORD-108316		37 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haematoma; Menorrhagia; Sleep Disorder	Aripiprazole			S	Unknown	5 Milligram Daily		Not Reported	
	Escitalopram			S	Unknown	15 Milligram Daily, Reduced To 15 Mg/Day		Not Reported	
	Risperidone			S	Unknown	0.5 Mg		Not Reported	
	Pregabalin			C	Unknown	Evening Dose Of 100 Mg		Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Pregabalin			C	Unknown	100 Milligram Daily,		Not Reported	

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Promethazine	C	Unknown	Evening Dose Of 100 Mg	Not Reported
Lorazepam	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported
Opipramol/Opipramol Hydrochloride	C	Unknown	In Crisis Situations With Temporary Effect	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004852	EXPEDITED (15-DAY)		LT, OT	FR-APOTEX-2019AP008372		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism; Thrombosis	Olanzapine			S	Oral	7.5 Mg, Unk		Apotex	
	Teralithe			S	Oral	2 Df, Unk		Not Reported	
	Seroplex			S	Oral	1 Df, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004904	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE-HET2019DE00239			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Qd		Hetero	
	L-Thyroxin			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Not Reported	
	Femibion /01597501/			C	Transplacental	0.8 Milligram, Qd		Not Reported	
	Progestan			C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]		Not Reported	
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Not Reported	
	Progynova /00045401/			C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16005710	NON-EXPEDITED			US-CELGENEUS-USA-20190207425			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Palpitations	Pomalyst			S	Oral	4 Milligram		Celgene
	Trazodone			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported
	Seroquel			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16006868	EXPEDITED (15-DAY)		HO	SG-ALLERGAN-1907760US		56 YR	Female	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	14818968	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2018-022334			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anhedonia; Apathy; Asthenia; Chest Pain; Decreased Appetite; Depressed Mood; Drug Ineffective; Drug Intolerance; Dysphonia; Gastritis; Palpitations; Parkinsonism; Psychiatric Symptom; Sleep Disorder; Tremor	Mirtazapine 15mg			S	Unknown	15 Milligram		Aurobindo
	Escitalopram 10 Mg			S	Unknown	10 Milligram		Aurobindo
	Venlafaxine			S	Oral	Unk		Aurobindo
	Bupropion			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	50 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16010486	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019020219			Unknown	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Qd,(20 [Mg/D])		Macleods
	L-Thyroxin			C	Transplacental	Unk, (112 [Mg/D (Bis 75 Mg/D)])		Not Reported
	Folic Acid			C	Transplacental	0.8 Milligram, Qd, (0.8 [Mg/D])		Not Reported
	Progestan			C	Transplacental	600 Milligram, Qd,(600 [Mg/D (3 X 200 Mg/D)])		Not Reported
	Dekristol			C	Transplacental	Unk, (2000 [I.E./D (Bis 1000 I.E./D)])		Not Reported
	Progynova			C	Transplacental	3 Milligram, Qd,(3 [Mg/D (3 X 1 Mg/D)])		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16010998	EXPEDITED (15-DAY)		CA, DE	DE-ACCORD-109190			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anencephaly; Congenital Anomaly; Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus	Escitalopram			S	Transplacental			Not Reported
	Levetiracetam			S	Transplacental	1500 Mg/ Day		Accord
	Candesartan			S	Transplacental	16 Mg/D		Not Reported
	Paroxetine			S	Transplacental	30 Mg/D		Not Reported
	Nepresol (Dihydralazine)			S	Transplacental	25mg/D		Not Reported
	L-Thyroxine			C	Transplacental			Not Reported
	Cytotec			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16012646	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SE29522		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Wall	Crestor			S	Oral			Astrazeneca

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Haematoma	Seroplex	S	Oral	Not Reported
	Cordarone	S	Oral	Not Reported
	Previscan (Fluindione)	S	Oral	Not Reported
	Plavix	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16012990	DIRECT		DS, OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Balance Disorder; Fall; Gait Disturbance; Muscular Weakness; Tremor	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Aurobindo	
	Lamotrigine			C				Not Reported	
	Aspirin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16013996	EXPEDITED (15-DAY)		OT	BE-OTSUKA-2019_004192		22 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Obstruction	Abilify Maintena			S	Unknown	400 Mg, Unk		Otsuka	
	Sipralexa			S	Unknown	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16014096	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2019081883		33 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Face Oedema; Face Oedema; Rash	Efexor Er			S	Oral	75 Mg, 1x/Day		Pfizer	
	Efexor Er			S	Oral	Unk		Pfizer	
	Cipralelex			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16014767	EXPEDITED (15-DAY)		HO	PHHY2019CH035787		58 YR	Male	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatriuria	Co-Valsartan Sandoz			S	Oral	1 Df, Qd		Not Reported
	Cipralex			S	Oral	10 Mg, Qd		Not Reported
	Pantozol			S	Oral	20 Mg, Qd		Not Reported
	Meto Zerok			C	Oral	25 Mg, Qd		Not Reported
	Prednison Galepharm			C	Oral	20 Mg, Qd		Not Reported
	Ecofenac			C	Oral	75 Mg, Q12h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16145879	DIRECT		HO			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pruritus; Skin Disorder; Skin Haemorrhage; Skin Lesion	Escitalopram (Generic For Lexapro)			S	Oral	Quantity:10 Mg Milligram(S);		Not Reported
	Clobetasol			C				Not Reported
	Loratadine			C				Not Reported
	Ketoconazole			C				Not Reported
	2% Topical Shampoo			C				Not Reported
	Betasept 4% Surgical Scrub			C				Not Reported
	Ibuprofen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	15885472	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1003426		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine (Chlorhydrate De)			S	Oral			Teva
	Anhydre							
	Escitalopram			S	Oral			Ivax
	Diazepam			S	Oral			Barr
	Prazepam			S	Oral			Not Reported
	Cocaine			S	Unknown	0.5g		Not Reported
	Tercian			S	Oral			Not Reported

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Atarax	S	Oral	Not Reported
Valium	S	Oral	Not Reported
Alcool	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	15887241	EXPEDITED (15-DAY)		HO	FR-ROCHE-2251342		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported	
	Valium			S	Oral			Not Reported	
	Paroxetine			S	Oral			Not Reported	
	Prazepam			S	Oral			Not Reported	
	Cocaine			S	Unknown	0.5g		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Tercian			S	Oral			Not Reported	
	Atarax			S	Oral			Not Reported	
	Alcool			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	15899435	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-003883			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral	28 Dosage Form, 1 Total		Aurobindo	
	Prazepam			S	Oral	20 Dosage Form, 1 Total		Not Reported	
	Diazepam			S	Oral	8 Dosage Form, 1 Total		Not Reported	
	Escitalopram			S	Oral	14 Dosage Form, 1 Total		Aurobindo	
	Cocaine			S	Unknown	0.5 Gram, 0.5g		Not Reported	
	Tercian			S	Oral	16 Dosage Form, 1 Total		Not Reported	
	Atarax			S	Oral	10 Dosage Form, 1 Total		Not Reported	
	Valium			S	Oral	3 Dosage Form, 1 Total		Not Reported	

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Alcohol			S		Oral		Unk, Non Renseignée		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Feb-2019	16015698	EXPEDITED (15-DAY)		CA	NL-TEVA-2019-NL-1017798			Male	NLD	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Fallot'S Tetralogy; Maternal Exposure During Pregnancy	Escitalopram (Escitalopram)			S		10 Milligram Daily; 1 Dd 10 Mg		Ivax		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Feb-2019	16015758	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1016480		23 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Confusional State; Logorrhoea; Seizure; Tachycardia	Escitalopram			S	Oral			Ivax		
	Valium			S	Oral			Not Reported		
	Lithium			S	Oral	1.2 Gram Daily;		Not Reported		
	Tercian			S	Oral	250 Milligram Daily;		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Feb-2019	16015917	EXPEDITED (15-DAY)		OT	AT-ACCORD-109327		21 YR	Female	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Neutropenia	Olanzapine			S	Unknown			Not Reported		
	Diazepam			S	Unknown			Accord		
	Trazodone/Trazodone Hydrochloride			S	Unknown			Not Reported		
	Quetiapine			S	Unknown			Not Reported		
	Lorazepam			S	Unknown	2-5 Mg		Not Reported		
	Dominal (Prothipendyl)			S		80 Mg From 30-Apr-2018 To 02-May-2018(Dose Reduced)		Not Reported		

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Acetylsalicylic Acid	S	Unknown	Not Reported
Lamotrigine	S	Unknown	Not Reported
Cipralex	S	Unknown	Not Reported
Halcion	C	Unknown	Not Reported
Zolpidem	C	Unknown	Not Reported
Quilonorm	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16015968	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-109705		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Poisoning Deliberate; Somnolence	Escitalopram			S	Oral			Not Reported	
	Prazepam			S	Oral	Np		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16016003	EXPEDITED (15-DAY)		OT	GB-ACCORD-109417		25 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased; Sexual Dysfunction	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16016067	EXPEDITED (15-DAY)		HO	FR-SAKK- 2019SA050144AA		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Plavix			S	Oral	Unk		Sanofi	
	Rosuvastatin Calcium			S		Unk		Not Reported	
	Fluindione			S	Oral	Unk		Not Reported	
	Escitalopram Oxalate			S	Oral	Unk		Not Reported	
	Cordarone			S	Oral	Unk		Not Reported	

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28-Feb-2019	16016272	EXPEDITED (15-DAY)		HO	FR-ROCHE-2270333		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Logorrhoea; Seizure; Tachycardia	Valium			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Tercian			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16016504	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-010002			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Depression; Dizziness; Drug Dependence; Hypotension; Irritability; Pruritus; Psychiatric Symptom; Somnolence; Tachycardia; Tinnitus; Withdrawal Syndrome	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Oral	10 Milligram, Unk		Aurobindo	
	Escitalopram 10 Mg Film-Coated Tablets Efg			S				Aurobindo	
	Orfidal			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16017847	DIRECT		OT			14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Grimacing	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Rite Aid	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16019367	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE- 1015684		< 1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Congenital Hydronephrosis	Escitalopram	S	Transplacental	20 Milligram Daily;	Ivax
	L-Thyroxin	C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]	Not Reported
	Femibion Schwangerschaft 1	C	Transplacental	.8 Milligram Daily; 0.8 [Mg/D]	Not Reported
	Progestan	C	Transplacental	600 Milligram Daily; 600 [Mg/D (3 X 200 Mg/D)]	Not Reported
	Dekristol	C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Not Reported
	Progynova	C	Transplacental	3 Milligram Daily; 3 [Mg/D (3 X 1 Mg/D)]	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16020038	EXPEDITED (15-DAY)		HO, OT	US-LUNDBECK-DKLU2061227		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Constipation; Dysphagia; Feeding Disorder; Gastrooesophageal Reflux Disease; Intentional Self- Injury; Liver Function Test Increased; Sedation Complication; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased	Clobazam			S	Unknown			Lundbeck	
	Clobazam			S	Unknown			Lundbeck	
	Clobazam			S	Unknown			Lundbeck	
	Valproic Acid			S	Unknown			Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Escitalopram Oxalate			S	Unknown			Not Reported	
	Clonidine			S	Unknown			Not Reported	
	Ranitidine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16020101	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMP ANY-US201902011641			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Oestrogen Increased; Breast Cancer;	Prozac			S	Unknown	80 Mg, Unknown		Eli Lilly And Co	
	Prozac			S				Eli Lilly And Co	

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Joint Noise; Lactation	Lexapro	S	Unknown	Unk Unk, Unknown	Not Reported
Puerperal Increased;	Lexapro	S			Not Reported
Lymphoma; Pituitary	Effexor	S	Unknown	Unk, Unknown	Not Reported
Tumour Benign; Renal	Effexor	S			Not Reported
Neoplasm; Weight	Clonazepam	S	Unknown	Unk Unk, Unknown	Not Reported
Decreased	Clonazepam	S			Not Reported
	Lithium	S	Unknown	Unk Unk, Unknown	Not Reported
	Lithium	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16151263	DIRECT	Y	OT			43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue;	Escitalopram Accord 20mg Tab			S	Oral			Not Reported	
Withdrawal Syndrome	Escitalopram, Accord, 5 Mg Tab			S	Oral			Accord	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	15879000	EXPEDITED (15-DAY)		HO	FR-ZYDUS-032976		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram	Paroxetine			S	Oral			Not Reported	
Abnormal; Miosis;	Escitalopram			S	Oral			Zydus Pharm	
Somnolence; Toxicity To	Prazepam			S	Oral			Not Reported	
Various Agents	Cocaine			S	Unknown			Not Reported	
	Cyamemazine			S	Oral			Not Reported	
	Hydroxyzine			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Ethanol			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	15959568	EXPEDITED (15-DAY)		HO	IT-ACCORD-106817		19 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Sopor	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	15989139	EXPEDITED (15-DAY)		OT	IT-ACCORD-053038		61 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Escitalopram			S	Unknown	20 Mg,Qd		Not Reported
	Sertraline			S				Accord
	Lorazepam			S	Oral	2.5 Mg,Qd		Accord
	Cipralex - H. Lundbeck A/S			S				Not Reported
	Brintellix - H. Lundbeck A/S			S	Unknown	Also Received As 5 Mg On Jun-2016 And 15 Mg Dose.		Not Reported
	Duloxetine			S		60 Mg,Qd		Not Reported
	Triatec Hct			C	Unknown	Strength: 15 Mg		Not Reported
	Cordarone			C	Unknown	Strength: 200 Mg Dose: 100 Mg		Not Reported
	Coumadin			C	Unknown			Not Reported
	Lansoprazole			C	Unknown	30 Mg,Qd		Not Reported
	Simvastatin			C	Unknown	20 Mg,Qd		Not Reported
	Ezetimibe			C	Unknown	10 Mg,Qd		Not Reported
	Alprazolam			C	Unknown	2 Mg,Qd		Not Reported
	Warfarin			C				Not Reported
	Amiodarone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020422	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR- APL-2019-009784			Unknown	POL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo	
	Ginkgo Biloba			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020423	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009804			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Logorrhoea; Seizure; Tachycardia	Escitalopram			S	Oral	Unk		Aurobindo	
	Valium			S	Oral	Unk		Not Reported	
	Lithium			S	Oral	1.2 Gram, Once A Day		Not Reported	
	Tercian			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020447	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-010130			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Daily,Morning		Aurobindo	
	Mirtazapine Film-Coated Tablet			S	Unknown	30 Milligram, Daily,Night		Aurobindo	
	Olanzapine Tablet			S	Unknown	5 Milligram, Daily		Aurobindo	
	Azathioprine			S	Unknown	75 Milligram, Daily,With Or Just After Food		Not Reported	
	Dihydrocodeine			S	Unknown	2 Dosage Form, As Necessary,Two To Be Taken Four Times A Day If Required.		Not Reported	
	Ferrous Fumarate			S	Unknown	420 Milligram, Daily,Morning And Night		Not Reported	
	Folic Acid			S	Unknown	5 Milligram, Daily,Morning		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020494	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-008271			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Anxiety; Crying; Depression; Derealisation; Diarrhoea; Dizziness; Dyspnoea; Gastric Ulcer; Insomnia; Nausea; Panic Attack; Vertigo	Escitalopram			S		Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020536	EXPEDITED (15-DAY)		CA, OT	NL-AUROBINDO-AUR-APL-2019-010261			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram Film-Coated Tablets 10mg			S	Transplacental	1 Dd 10 Mg		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020545	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2019-010273			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Hydronephrosis	Escitalopram			S	Transplacental	20 Milligram, Once A Day (20 [Mg/D])		Aurobindo	
	L-Thyroxin			C	Transplacental	112 Microgram, Once A Day (112 [Mg/D (Bis 75 Mg/D))		Not Reported	
	Folic Acid			C	Transplacental	0.8 Milligram, Once A Day		Not Reported	
	Progestan			C	Transplacental	600 Milligram, Once A Day (600 [Mg/D (3 X 200 Mg/D)])		Not Reported	

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Dekristol	C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]	Not Reported
Progynova	C	Transplacental	3 Milligram, Once A Day(3 [Mg/D (3 X 1 Mg/D)])	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16021039	NON-EXPEDITED			US-PFIZER INC-2019085830		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Alprazolam			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16021345	EXPEDITED (15-DAY)		HO, OT	FR-APOTEX-2019AP008714		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse;	Paroxetine			S	Oral	28 Df, Single Dose		Glaxosmithkline	
Electrocardiogram	Valium			S	Oral	3 Df, Single Dose		Not Reported	
Abnormal; Miosis;	Diazepam			S	Oral	8 Df, Sindle Dose		Not Reported	
Somnolence; Toxicity To	Escitalopram			S	Oral	14 Df, Single Dose		Not Reported	
Various Agents	Atarax /00058401/			S	Oral	10 Df, Single Dose		Not Reported	
	Alcool			S	Oral	Unk		Not Reported	
	Tercian /00759301/			S	Oral	16 Df, Single Dose		Not Reported	
	Prazepam			S	Oral	20 Df, Single Dose		Not Reported	
	Cocaine			S	Unknown	0.5 G, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16022129	DIRECT		OT			46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Feeling Abnormal; Product Storage Error; Suspected Product Quality Issue	Lexapro 10mg Rx #: 182774806256 (1/7/19) Keppra	S	Oral	Quantity:1 Tablet(S);		Forest
		C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16022627	DIRECT	Y	HO			22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Lexapro			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16024220	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2019-006286		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral			Not Reported	
	Cipralax			S	Oral	Total		Not Reported	
	En			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16024306	EXPEDITED (15-DAY)		OT	AU-OTSUKA-2019_003613			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness; Neutropenia	Rexulti			S	Oral	1 Mg, Qd		Otsuka	
	Rexulti			S	Oral	2 Mg, Qd		Otsuka	
	Rexulti			S	Oral	2 Mg, Unk		Otsuka	
	Clopixol			S	Unknown	Unk		Not Reported	
	Lexapro			S	Oral	30 Mg, Unk		Not Reported	
	Clozapine			C	Oral	400 Mg, Qd		Not Reported	
	Clozapine			C	Oral	400 Mg, Qd		Not Reported	
	Lithium			C	Oral	250 Mg, Unk		Not Reported	

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Symbicort	C	Unknown	Unk	Not Reported
Mobic	C	Oral	15 Mg, Unk	Not Reported
Fenofibrate	C	Oral	145 Mg, Unk	Not Reported
Pantoprazole	C	Oral	40 Mg, Unk	Not Reported
Targin	C	Unknown	Unk	Not Reported
Colecalciferol	C	Unknown	1000 Iu, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16025353	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1907497US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatriuria	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qam		Allergan	
	Co Valsartan [Valsartan]			S	Oral	Actual:160/12.5 Mg, 1-0-0-0		Not Reported	
	Pantozol			S	Oral	20 Mg, Qpm		Not Reported	
	Meto Zerok			C	Oral	Actual: 50mg, 1/2-0-0-0		Not Reported	
	Prednison Galepharm			C	Oral	20 Mg, Qam		Not Reported	
	Ecofenac			C	Oral	Actual: 75mg, 1-0-1-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	13533497	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170506438		30 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Imodium		Y	S	Unknown			Not Reported	
	Imodium			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Tecta			S	Unknown			Not Reported	
	Escitalopram Oxalate			S	Unknown			Not Reported	

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	Acetaminophen W/Codeine Phosphate	S	Unknown					Not Reported	
	Loperamide Hydrochloride	C	Unknown					Not Reported	
	Multivitamins	C	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	14177479	EXPEDITED (15-DAY)		HO	CZ-ACCORD-060891		45 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Escitalopram			S	Oral			Accord	
	Sertraline			S	Oral			Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	14699222	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-017424			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Therapy; Electrocardiogram Qt Prolonged	Hydroxyzine			S	Oral	Unk		Aurobindo	
	Seroplex			S	Oral	20 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	15989148	EXPEDITED (15-DAY)		OT	IT-ACCORD-108509		35 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anhedonia; Apathy; Asthenia	Escitalopram			S	Oral			Not Reported	
	Seroquel			S	Oral	300 Mg Film-Coated Tablets 200 Mg Prolonged-Release Tablets		Not Reported	
	Lamotrigine			S	Oral			Not Reported	

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02-Mar-2019	16025733	EXPEDITED (15-DAY)		OT	GB-ACCORD-109837		81 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Product Dispensing Error	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16025799	EXPEDITED (15-DAY)		HO, LT, OT	FR-ACCORD-109352		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Suicide Attempt	Escitalopram			S	Unknown	Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy		Not Reported
	Olanzapine			S	Unknown	15 Mg, Unk		Not Reported
	Methyl dopa			S	Oral			Accord
	Imovane			S	Oral	1tab/Dy, Oral Drug Unspecified Form		Not Reported
	Lepticur			S	Unknown	Unk		Not Reported
	Abilify			S	Oral	10 Mg, Unk		Not Reported
	Seroplex			S	Unknown	Unk,Also Received 10 Mg For Melancholia,5 Mg For Major Depression		Not Reported
	Depamide			S	Oral	300 Mg, Oral Drug Unspecified Form		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Anafranil			S	Oral	Daily Dose Increased. Oral Drug Unspecified Form		Not Reported
	Zyprexa			S	Unknown	15 Mg, Unk		Not Reported
	Zopiclone			S	Oral	1tab/Dy		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16025924	EXPEDITED (15-DAY)		CA, OT	DE-ACCORD-110150		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Congenital Choroid Plexus Cyst; Off Label Use; Patent Ductus Arteriosus; Respiratory Disorder Neonatal; Ventricular Septal Defect	Quetiapine			S	Transplacental	50 Mg/D/Varying Dosage Between 25 And 50 Mg/D		Not Reported	
	Lamictal			S	Transplacental	125 Mg/D / Slowly Reduced		Not Reported	
	Cipralex			S	Transplacental	20 Mg/D / Initial 20mg/D, Dosage Reduction To 10mg/D, Later To 5mg/D		Not Reported	
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16025950	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009193			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intracranial Haematoma	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Kardegic			S	Oral	75 Milligram, Once A Day		Not Reported	
	Levocetirizine			C	Unknown	5 Milligram, Once A Day		Not Reported	
	Amlodipine			C	Unknown	5 Milligram, Once A Day		Not Reported	
	Levothyroxine			C	Unknown	50 Microgram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16026046	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-011087			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Lymphoma	Escitalopram			S	Unknown	Unk		Aurobindo	
	Bromazepam			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2019	16026696	EXPEDITED (15-DAY)		OT	IT-APOTEX-2019AP008577		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Olanzapine			S	Oral	20 Mg, In Total		Apotex	
	Escitalopram Oxalate			S	Oral	50 Mg, In Total		Not Reported	
	Tavor /00273201/			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2019	16026701	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0105076		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Lamotrigine Tablets			S	Unknown			Not Reported	
	Lamotrigine Tablets			S				Not Reported	
	Escitalopram			S	Unknown	Every Morning		Not Reported	
	Escitalopram			S				Not Reported	
	Escitalopram			S		Every Morning		Not Reported	
	Escitalopram			S		Every Morning		Not Reported	
	Testosterone 50mg/5g - Gel			S	Unknown	50 Mg/5 G Every Morning		Not Reported	
						On The Right Upper Extremity			
	Lithium			S	Unknown	Every Bedtime		Not Reported	
	Lurasidone			S	Unknown	After Dinner		Not Reported	
	Lorazepam			S	Unknown	As Necessary		Not Reported	
	Lorazepam			S		As Necessary		Not Reported	
	Bupropion			S	Unknown	Every Morning		Not Reported	
	Bupropion			S		Every Morning		Not Reported	
	Bupropion			S		Every Morning		Not Reported	
	Buspirone			S	Unknown			Not Reported	
	Buspirone			S				Not Reported	
	Buspirone			S				Not Reported	

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Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Aripiprazole	S	Unknown	Every Bedtime	Not Reported
Aripiprazole	S		Every Bedtime	Not Reported
Benzotropine Mesylate	C	Unknown	As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2019	16026756	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1017222		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown			Ivax
	Kratom			S	Oral			Not Reported
	Kratom			S	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Fexofenadine			C	Unknown			Not Reported
	Acetaminophen			C	Unknown	Restricted Use To The Recommended 3000 Mg Per Day Limit		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	12984666	EXPEDITED (15-DAY)		HO	MY-ALLERGAN-1678334US			Female	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Asthenia; Cognitive Disorder; Hypophagia; Product Compounding Quality Issue	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	14690133	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-MYLANLABS-2018M1017925		62 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Moclobemide			S	Oral	150 Mg, In Afternoon		Not Reported
	Zolpidem			S	Oral	10 Mg, At Bedtime		Not Reported
	Sertraline			S	Oral	50 Mg, At Night		Not Reported
	Venlafaxine			S	Oral	150 Mg In The Morning, In The Afternoon		Not Reported
	Metoprolol			S		Unk		Not Reported
	Ivabradine			S	Unknown	Unk		Mylan
	Escitalopram			S	Unknown	Unk		Mylan
	Trazodone			S	Unknown	Unk		Mylan
	Cyproheptadine			S	Oral	16 Milligram		Mylan
	Sotalol			C				Mylan
Warfarin			C				Mylan	
Ginkgo Biloba Extract /01003110/			C				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15720271	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1857410US			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Rize			C	Oral	5 Mg, Q8hr		Not Reported
	Atarax-P			C				Not Reported
	Meylon			C	Intravenous (not otherwise specified)	Unk		Not Reported

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Nauzelin	C	Oral	10 Mg, Q8hr	Not Reported
Sennoside	C	Oral	Unk	Not Reported
Merislon	C	Oral	Unk, Prn	Not Reported
Cercine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Pl	C	Oral	Unk	Not Reported
Pariet	C	Oral	Unk	Not Reported
Amlodipine	C	Oral	Unk	Not Reported
Mohrus L	C	Topical	Unk	Not Reported
Tocopheryl Acetate	C	Oral	Unk	Not Reported
Loxonin	C	Unknown		Not Reported
Loxonin	C	Topical	Unk	Not Reported
Rebamipide	C			Not Reported
Candesartan	C	Oral	Unk	Not Reported
Brotizolam	C	Oral	Unk	Not Reported
Adetphos	C	Oral	Unk	Not Reported
Adetphos	C	Intravenous (not otherwise specified)	Unk	Not Reported
Methycobal	C			Not Reported
Kashiwadol	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15736971	EXPEDITED (15-DAY)		HO, OT	PL-ALLERGAN-1857960US			Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Metamizol			S	Oral	500 Mg, Twice A Day		Not Reported	
	Tramadol Hydrochloride			S	Unknown	100 Mg, Bid		Not Reported	
	Buprenorphine			S	Unknown	35 Mg, Every 4 Days		Not Reported	
	Metoclopramide			S	Oral	10 Mg, Three Times A Day		Not Reported	

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Omeprazole	S	Unknown	For About 3 Weeks 20 Mg, In The Morning, Fasting	Not Reported
Alprazolam	S	Unknown	Unk	Not Reported
Ketoprofen	S	Oral	100 Mg, 3 Times A Day	Not Reported
Zoledronic Acid	C	Unknown	Unk	Not Reported
Effentora	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Valproic Acid	C	Unknown	Unk	Not Reported
Heparin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15783626	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2018M1026176		60 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia; Anxiety; Apathy; Decreased Appetite; Drug Ineffective; Major Depression; Self Esteem Decreased; Sexual Dysfunction; Social Avoidant Behaviour; Weight Increased	Duloxetine			S	Unknown	60 Milligram, Qd		Not Reported
	Duloxetine			S				Not Reported
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Sertraline			S	Oral	100 Milligram, Qd		Not Reported
	Lorazepam			S	Oral	2.5 Milligram, Qd		Not Reported
	Brintellix			S	Unknown	15 Milligram, Qd		Mylan
	Brintellix			S	Unknown	10 Milligram, Qd		Mylan
	Brintellix			S	Unknown	10 Milligram, Qd		Mylan
	Brintellix			S	Unknown	5 Milligram, Qd		Mylan
	Amiodarone			C	Unknown	Unk		Mylan
	Ezetimibe			C	Unknown	10 Milligram, Qd		Mylan
	Simvastatin			C	Unknown	20 Milligram, Qd		Mylan

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	Coumadin		C		Unk		Mylan
	Lansoprazole		C	Unknown	30 Milligram, Qd		Mylan
	Ramipril + Hydrochlorotiazida		C	Unknown	Unk		Mylan
	Alprazolam		C	Unknown	2 Milligram, Qd		Mylan
	Triatec Hct		C		15 Milligram, Qd		Mylan
	Cordarone		C	Unknown	200 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16027552	EXPEDITED (15-DAY)		HO, OT	FR-APOTEX-2019AP008629		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia;	Clopidogrel			S	Oral	75 Mg, Qd		Apotex
Haematoma Muscle	Escitalopram			S	Oral	5 Mg, Qd, 1-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16027553	EXPEDITED (15-DAY)		HO, LT, OT	FR-APOTEX-2019AP008610		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety; Apathy;	Olanzapine			S	Unknown	15 Mg, Unk		Apotex
Asthenia; Coordination	Lepticur			S	Unknown	Unk		Not Reported
Abnormal; Dysstasia; Gait	Methyldopa			S	Oral	Unk		Not Reported
Inability; Insomnia; Off	Abilify			S	Oral	10 Mg, Unk		Not Reported
Label Use; Suicide	Seroplex			S	Unknown	Unk		Not Reported
Attempt	Seroplex			S	Unknown	10 Mg, Qd		Not Reported
	Seroplex			S	Unknown	5 Mg, Qd		Not Reported
	Depamide			S	Oral	300 Mg, Qd		Not Reported
	Seresta			S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening.		Not Reported
	Escitalopram			S	Unknown	Dose Increased To 10		Not Reported

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Anafranil	S	Oral	Mg/Day. Previously 5mg. 1tab/Dy	Not Reported
Zyprexa	S	Unknown	75 Mg, Qd (Daily Dose Increased. Oral Drug Unspecified Form)	Not Reported
Zopiclone	S	Oral	15 Mg, Unk	Not Reported
Imovane	S	Oral	7.5 Mg, Qd (1tab/Dy)	Not Reported
			7.5 Mg, Qd (1tab/Dy, Oral Drug Unspecified Form)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16027909	EXPEDITED (15-DAY)		HO	PT-APOTEX- 2019AP008753		60 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Delusion Of Grandeur; Drug Withdrawal Syndrome; Euphoric Mood; Impulsive Behaviour; Irritability; Mania; Pressure Of Speech; Psychomotor Hyperactivity; Treatment Noncompliance	Escitalopram			S	Unknown	20 Mg, Unk		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16030335	DIRECT		OT			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eclampsia; Foetal Heart Rate Deceleration Abnormality; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Meconium Abnormal; Placenta	Escitalopram			S	Oral		10 MTH	Not Reported
	Prenatal Vitamins			C				Not Reported
	Tylenol			C				Not Reported

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Praevia; Pregnancy; Small
Size Placenta

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16030902	NON-EXPEDITED			US-PFIZER INC- 2019089788			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Scar; Skin Burning Sensation; Skin Haemorrhage	Venlafaxine Hcl Lexapro			S S		Unk Unk		Pfizer Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16031187	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB- 1017143			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram			S		10 Milligram Daily; Morning		Ivax	
	Azathioprine			S		75 Milligram Daily; With Or Just After Food		Not Reported	
	Dihydrocodeine			S		Two To Be Taken Four Times A Day If Required.		Not Reported	
	Ferrous Fumarate			S		420 Milligram Daily; Morning And Night		Not Reported	
	Mirtazapine			S		30 Milligram Daily; Night		Teva	
	Folic Acid			S		5 Milligram Daily; Morning		Actavis	
	Olanzapine			S		5 Milligram Daily;		Teva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16032138	EXPEDITED (15-DAY)		HO	CH-ALLERGAN- 1908174US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Bid		Allergan	
	Xarelto			S	Oral	1 Df		Not Reported	

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Quetiapin Sandoz	C	Oral	25 Mg, Qd	Not Reported
Podomexef	C	Oral	200 Mg	Not Reported
Circadin	C	Oral	1.5 Df	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16032579	EXPEDITED (15-DAY)		OT	US-HETERO CORPORATE- HET2019US00249		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug- Induced Liver Injury	Escitalopram			S				Hetero	
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported	
	Valsartan			C	Unknown	Unk		Not Reported	
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported	
	Clonazepam			C	Unknown	Unk		Not Reported	
	Fexofenadine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	14776776	EXPEDITED (15-DAY)		HO, OT	SI-ACCORD-065805		48 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Sclerosis; Off Label Use; Palpitations	Escitalopram			S		10 Mg, Qd (1 Tablet In Morning)		Not Reported	
	Pregabalin			S		150 Mg, Bid		Not Reported	
	Fty 720			S	Unknown	0.5 Mg, Qd		Not Reported	
	Fampridine			S		10 Mg, Bid		Not Reported	
	Tolterodine/Tolterodine L- Tartrate			S		4 Mg, Qd (1 Tablet In Morning)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	15685235	EXPEDITED (15-DAY)		HO	IE-009507513- 1811IRL011820		55 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Therapy Non-Responder	Mirtazapine	S	Oral	Unk	Merck
	Amitriptyline Hydrochloride	S		Unk	Not Reported
	Trimipramine	S		Unk	Not Reported
	Sertraline Hydrochloride	S		Unk	Not Reported
	Escitalopram	S		Unk	Not Reported
	Fluoxetine	S		Unk	Not Reported
	Fluvoxamine Maleate	S		Unk	Not Reported
	Duloxetine Hydrochloride	S		Unk	Not Reported
	Venlafaxine Hydrochloride	S		Unk	Not Reported
	Phenelzine Sulfate	S		Unk	Not Reported
	Moclobemide	S		Unk	Not Reported
	Agomelatine	S		Unk	Not Reported
	Valproate Sodium	S		Unk	Not Reported
	Lithium	S		Unk	Not Reported
	Olanzapine	S		Unk	Not Reported
	Quetiapine Fumarate	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	15887384	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-197416		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	In Total		Not Reported
	Paroxetine			S	Oral	In Total		Sun
	Prazepam			S	Oral	In Total		Not Reported
	Cocaine			S	Unknown	0.5g ()		Not Reported
	Tercian			S	Oral	In Total		Not Reported
	Atarax			S	Oral	In Total		Not Reported
	Valium			S	Oral	In Total		Not Reported

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	Alcohol		S	Oral		Non Renseignee ()			Not Reported
	Diazepam		S	Oral		In Total			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	15901155	EXPEDITED (15-DAY)		HO	RU-ALLERGAN-1904645US			Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotonia; Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	50 Df		Allergan	
	Phenibut/Aminophenylbutyric Acid			S	Oral	60 Df		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	15909003	EXPEDITED (15-DAY)		OT	RU-ALLERGAN-1904808US			Male	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Erectile Dysfunction; Hyperhidrosis; Product Use In Unapproved Indication; Salivary Hypersecretion	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Sonapax			C	Unknown			Not Reported	
	Amitriptyline Hydrochloride			C	Unknown			Not Reported	
	Atarax			C	Unknown	20 Mg, Qd		Not Reported	
	Paxil			C	Unknown	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16033156	EXPEDITED (15-DAY)		HO	FR-ACCORD-110249		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Bendamustine/Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Pantoprazole			S	Oral	Long Cours		Not Reported	
	Loxapac			S	Oral			Not Reported	
	Levothyrox			S	Oral			Not Reported	

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	Fenofibrate		S	Oral				Not Reported	
	Truxima		S	Intravenous (not otherwise specified)				Not Reported	
	Valaciclovir		S	Oral				Not Reported	
	Lorazepam		S	Oral	Long Cours			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16033318	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2019-011337			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Obstruction; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	400 Milligram		Aurobindo	
	Sipralexa			S	Unknown	20 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16033618	NON-EXPEDITED			US-IMPAX LABORATORIES, LLC-2018-IPXL-02491		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Restless Legs Syndrome; Tremor	Rytary			S	Unknown	Unk		Impax	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16035123	EXPEDITED (15-DAY)		HO	FR-APOTEX-2019AP008679		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Miosis; Orthostatic Hypotension; Somnolence	Olanzapine			S	Oral	Unk, Dose Exacte Lors De L'Imv Inconnue		Apotex	
	Escitalopram			S	Oral	Unk (Dose Exacte Lors De L'Imv Inconnue)		Not Reported	
	Bromazepam			S	Oral	120 Mg, Unk, Prise Estimée À 20 Cp De Bromazépam 6 Mg		Not Reported	

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Aripiprazole	S	Oral	Unk (Dose Exacte Lors De L'Imv Inconnue)	Not Reported
Zolpidem	S	Oral	Unk, Dose Exacte Lors De L'Imv Inconnue	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16036709	EXPEDITED (15-DAY)	HO		PHHY2019CH039055		57 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome; Serotonin Syndrome	Risperidone			S	Oral	0.5 Mg, Qd		Novartis	
	Risperidone			S	Oral	3 Mg, Qd		Novartis	
	Risperidone			S	Oral	2 Mg, Qd		Novartis	
	Clopin (Clozapine)			S	Oral	25 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Buprenorphine			C	Unknown			Not Reported	
	Lorazepam			C	Unknown	Unk Unk, Prn		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	
	Zolpidem			C	Unknown	Unk Unk, Prn		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16036749	EXPEDITED (15-DAY)	HO		PHHY2019IT047868		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Mg, Total		Novartis	
	Cipralex			S	Oral	300 Mg, Total		Not Reported	
	En			S	Oral	40 Mg, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16037464	EXPEDITED (15-DAY)		CA, DE	DE-MYLANLABS-2019M1018800			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anencephaly; Foetal Exposure During Pregnancy	Levetiracetam	S	Transplacental	1500 Milligram, Qd (1500 [Mg/D])	Not Reported
	Escitalopram	S	Transplacental	220 Milligram, Qd (20 [Mg/D])	Not Reported
	Candesartan	S	Transplacental	16 Milligram, Qd (16 [Mg/D])	Not Reported
	Paroxetine	S	Transplacental	30 Milligram, Qd (30 [Mg/D])	Not Reported
	Nepresol /00007602/	S	Transplacental	25 Milligram, Qd (25 [Mg/D])	Mylan
	L-Thyroxin /00068001/	C	Transplacental	Unk	Mylan
	Cytotec	C	Transplacental	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16037633	EXPEDITED (15-DAY)		DE, OT	CH-DSJP-DSE-2019-107019			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Death; Drug Interaction; Haematuria; Melaena; Subcutaneous Haematoma	Lixiana			S	Oral	30 Mg, Qd		Daiichi
	Cipralex			S	Oral	20 Mg, Qd		Not Reported
	Coversum N Combi			C		Unk		Not Reported
	Remeron			C		Unk		Not Reported
	Torem /01036501/			C		Unk		Not Reported
	Pantozol /01263204/			C		Unk		Not Reported
	Zolpidem Tartrate			C		Unk		Not Reported
	Novalgine /06276704/			C		Unk		Not Reported
	Kalcipos D3			C		Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Spiriva			C		Unk		Not Reported
	Aldactone /00006201/			C		Unk		Not Reported
	Beloc Zok			C		Unk		Not Reported
	Lasix /00032601/			C		Unk		Not Reported

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Becozym /07503601/	C	Unk	Not Reported
Benerva Mit Acetylcholin	C	Unk	Not Reported
Co-Amoxi	C	Unk	Not Reported
Spiricort	C	Unk	Not Reported
Spiolto Respimat	C	Unk	Not Reported
Diclofenac	C	Unk	Not Reported
Pulmicort	C	Unk	Not Reported
Ipramol	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16038196	EXPEDITED (15-DAY)		DE, OT	CH-ALLERGAN-1908197US			Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Death; Drug Interaction; Haematuria; Melaena; Subcutaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Lixiana			S	Unknown	30 Mg, Qd		Not Reported
	Coversum N Combi			C	Unknown			Not Reported
	Remeron			C	Unknown			Not Reported
	Torem			C	Unknown			Not Reported
	Pantozol			C	Unknown			Not Reported
	Zolpidem Tartrate			C	Unknown			Not Reported
	Novalgine (Metamizole Sodium)			C	Unknown			Not Reported
	Kalcipos-D			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Aldactone			C	Unknown			Not Reported
	Beloc Zoc			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Becozyme			C	Unknown			Not Reported
	Benerva Mit Acetylcholin			C	Unknown			Not Reported

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Co-Amoxi	C	Unknown	Not Reported
Spiricort	C	Unknown	Not Reported
Spiolto Respimat	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Pulmicort	C	Unknown	Not Reported
Ipramol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16038790	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1018520		57 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Microscopic	Escitalopram			S		5mg Uppttrappades Till 20 Mg.		Ivax
	Escitalopram			S	Unknown			Ivax
	Duloxetine			S		30 Mg Uppttrappat Till 60 Mg.		Teva
	Duloxetine			S	Unknown			Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	14101684	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-059985		50 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Misuse; Intentional Self-Injury; Sopor	Escitalopram Accord			S	Oral	Strength: 20 Mg		Accord
	Losartan			S	Oral			Accord
	Haldol			S	Oral	Strength: 2 Mg/ML, Oral Drops- Janssen - Cil		Not Reported
	Delorazepam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	14685232	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-BAUSCH-BL-2018-008064		62 YR	Female	POL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apallic Syndrome; Apallic Syndrome; Arrhythmia; Atrial Tachycardia; Cardiac Disorder; Drug Ineffective; Drug Interaction; Electrocardiogram Qt Prolonged; Fatigue; Initial Insomnia; Insomnia; Ischaemic Stroke; Middle Insomnia; Palpitations; Syncope	Zolpidem			S	Oral	At Bedtime		Not Reported
	Venlafaxine			S	Oral	In The Morning, In The Afternoon		Not Reported
	Metoprolol Vp			S	Unknown			Not Reported
	Mobemid			S	Oral	In Afternoon		Not Reported
	Ivabradine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Sertraline			S	Oral	At Night		Not Reported
	Trazodone			S	Unknown			Not Reported
	Cyproheptadine			S	Oral			Not Reported
	Sotalol			C				Not Reported
	Warfarin			C				Not Reported
	Ginkgo Biloba Extract			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	15945670	EXPEDITED (15-DAY)		DE, HO, LT	GB-ACCORD-105825		88 YR	Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastric Ulcer Haemorrhage; Gastrointestinal Pain	Escitalopram			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Dihydrocodeine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16038965	NON-EXPEDITED			US-APOTEX-2018AP023706		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sexual Dysfunction; Treatment Noncompliance	Lamotrigine			S	Unknown	100 Mg, Unk		Apotex
	Lamotrigine			S				Apotex
	Lamotrigine			S				Apotex
	Enalapril			S	Unknown	20 Mg, Q.Am		Apotex

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Mirtazapine	S	Unknown	22.5 Mg, Q.H.S.	Apotex
Mirtazapine	S			Apotex
Mirtazapine	S			Apotex
Alprazolam	S	Unknown	1 Mg, Tid, Prn	Apotex
Alprazolam	S			Apotex
Alprazolam	S			Apotex
Escitalopram	S	Unknown	20 Mg, Bid	Apotex
Escitalopram	S			Apotex
Escitalopram	S			Apotex
Lansoprazole	S	Unknown	30 Mg, Q.Am	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16039752	EXPEDITED (15-DAY)		CA, HO	NO-ALLERGAN-1908255US			Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Duodenal Stenosis; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Truxal			S	Transplacental	2 Df, Qhs		Not Reported
	Seroquel			S	Transplacental	100 Mg, Qd		Not Reported
	Furadantin			S	Transplacental	50 Mg, Q8hr		Not Reported
	Mirtazapin Orion			S	Transplacental	15 Mg, Prn (At Night If Necessary, As Required)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16039782	EXPEDITED (15-DAY)		OT	ES-ACCORD-110454		83 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral			Not Reported
	Idaptan			S	Oral			Not Reported
	Nifedipine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16041577	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-110544		60 YR	Male	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Mania	Escitalopram			S		Less Than 12 Months		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16042627	EXPEDITED (15-DAY)		CA, HO	NO-ASTRAZENECA-2019SE33247		< 1 DAY	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duodenal Stenosis; Foetal Exposure During Pregnancy	Seroquel			S	Transplacental			Zeneca	
	Truxal			S	Transplacental	2 Dosage Forms At Night. Strength Of Dosage Forms Not Known.		Not Reported	
	Cipralext			S	Transplacental			Not Reported	
	Mirtazapine			S	Transplacental	15 Mg At Night If Necessary.		Not Reported	
	Furadantin			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16044223	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19P-163-2686375-00			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Dysphagia; Feeding Disorder; Fluid Intake Reduced; Gastrooesophageal Reflux Disease; Intentional Self-Injury; Liver Function Test Increased; Sedation; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased; Weight Decreased	Valproic Acid			S	Unknown			Not Reported	
	Clobazam			S	Unknown	15mg In The Morning, 15 Mg In The Unknown		Not Reported	
	Clobazam			S	Unknown	Hs		Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Escitalopram Oxalate			S	Unknown			Not Reported	
	Clonidine			S	Unknown	Hs		Not Reported	
	Ranitidine			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16044381	EXPEDITED (15-DAY)		DE	BE-ALLERGAN-1908340US			Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Q Year		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16044386	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	NO-ALLERGAN-1908346US			Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd (5 Mg (1 Tbl) X1 Daglig)		Allergan	
	Eliquis			S	Oral	5 Mg, Q12h (5 Mg (1 Tbl) X1 Daglig)		Not Reported	
	Albyl-E			S	Oral	75 Mg, Qd (1 Tbl (75 Mg) X1 Daglig)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	15839364	EXPEDITED (15-DAY)		HO, LT	HU-ALLERGAN-1902085US			Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Intentional Overdose; Muscle Rigidity; Myoglobin Blood Increased; Serotonin Syndrome; Serotonin Syndrome; Suicidal Ideation; Suicide Attempt; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Overdose: Unknown Dose		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Moclobemid			S	Unknown	Overdose: Unknown Dose		Not Reported	
	Moclobemid			S				Not Reported	
	Sertraline Hcl			S	Unknown	Overdose: Unknown Dose		Not Reported	
	Sertraline Hcl			S				Not Reported	
	Cyproheptadin			C	Unknown	Unk		Not Reported	
	Benzodiazepine Derivatives			C				Not Reported	
	Monoamine Oxidase A Inhibitors			C				Not Reported	
	Ssri			C				Not Reported	

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07-Mar-2019	15885120	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1903980US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Infective Spondylitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Quetiapine Fumarate			C	Oral	100 Mg, Qd		Not Reported	
	Quetiapine Fumarate			C	Oral	200 Mg, Qd		Not Reported	
	Quetiapine Fumarate			C	Oral	100 Mg, Qd		Not Reported	
	Quetiapine Fumarate			C	Oral	200 Mg, Qd		Not Reported	
	Quetiapine Fumarate			C	Oral	50 Mg, Qd		Not Reported	
	Quetiapine Fumarate			C	Oral	300 Mg, Qd		Not Reported	
	Lithium Carbonate			C	Oral	100 Mg, Qd		Not Reported	
	Lithium Carbonate			C	Oral	200 Mg, Qd		Not Reported	
	Lithium Carbonate			C	Oral	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16044954	EXPEDITED (15-DAY)		HO	FR-ACCORD-110856		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Liver Disorder	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16049430	EXPEDITED (15-DAY)		OT	SI-ALLERGAN-1908583US			Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Anxiety; Arthralgia; Blood Pressure	Escitalopram Oxalate - Bp			S	Oral	1/2 Tablet		Allergan	

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Increased; Blood Urea	Helex	S	Oral	Unk	Not Reported
Increased; Cognitive	Amlopin	S	Oral	Unk	Not Reported
Disorder; Confusional	Pamorelin	S	Unknown	22.5 Mg	Not Reported
State; Coordination	Symbicort	S	Unknown	Unk	Not Reported
Abnormal; Cough;	Valsacor	S	Oral	Unk	Not Reported
Depersonalisation/Dereali					
sation Disorder;					
Depression; Diabetes					
Mellitus; Diplopia;					
Disturbance In Attention;					
Drug Dependence; Dry					
Mouth; Dysgeusia;					
Dysgeusia; Dysphagia;					
Dysphonia; Dyspnoea;					
Dysstasia; Erectile					
Dysfunction;					
Extrasystoles; Flatulence;					
Gout; Gynaecomastia; Hot					
Flush; Hyperglycaemia;					
Hypertension; Initial					
Insomnia; Insomnia;					
Intraocular Pressure					
Increased; Irritability; Joint					
Stiffness; Joint Swelling;					
Libido Decreased; Loss Of					
Libido; Memory					
Impairment; Mental					
Disorder; Mood Altered;					
Muscle Spasms;					
Musculoskeletal Stiffness;					
Nervousness; Nightmare;					
Nocturia; Oedema					
Peripheral; Orthopnoea;					
Penis Disorder; Photopsia;					
Pruritus; Psychiatric					
Disorder Prophylaxis;					
Sexual Dysfunction;					
Somnolence; Testicular					
Atrophy; Tinnitus; Urinary					
Incontinence; Vertigo;					
Vision Blurred; Visual					
Impairment					

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16049657	EXPEDITED (15-DAY)		OT	SI-ARBOR PHARMACEUTICALS, LLC-SI-2019ARB000329			Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Anxiety;	Triptodur			S	Intramuscular	Vial (22.5 Mg, Unknown)		Arbor	
Arthralgia; Blood Pressure Increased; Blood Urea Increased; Cognitive Disorder; Confusional State; Coordination Abnormal; Cough; Depersonalisation/Derealisation Disorder;	Helex			S	Unknown	Unk		Not Reported	
Depression; Depression; Diabetes Mellitus;	Amlopin /00972401/			S	Oral	Unk		Not Reported	
Diplopia; Disturbance In Attention; Drug Dependence; Dry Mouth; Dysphagia; Dysphonia; Dyspnoea; Dysstasia; Erectile Dysfunction; Extrasystoles; Flatulence; Gout; Gynaecomastia; Hot Flush; Hyperglycaemia; Hypertension; Initial Insomnia; Insomnia; Intraocular Pressure Increased; Irritability; Joint Stiffness; Joint Swelling; Joint Swelling; Libido Decreased; Loss Of Libido; Memory Impairment; Mental Disorder; Mood Altered; Muscle Spasms; Musculoskeletal Stiffness; Nervousness; Nightmare; Nocturia; Oedema	Cipralext /01588501/			S	Oral	1/2 Tablet In The Morning And Evening , Coated Tablet ,Film (0.5 Dosage Forms,2 In 1 D)		Not Reported	
	Symbicort			S	Unknown	Powders, Unit Dose		Not Reported	
	Valsacor			S		Unk		Not Reported	

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Peripheral; Oedema
Peripheral; Orthopnoea;
Penis Disorder; Photopsia;
Pruritus; Sexual
Dysfunction; Sexual
Dysfunction; Somnolence;
Somnolence; Taste
Disorder; Taste Disorder;
Testicular Atrophy;
Tinnitus; Urinary
Incontinence; Vertigo;
Vision Blurred; Visual
Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	15860151	EXPEDITED (15-DAY)		OT	ZA-TAKEDA- 2019TUS002168			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine	Vortioxetine			S	Oral	10 Milligram, Qd		Takeda
Phosphokinase Increased; Blood Pressure Increased;	Aspavor			S	Unknown	20 Milligram, Qd		Not Reported
Constipation; Energy Increased; Irritability;	Lexamil			S	Unknown	Unk		Not Reported
Myoglobin Blood Increased; Rhabdomyolysis	Ecotrin			C	Unknown	Unk, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16049986	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-109278		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Acute; Septic Shock	Repaglinide			S	Oral	2 Mg, Qd		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Oxybutynin/Oxybutynin Hydrochloride			S	Oral	15 Mg, Qd		Accord
	Tacrolimus			S	Oral	3 Mg, Qd		Accord
	Atorvastatin/Atorvastatin			S	Oral	10 Mg, Qd		Not Reported

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Calcium				
Bisoprolol	S	Oral	2 Df, Total	Not Reported
Amphotericin B	S	Buccal	10 Percent	Not Reported
Prograf	S	Oral		Not Reported
Amiodarone	S	Oral		Not Reported
Driptane	S	Oral	5 Mg, Scored Tablet,	Not Reported
Bisoce	S	Oral	Strength 1.25 Mg	Not Reported
Lactulose	S	Oral	2 Df, Qd	Not Reported
Lansoprazole	S	Oral	15 Mg, Qd	Not Reported
Trimebutine	S	Oral	300 Mg, Qd	Not Reported
Amphotericin B/Tetracycline	S	Buccal	3 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16049990	EXPEDITED (15-DAY)		HO	FR-ACCORD-110915		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia;	Clopidogrel			S	Oral			Not Reported
Haematoma Muscle	Escitalopram			S	Oral	1-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16050506	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-995134			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Feeding Disorder; Hallucination; Product Dose Omission; Sedation; Somnolence	Austedo			S	Unknown	48 Milligram Daily;		Teva
	Austedo			S	Unknown	36 Milligram Daily; One 12 Mg Tablet In The Morning And Two 12 Mg Tablets At Night		Teva
	Austedo			S	Unknown	24 Milligram Daily;		Teva
	Austedo			S	Unknown	12 Milligram Daily; Current Dose		Teva

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Lexapro			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16050524	EXPEDITED (15-DAY)		DE, OT	US-009507513-1903USA002288		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suspected Suicide Attempt	Prinivil			S	Oral	Cause Rank: 7		Merck	
	Bupropion			S	Oral	Cause Rank: 1; Bupropion Concentration In Blood 12.2 Mcg/ML (Autopsy)		Not Reported	
	Verapamil			S	Oral	Cause Rank: 2; Verapamil Concentration In Blood 2.3 Mcg/ML (1 H, Peripheral Blood (Pe))		Not Reported	
	Escitalopram			S	Oral	Cause Rank: 3		Not Reported	
	Alcohol			S	Oral	Cause Rank: 4		Not Reported	
	Diphenhydramine			S	Oral	Cause Rank: 5		Not Reported	
	Hydrochlorothiazide			S	Oral	Cause Rank: 6		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16050558	EXPEDITED (15-DAY)		DE, OT	US-009507513-1903USA003074		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Prinivil			S	Oral			Merck	
	Amlodipine			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16050946	NON-EXPEDITED			US-TAKEDA-2019TUS011027		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hypoaesthesia; Paraesthesia	Trintellix	S	Unknown	5 Milligram	Takeda
	Trintellix	S	Unknown	10 Milligram	Takeda
	Trintellix	S	Unknown	20 Milligram	Takeda
	Lexapro	S	Unknown	30 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16051018	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2019-011822			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Milligram In Total		Aurobindo	
	Cipraxel			S	Oral	300 Milligram In Total		Not Reported	
	En			S	Oral	40 Milligram In Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16051679	EXPEDITED (15-DAY)		DE, HO, OT	JP-ASTELLAS- 2016JP020682		62 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased;	Tacrolimus			S	Unknown			Astellas	
Blood Creatine	Tacrolimus			S	Unknown			Astellas	
Phosphokinase Increased;	Tacrolimus			S	Unknown			Astellas	
Constipation;	Tacrolimus			S	Unknown			Astellas	
Constipation; Deep Vein	Tacrolimus			S	Unknown			Astellas	
Thrombosis; Depression;	Tacrolimus			S	Unknown			Astellas	
Dysuria; Hot Flush;	Tacrolimus			S	Unknown			Astellas	
Hyperglycaemia;	Tacrolimus			S	Unknown			Astellas	
Hyponatraemia; Influenza;	Tacrolimus			S	Unknown			Astellas	
Insomnia; Insomnia;	Tacrolimus			S	Unknown			Astellas	
Insomnia; Interstitial Lung	Predonine /00016201/			S	Oral			Not Reported	
Disease; Mental Disorder;	Predonine /00016201/			S	Oral			Not Reported	
Pneumatosis Intestinalis;	Predonine /00016201/			S	Oral			Not Reported	
Pneumoretroperitoneum;	Predonine /00016201/			S	Oral			Not Reported	
Pulmonary Congestion;	Predonine /00016201/			S	Oral			Not Reported	
Steroid Diabetes; White	Predonine /00016201/			S	Oral			Not Reported	
Blood Cell Count	Predonine /00016201/			S	Oral			Not Reported	
Increased	Predonine /00016201/			S	Oral			Not Reported	

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Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral		Not Reported
Predonine /00016201/	S	Oral	30 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	25 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	20 Mg/Day, Unknown Freq.	Not Reported
Predonine /00016201/	S	Oral	15 Mg/Day, Unknown Freq.	Not Reported
Basen /01290601/	S	Oral	0.6 Mg, Once Daily	Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Remeron	S	Oral		Not Reported
Lexapro /01588501/	S	Oral		Not Reported
Lexapro /01588501/	S			Not Reported
Lexapro /01588501/	S	Oral		Not Reported
Ursodeoxycholic Acid	C	Oral		Not Reported
Blopress	C	Oral		Not Reported
Bonalon	C	Oral		Not Reported
Hustazol /00398402/	C	Oral		Not Reported
Juvela /00110502/	C	Oral		Not Reported
Baktar	C	Oral		Not Reported
Nexium /01479302/	C	Oral		Not Reported

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Humalog	C	Unknown	2-6 Units With Insulin Scale, Once Daily	Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral		Not Reported
Prednisolone	C	Oral	3 Mg/Day, Unknown Freq.	Not Reported
Prednisolone	C	Oral	1 Mg/Day, Unknown Freq.	Not Reported
Glufast	C	Oral		Not Reported
Glufast	C	Oral	30 Mg/Day, Unknown Freq.	Not Reported
Seroquel	C	Oral		Not Reported
Amoban	C	Oral		Not Reported
Hustazol /00398402/	C	Oral	Unk Unk, Unknown Freq.	Not Reported
Rize /00624801/	C	Oral		Not Reported
Rize /00624801/	C	Oral		Not Reported
Rize /00624801/	C	Oral	5 Mg/Day, Unknown Freq.	Not Reported
Magnesium Oxide	C	Oral		Not Reported
Magnesium Oxide	C	Oral		Not Reported
Sennoside /00571901/	C	Oral		Not Reported
Risperidone	C	Oral		Not Reported
Abilify	C	Oral		Not Reported
Tetramide	C	Oral		Not Reported
Urso /00465701/	C	Oral		Not Reported
Reslin	C	Oral		Not Reported
Furosemide	C	Oral		Not Reported
Sycrest	C	Oral		Not Reported

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Sycrest	C	Oral		Not Reported
Sycrest	C	Oral	10 Mg/Day, Unknown Freq.	Not Reported
Sycrest	C	Oral	15 Mg/Day, Unknown Freq.	Not Reported
Contomin	C	Oral	25-50 Mg, As Needed	Not Reported
Contomin	C	Oral		Not Reported
Contomin	C	Oral		Not Reported
Novorapid	C	Unknown	Scale 2-4 Units, Once Daily	Not Reported
Ebrantil /00631801/	C	Oral		Not Reported
Amitiza	C	Oral		Not Reported
Amitiza	C	Oral	24 Mg/Day, Unknown Freq.	Not Reported
Tryptanol /00002202/	C	Oral	75 Mg/Day	Not Reported
Inavir /00587301/	C	Oral	40 Mg/Day, Unknown Freq.	Not Reported
Calonal	C	Oral	400 Mg/Day, Unknown Freq.	Not Reported
Lixiana	C	Oral	60 Mg/Day, Unknown Freq.	Not Reported
Daiphen	C	Oral	1 Df/Day, Unknown Freq.	Not Reported
Brotizolam	C	Oral	0.25 Mg/Day, Unknown Freq.	Not Reported
Candesartan	C	Oral	2 Mg/Day, Unknown Freq.	Not Reported

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08-Mar-2019	16051951	EXPEDITED (15-DAY)		OT	IE-TEVA-2019-IE-1020533			Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Product Substitution Issue	Escitalopram			S	Oral			Ivax	

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08-Mar-2019	16052161	NON-EXPEDITED			US-SA-2019SA064337		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Allegra			S				Sanofi	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Duloxetine Hydrochloride			S	Oral	35 Mg, Qd		Not Reported	
	Sertraline Hydrochloride			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16053461	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1021305		31 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion; Dizziness; Headache; Heart Rate Irregular; Mania	Escitalopram			S	Unknown	20mg/ML; One Drop On 21. And 22. Aug. 2018		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16053620	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1021518		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral			Actavis	
	Cipralext 20 Mg/ML Gocce Orali, Soluzione			S	Oral			Not Reported	
	En 2 Mg Compresse			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16053699	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS-2019M1021553		87 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Disorder; Pulmonary Fibrosis	Atorvastatin			S	Oral	10 Milligram, Qd		Not Reported	

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Paracetamol	S	Oral	1500 Milligram, Qd	Not Reported
Ramipril	S	Oral	5 Milligram, Qd	Not Reported
Amiodarone	S	Oral	200 Milligram, Qd	Not Reported
Pantoprazole	S	Oral	20 Milligram, Qd	Not Reported
Lorazepam	S	Oral	1 Milligram, Qd	Not Reported
Escitalopram	S	Oral	10 Milligram, Qd	Not Reported
Kardegic	S	Oral	1 Dosage Form, Qd	Mylan
Caltrate Vitamine D3	S	Oral	Unk	Mylan
Levothyrox	S	Oral	1, Qd	Mylan

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08-Mar-2019	16053740	EXPEDITED (15-DAY)	LT		FR-MYLANLABS-2019M1021539		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Pneumonia Aspiration; Rhabdomyolysis; Toxicity To Various Agents	Alprazolam			S	Oral	Inconnue		Not Reported	
	Mirtazapine			S	Oral	Inconnue		Not Reported	
	Escitalopram			S	Oral	Inconnue		Not Reported	
	Methadone			S	Oral	Inconnue		Mylan	
	Havlane			S	Oral	Inconnue		Mylan	
	Theralene			S	Oral	Inconnue		Mylan	
	Tercian /00759301/			S	Oral	Inconnue		Mylan	

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08-Mar-2019	16053761	EXPEDITED (15-DAY)	OT		US-TEVA-2019-US-1019169		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Neuropathy	Methotrexate			S	Unknown	20 Milligram Daily;		Barr	
	Gabapentin			S	Unknown	600 Milligram Daily;		Ivax	
	Sulfonamide (Bactrim)			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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Peripheral; Product Use In Unapproved Indication; Rash Papular; Skin Burning Sensation	Xeljanz Xr	S	Oral	11 Milligram Daily;	Not Reported
	Lexapro	S	Unknown	20 Milligram Daily;	Not Reported
	Celebrex	S	Unknown		Not Reported
	Omeprazole	C		120 Milligram Daily;	Not Reported
	Folic Acid	C		1 Milligram Daily;	Not Reported
	Duloxetine Hcl	C		600 Milligram Daily;	Not Reported
	Pravastatin Sodium	C		40 Milligram Daily;	Not Reported
	Alendronate Sodium	C		Every Monday Morning	Not Reported
	Amitriptyline	C		Took 20 Or 30 Milligram At Night	Not Reported
	Zyrtec	C			Not Reported
	Cymbalta	C			Not Reported

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08-Mar-2019	16186130	DIRECT		DS, OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Visual Impairment	Escitalopram (Generic Lexipro)			S	Oral	Quantity:1 Df Dosage Form;		Cipla
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Valsartan			C				Not Reported
	Asa			C				Not Reported
	Vit C			C				Not Reported
	D3			C				Not Reported
	B6			C				Not Reported
	B12			C				Not Reported
	Fish Oil			C				Not Reported
	Occuvite			C				Not Reported
	Coq10			C				Not Reported
	Acetyl/Carnitine			C				Not Reported

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10-Mar-2019	16054902	EXPEDITED (15-DAY)		OT	PL-ACCORD-111209			Female	POL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Learning Disorder; Mental Impairment; Therapeutic Product Effect Incomplete	Escitalopram			S		37.5 Mg Per Day		Not Reported	
	Tianeptine/Tianeptine Sodium			C		10 Mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2019	16056738	DIRECT	Y	HO			88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysphagia	Escitalopram			S	Oral		4 DAY	Not Reported	
	Apixaban			C		Not Reported			
	Amlodipine			C		Not Reported			
	Cefdinir			C		Not Reported			
	Clonidine			C		Not Reported			
	Losartan			C		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	14632276	NON-EXPEDITED			US-ALLERGAN-1809820US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Interaction; Fatigue; Nervousness	Oxytrol			S	Transdermal	Unk		Allergan	
	Lexapro			S	Unknown	Unk		Allergan	
	Vitamin D2			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	15022508	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-007213		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abnormal Sleep-Related Event; Anxiety; Depressed Mood; Endometriosis; Feeling Abnormal; Heart Rate Increased;	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustments		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Estarylla			S				Not Reported	

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Nervousness; Panic Reaction; Premenstrual Syndrome; Somnolence; Stress	Lexapro	S	Unk	Not Reported
	Adderall	S		Not Reported
	Hydroxyzine	S		Not Reported
	Mometasone Furoate	C		Not Reported
	Terbinafine Hcl	C		Not Reported
	Ritalin	C		Not Reported
	Modafinil	C		Not Reported
	Zingiber Officinale	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Promethazine	C		Not Reported
	Nitrofurantoin	C		Not Reported
	Mefenamic Acid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Ibuprofen	C		Not Reported
	Mucinex	C		Not Reported
	Nuvigil	C		Not Reported
	Prozac	C		Not Reported
	Tylenol Extra Strength	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	15784456	EXPEDITED (15-DAY)		OT	DE-ACCORD-099195		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cyst	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16003811	EXPEDITED (15-DAY)		OT	FR-ACCORD-109010		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Lichen Planus	Hydrochlorothiazide			S	Oral			Not Reported	
	Esomeprazole/Esomeprazole			S	Oral			Not Reported	
	Magnesium/Esomeprazole								
	Sodium								
	Atorvastatin/Atorvastatin			S	Oral			Not Reported	
	Calcium								
	Aldactone			S	Oral	Strength: 25 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lamotrigine	S	Oral	Not Reported
Xeroquel	S	Oral	Not Reported
Perindopril/Perindopril Erbumine	S	Oral	Not Reported
Kardegic	S	Oral	Not Reported
Verapamil	S	Oral	Not Reported
Teralithe	S	Oral	Not Reported
Seroplex	S	Oral	Not Reported
Macrogol/Macrogol Stearate	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16015896	EXPEDITED (15-DAY)		HO, OT	PT-LUPIN PHARMACEUTICALS INC.-2019-01132		60 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome; Mania	Escitalopram Oxalate			S	Unknown	Unk, Less Than 12 Months		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16032648	EXPEDITED (15-DAY)			JP-ALLERGAN- 1908200US			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Activation Syndrome; Aggression	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Amlodipine			C	Oral	5 Mg		Not Reported
	Forxiga			C	Oral	5 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg		Not Reported
	Glactiv			C	Oral	100 Mg		Not Reported
	Lansoprazole			C	Oral	15 Mg		Not Reported
	Pitavastatin Calcium			C	Oral	2 Mg		Not Reported
	Merislon			C	Oral	18 Mg		Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16055282	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-201175		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Slow Speech	Lorazepam			S	Oral	In Total		Sun	
	Cipralext 20 Mg/Ml Gocce Orali, Soluzione			S	Oral	In Total		Not Reported	
	En 2 Mg Compresse			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16055789	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD- MAC2019020403			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Mania	Escitalopram			S	Unknown	20 Milligram, Less Than 12 Months		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16055943	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2019AP008992			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20.0 Mg, Qd		Apotex	
	Aripiprazole			S	Oral	2.0 Mg, Unk		Apotex	
	Teva Escitalopram			S	Unknown	20.0 Mg, Qd		Not Reported	
	Serax /00040901/			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16056641	NON-EXPEDITED			US-SUNOVION- 2019SUN000827		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Movement Disorder	Latuda	S	Oral	20 Mg	Sunovion
	Lexapro	S	Unknown	20 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16057770	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP008991		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Escitalopram			S	Oral	5.0 Mg, Unk		Apotex
	Saphris			S	Oral	1.25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16057778	EXPEDITED (15-DAY)		HO	PT-TEVA-2019-PT-1023171		60 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mania; Withdrawal Syndrome	Escitalopram			S		Less Than 12 Months		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16058080	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC-2019SUN00102		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug-Induced Liver Injury	Escitalopram			S	Unknown	Unk		Taro
	Kratom			S	Oral	Used On Multiple Occasions		Not Reported
	Kratom			S	Oral			Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

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Fexofenadine	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Recommended 3000 Mg Per Day Limit	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16058515	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1903023US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Prescribed; Dyspnoea; Electrocardiogram Qt Prolonged; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Xalkori			S	Oral	1 Df, Bid		Not Reported
	Carteol F			C	Ophthalmic	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	16059684	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1909665US			Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Coaprovel			S	Oral	312.5 Mg, Qd		Not Reported
	Urbason			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown			Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Alendronic Acid W/Colecalciferol			C	Oral	70 Mg		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	14778062	EXPEDITED (15-DAY)		HO, OT	TW-LUPIN PHARMACEUTICALS INC.-2018-02953		71 YR	Female	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Pain Upper; Dyskinesia; Insomnia; Respiratory Distress; Trismus	Escitalopram	S	Unknown	10 To 15 Mg, Qd For 6 Months	Lupin
	Escitalopram	S	Unknown	20 Mg, Qd	Lupin
	Escitalopram	S	Unknown	10 To 15 Mg, Qd For 6 Months	Lupin
	Quetiapine	S	Unknown	50 Mg, Qd 3 Days	Lupin
	Quetiapine	S	Unknown	100 Mg, Qd	Lupin
	Quetiapine	S	Unknown	50 Mg, Qd	Lupin
	Sertraline	C	Unknown	80 Mg, Qd	Not Reported
	Venlafaxine	C	Unknown	150 Mg, Qd	Not Reported
	Mirtazapine	C	Unknown	45 Mg, Qd	Not Reported
	Risperidone	C	Unknown	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	15453252	EXPEDITED (15-DAY)		HO, OT	SE-ALLERGAN-1847234US			Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Anxiety; Bedridden; Decreased Appetite; Depression; Diarrhoea; Fatigue; Feeling Abnormal; Flushing; Hospitalisation; Palpitations; Peripheral Coldness; Product Dose Omission; Serotonin Syndrome; Tremor; Underdose; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Voxra			C	Unknown	150 Mg, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	15865467	EXPEDITED (15-DAY)		DS, OT	ES-AUROBINDO-AUR-APL-2018-055547			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Female Sexual Dysfunction; Loss Of Libido	Sertraline			S	Oral	50 Milligram, Daily		Aurobindo	
	Sertraline			S	Oral	100 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Enalapril			C	Unknown	20 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16060117	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-012412			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Mania	Escitalopram			S	Unknown	20 Milligram, Less Than 12 Months		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16060417	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-012534			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Chromaturia; Cytomegalovirus Test Positive; Decreased Appetite; Drug Interaction; Drug-Induced Liver Injury; Dysuria; Fatigue; Hepatic Steatosis; Hyperbilirubinaemia; Malaise; Micturition Urgency; Pollakiuria; Pruritus; Pyrexia; Serum Ferritin Increased;	Escitalopram			S	Unknown	Unk		Aurobindo	
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported	
	Mitragyna Speciosa			S	Unknown	Unk		Not Reported	
	Valsartan			C	Unknown	Unk		Not Reported	
	Metoprolol Tartrate			C	Unknown	Unk		Not Reported	
	Clonazepam			C	Unknown	Unk		Not Reported	
	Fexofenadine			C	Unknown	Unk		Not Reported	

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Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16062110	EXPEDITED (15-DAY)		HO	PT-HETERO CORPORATE- HET2019PT00275		60 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder; Mania; Withdrawal Syndrome	Escitalopram			S	Unknown	20 Mg		Hetero	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16062375	EXPEDITED (15-DAY)		LT	NO-MYLANLABS- 2019M1021648		56 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Dehydration; Haemorrhage; Hyperhidrosis; Muscle Rigidity; Nausea; Neuroleptic Malignant Syndrome; Pyrexia; Tremor; Vomiting	Fluoxetine			S	Oral	Unk		Not Reported	
	Trilafon /00023401/			S	Oral	Unk		Mylan	
	Cymbalta			S	Oral	Unk		Mylan	
	Remeron			S	Oral	Unk		Mylan	
	Efexor			S	Oral	Unk		Mylan	
	Stemetil /00013301/			S	Oral	Unk		Mylan	
	Ibux			S	Oral	Unk		Mylan	
	Fluanxol /00109702/			S	Oral	Unk		Mylan	
	Vallergan			S	Oral	Unk		Mylan	
	Nozinan /00038601/			S	Oral	Unk		Mylan	
	Zyprexa			S	Oral	Unk		Mylan	
	Sobril			S	Oral	Unk		Mylan	
	Truxal /00012101/			S	Oral	Unk		Mylan	
	Cipralext /01588501/			S	Oral	Unk		Mylan	
	Abilify			S	Oral	Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16062789	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1021731			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Escitalopram			S		10 Milligram Daily; Morning		Ivax
	Ferrous Fumarate			S		420 Milligram Daily; Morning And Night		Not Reported
	Olanzapine			S		5 Milligram Daily;		Teva
	Mirtazapine			S	Oral	30 Milligram Daily; Night		Teva
	Folic Acid			S		5 Milligram Daily; Morning		Actavis
	Dihydrocodeine			S		Four Times Daily. With Or Just After Food/M meal		Not Reported
	Azathioprine			S		75 Milligram Daily; Morning, Lunch And Tea Time (With Or Just After Food/M meal)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16063039	EXPEDITED (15-DAY)		OT	SI-ALLERGAN-1909231US			Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Anxiety; Arthralgia; Blood Pressure Increased; Blood Urea Increased; Cognitive Disorder; Confusional State; Coordination Abnormal; Cough; Depersonalisation/Derealisation Disorder; Depression; Depression; Diabetes Mellitus; Diplopia; Disturbance In Attention; Drug	Triptorelin Pamoate - Bp			S	Unknown	22.5 Mg, Unknown		Allergan
	Helex			S	Oral			Not Reported
	Amlopin			S	Oral	Unk Unk, Unknown		Not Reported
	Cipraxex			S	Oral	0.5 Df, Bid		Not Reported
	Symbicort			S	Unknown	Unk		Not Reported
	Valsacor			S	Unknown	Unk		Not Reported

Dependence; Dry Mouth;
Dysgeusia; Dysphagia;
Dysphonia; Dyspnoea;
Dysstasia; Erectile
Dysfunction; Erectile
Dysfunction;
Extrasystoles; Flatulence;
Gout; Gynaecomastia; Hot
Flush; Hyperglycaemia;
Hypertension; Initial
Insomnia; Insomnia;
Intraocular Pressure
Increased; Irritability; Joint
Stiffness; Joint Swelling;
Joint Swelling; Libido
Decreased; Loss Of
Libido; Memory
Impairment; Mental
Disorder; Mood Altered;
Muscle Spasms;
Musculoskeletal Stiffness;
Nervousness; Nightmare;
Nocturia; Oedema
Peripheral; Oedema
Peripheral; Off Label Use;
Orthopnoea; Penis
Disorder; Photopsia;
Pruritus; Sexual
Dysfunction; Sexual
Dysfunction; Somnolence;
Somnolence; Taste
Disorder; Testicular
Atrophy; Tinnitus; Urinary
Incontinence; Vertigo;
Vision Blurred; Visual
Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16063462	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019103474		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depression; Fall; Seizure; Tremor	Xanax	S	Unk	Pfizer
	Fentanyl Citrate	S	1200 Mg, Unk	Unknown
	Lexapro	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16064285	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1022442		87 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hypokalaemia	Escitalopram			S		15 Milligram, Qd		Not Reported	
	Seguril			S	Oral	1-1/2-0		Mylan	
	Lexatin /00424801/			C		1-0-1		Mylan	
	Candesartan Ratio			C		16 Milligram, Qd		Mylan	
	Dolocatil			C		Unk		Mylan	
	Aldocumar			C		Unk		Mylan	
	Pantoprazol Kern Pharma			C		20 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16064666	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022443		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Lymphopenia; Neutropenia	Pantoprazole			S	Oral	Long Cours		Not Reported	
	Fenofibrate			S	Oral	Unk		Not Reported	
	Valaciclovir			S	Oral	Unk		Not Reported	
	Lorazepam			S	Oral	Long Cours		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Loxapac /00401802/			S	Oral	Unk		Mylan	
	Bendamustine Accord			S	Intravenous (not otherwise specified)	346 Milligram, Monthly		Mylan	
	Levothyrox			S	Oral	Unk		Mylan	
	Truxima			S	Intravenous (not	720 Milligram, Monthly		Mylan	

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16206572	DIRECT					42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Affective Disorder; Emotional Disorder; Therapeutic Response Changed	Generic Escitalopram			S		Quantity:1 Df Dosage Form;		Not Reported	
	Lexapro			C				Not Reported	
	Multivitamin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	15909036	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1904656US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Disturbance In Attention; Feeling Abnormal; Intestinal Obstruction; Medication Error	Memantine Hcl Unk			S	Unknown	5 Mg, Bid		Allergan	
	Lexapro			S	Unknown	20 Mg, Qd		Allergan	
	Aromasin			S	Oral	25 Mg, Qd		Not Reported	
	Lialda			S		1.2 G (4 Df At Once), Qd, Unknown Route		Not Reported	
	Klonopin			S	Unknown	0.25 Mg, Bid		Not Reported	
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16066371	EXPEDITED (15-DAY)		OT	GB-TORRENT-00020564		50 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram			S				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16067749	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1022971		34 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity	Escitalopram			S	Unknown	5 Milligram		Not Reported	
	Quetiapine Fumarate			S	Unknown	12.5 Milligram		Mylan	
	Novaminsulfon			C	Unknown	Unk		Mylan	
	Pantoprazol /01263201/			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16067756	EXPEDITED (15-DAY)		HO	DE-MYLANLABS- 2019M1022969		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dysphagia; Nausea; Vertigo	Amiodarone			S	Unknown			Not Reported	
	Melperone Hydrochloride			S	Unknown			Mylan	
	Cipralext /01588501/			S	Unknown	10 Milligram, Qd		Mylan	
	Escitalopram			C	Unknown	From Beta Pharm		Mylan	
	L-Tyrosine			C	Unknown	Unk		Mylan	
	Candesartan			C	Unknown	Unk		Mylan	
	Metoprolol			C	Unknown	Unk		Mylan	
	Mcp /00041901/			C	Unknown	Unk		Mylan	
	Xarelto			C	Unknown	Unk		Mylan	
	Amlodipin /00972401/			C	Unknown	Unk		Mylan	
Kalinor /00031402/			C	Unknown			Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16069191	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1910435US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Seizure; Tremor	Lexapro			S	Unknown			Allergan	
	Fentanyl			S	Unknown	1200 Mg		Not Reported	
	Xanax			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16206839	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bruxism; Muscle Spasms; Tremor	Escitalopram 10mg			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	14538861	NON-EXPEDITED			US-PFIZER INC-2018065754		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Venlafaxine Hcl			S		Unk		Pfizer	
	Amitriptyline			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Prozac			S		Unk		Not Reported	
	Zyprexa			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	15516053	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US16837			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Depression; Drug Ineffective; Feeling Abnormal; General Physical Health Deterioration; Impaired Work Ability; Irritability; Mental Impairment	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
	Escitalopram			S	Oral	10 Mg, Unk		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	15662130	EXPEDITED (15-DAY)		DS, HO, OT	PT-ALLERGAN-1854945US			Female	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Dystonia; Gait Disturbance; Stiff Person Syndrome	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Insulin			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	15972660	EXPEDITED (15-DAY)		DS, HO, OT	GB-ACCORD-107135		31 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Micturition Urgency; Pollakiuria	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	15998200	EXPEDITED (15-DAY)		HO	IT-ACCORD-108230		27 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor; Suicide Attempt	Escitalopram			S	Oral			Not Reported	
	Delorazepam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16070806	EXPEDITED (15-DAY)		HO	NL-ACCORD-112780			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation Neonatal; Exposure Via Breast Milk; Hypertonia Neonatal; Maternal Exposure During Pregnancy	Escitalopram			S		1x Daily 1 Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16070815	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2019-012647			Unknown	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S	Unknown	Unk		Aurobindo
	Coaprovel			S	Oral	312.5 Milligram, Daily		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Alendronic Acid;Colecalciferol			C	Oral	70 Milligram		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Urbason			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16071593	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2019020447			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Interaction; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S	Unknown	Unk		Macleods
	Coaprovel			S	Oral	312.5 Milligram, Qd		Not Reported
	Alendronic Acid Sodium Salt Trihydrate/Colecalciferol			C	Oral	70 Milligram		Not Reported
	Alprazolam Abc			C	Oral	Unk		Not Reported
	Colecalciferol			C	Unknown	Unk		Not Reported
	Eutirox			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown	Unk		Not Reported
	Urbason			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16071911	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-		26 YR	Male	USA

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BMS-2019-025245

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Blood Pressure Decreased; Constipation; Contusion; Depression Suicidal; Ejaculation Failure; Gastric Ulcer; Heart Rate Increased; Hypoacusis; Paraesthesia; Sexual Dysfunction; Syncope; Visual Impairment; Weight Decreased	Eliquis			S	Unknown	10 Milligram		Bristol Myers Squibb
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16072139	NON-EXPEDITED			US-SA-2019SA065081			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Ambien			S				Sanofi
	Diphenhydramine Hydrochloride			S				Sanofi
	Carbidopa/Levodopa			S				Not Reported
	Ciprofloxacin Salt Not Specified			S				Not Reported
	Hydrocortisone			S				Sanofi
	Oxaprozin			S				Not Reported
	Demerol			S				Sanofi
	Donepezil Hydrochloride			S				Not Reported
	Fentanyl			S		Unk		Not Reported
	Gabapentin			S				Not Reported
	Cefalexin			S				Not Reported
	Levetiracetam			S		Unk		Not Reported
	Lamotrigine			S				Not Reported
	Paroxetine Hydrochloride			S				Not Reported
	Promethazine			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Zonisamide			S				Not Reported

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	Hydrocodone		S						Not Reported
	Talwin [Pentazocine Lactate]		S						Not Reported
	Nabumetone		S						Not Reported
	Indocin [Indometacin Sodium]		S		Unk				Not Reported
	Hycotuss		S						Not Reported
	Provigil [Modafinil]		S						Not Reported
	Amitriptyline		S						Not Reported
	Codeine		S						Not Reported
	Duloxetine		S						Not Reported
	Tiagabine		S						Not Reported
	Escitalopram		S						Not Reported
	Pramipexole		S						Not Reported
	Ropinirole		S						Not Reported
	Trazodone		S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16072493	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190311949			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Drug Interaction;	Risperidone			S	Unknown			Not Reported	
Electrocardiogram Qt Prolonged; Torsade De Pointes	Haloperidol			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16072832	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019106802		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Drug Abuse; Dry Mouth; Intentional Overdose; Slow Speech	Lorazepam			S	Oral	20 Mg, Single		Pfizer	
	Ciprallex [Escitalopram Oxalate]			S	Oral	300 Mg, Single		Not Reported	
	En			S	Oral	40 Mg, Single		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16074214	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1023673		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram Oxalate			S				Ivax	
	Coaprovel 300/12.5mg Tablets			S	Oral	312.5 Milligram Daily;		Not Reported	
	Urbason 4 Mg Compresse			C				Not Reported	
	Paracetamol			C				Not Reported	
	Alprazolam Abc 0,75 Mg/MI			C				Not Reported	
	Gocce Orali, Soluzione								
	Eutirox 75 Microgrammi			C				Not Reported	
	Compresse								
	Pantoprazole Sodium			C				Not Reported	
	Sesquihydrate								
	Acido Alendronico Sale Sodico			C	Oral			Not Reported	
	Triidrato/Colecalciferolo								
	Colecalciferol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16074346	EXPEDITED (15-DAY)		DE, OT	DE-ALLERGAN-1910683US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Overdose; Road Traffic Accident; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Mirtazapin			S	Unknown	30 Mg, Qd		Not Reported	
	Olynth			C	Unknown	1 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	15735064	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2018M1094037		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Apathy; Asthenia; Coordination Abnormal; Dysstasia; Gait Inability; Insomnia; Off Label Use;	Zopiclone			S	Oral	7.5 Milligram, Qd (1tab/Dy)		Not Reported	
	Olanzapine			S	Unknown	15 Milligram		Not Reported	
	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported	

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Suicide Attempt	Escitalopram	S	Unknown	10 Milligram, Qd	Not Reported
	Lepticur	S	Unknown	Unk	Mylan
	Depamide	S	Oral	300 Milligram, Qd	Mylan
	Seroplex	S	Unknown	10 Milligram, Qd	Mylan
	Seroplex	S	Unknown	5 Milligram, Qd	Mylan
	Seroplex	S			Mylan
	Dopamide	S	Oral	Unk	Mylan
	Abilify	S	Unknown	10 Milligram	Mylan
	Seresta	S	Oral	Half A Tablet In The Morning And At Mid Day And 1 Tab In The Evening	Mylan
	Anafranil	S	Oral	75 Milligram, Qd	Mylan
	Lexapro	S	Unknown	10 Milligram, Qd (Dose Increased To 10 Mg/Day. Previously 5mg. 1tab/Dy)	Mylan
	Zyprexa	S	Unknown	15 Milligram	Mylan
	Imovane	S	Oral	7.5 Milligram, Qd	Mylan
	Methyl dopa	S		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	15742726	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1094501		19 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Product Misuse; Sopor	Escitalopram			S	Oral	280 Milligram, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16075866	EXPEDITED (15-DAY)		HO	IT-ACCORD-113077		49 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Lorazepam			S	Oral			Accord

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Aripiprazole			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076193	EXPEDITED (15-DAY)		DE	FR-ACCORD-112682		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral			Not Reported	
	Kardegic			S	Oral			Not Reported	
	Xarelto			S	Oral	20 Mg/J		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078635	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US- 2019PER000034		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Doxepin			S	Oral	Unk		Pernix	
	Acetaminophen			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078749	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS- 2019GMK040203			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od (1 Every 1 Day)		Glenmark	
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported	
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported	
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported	
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported	

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Escitalopram	S	Transplacental	20 Mg, Od (1 Every 1 Day)	Not Reported
Methadone	S	Transplacental	70 Mg, Od (1 Every 1 Day)	Not Reported
Nortriptyline	S	Transplacental	20 Mg, Od (1 Every 1 Day)	Not Reported
Quetiapine	S	Transplacental	300 Mg, Bid (1 Every 12 Hours)	Not Reported
Rabeprazole	S	Transplacental	Unk	Not Reported
Zopiclone	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078948	EXPEDITED (15-DAY)		DE	US-PERNIX THERAPEUTICS-US- 2019PER000043		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Doxepin			S	Oral	Unk		Pernix
	Escitalopram			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Ethanol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16079243	NON-EXPEDITED			US-TEVA-2019-US- 1014586			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event	Escitalopram Tablets			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	15401455	EXPEDITED (15-DAY)		DE, HO, OT	FR-ACCORD-072310		41 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Intentional Overdose; Poisoning Deliberate; Suicide Attempt; Toxicity	Escitalopram			S	Oral			Not Reported
	Paracetamol			S	Oral			Accord
	Dextropropoxyphene/Dextroprop			S	Oral	Unk		Not Reported

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To Various Agents; Unresponsive To Stimuli	oxyphene					
	Hydrochlori/Dextropropoxyphene					
	Napsilate					
	Baclofen	S	Oral	Unk		Not Reported
	Valpromide	S	Oral	Unk		Not Reported
	Baclofen	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16080746	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-013729			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Citalopram			S	Unknown	Unk		Aurobindo
	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Acetaminophen;Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	420 Milligram		Not Reported
	Morphine			S	Unknown	30 Milligram		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16080836	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-013916			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Urticaria	Escitalopram Tablets			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Omalizumab			S	Subcutaneous	300 Milligram		Not Reported
	Reactine [Cetirizine			C	Oral	1 Dosage Form, Two		Not Reported

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Hydrochloride]				Times A Day	
Ventolin		C		1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16080837	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013451		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Diarrhoea; Drug Ineffective; Haemorrhage; Product Substitution Issue; Pruritus	Escitalopram Tablets			S	Oral	20 Milligram, Two Times A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16080838	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-013644			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16080863	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013877			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective	Citalopram			S	Unknown	Unk		Aurobindo
	Cipralext			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16081693	EXPEDITED (15-DAY)		LT	PHEH2019US011774		19 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation	Gilenya			S	Oral	0.5 Mg, Qd		Novartis

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Lexapro			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-Mar-2019	16081891	NON-EXPEDITED		OT	US-DRREDDYS- USA/USA/18/0099939		69 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Akathisia; Serotonin Syndrome	Olanzapine Film-Coated Tablet			S	Unknown					Not Reported
	Escitalopram			S	Unknown					Not Reported
	Mirtazapine			S	Unknown					Not Reported
	Trazodone			S	Unknown					Not Reported
	Lorazepam			S	Unknown					Not Reported
	Gabapentin			C	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Mar-2019	14310063	EXPEDITED (15-DAY)		HO, OT	SI-MYLANLABS- 2017M1079500		48 YR	Female	SVN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Multiple Sclerosis; Palpitations; Product Use In Unapproved Indication	Pregabalin			S	Unknown	150 Mg, Bid				Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd (1 Tablet In Morning)				Not Reported
	Tolterodine			S	Unknown	4 Mg, Qd (1 Tablet In Morning)				Not Reported
	Fty 720			S	Unknown	0.5 Mg, Qd				Mylan
	Fampridine			S	Unknown	10 Mg, Bid				Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Mar-2019	15411294	NON-EXPEDITED			US-PFIZER INC- 2018380773			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Clindamycin Hcl			S		Unk				Pfizer

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Procardia	S	Unk	Pfizer
Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Fetzima	S	Unk	Not Reported
Viibryd	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16023713	EXPEDITED (15-DAY)		OT	FI-MYLANLABS-2019M1018258			Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Olanzapine			S		Upto 20 Milligram		Not Reported
	Risperdal			S		Increased Upto 4 Milligram		Mylan
	Abilify			S	Intramuscular	400 Milligram		Mylan
	Escitalopram /01588502/			S		Unk		Mylan
	Temesta /00273201/			S		Unk		Mylan
	Xeplion			S		Unk (Injection Was Given Once)		Mylan
	Cisordinol /00876702/			S		50 Milligram		Mylan
	Ativan			S		4 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16066055	EXPEDITED (15-DAY)		DS	IT-ACCORD-112283		19 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autism Spectrum Disorder	Escitalopram			S	Oral			Not Reported
	Risperidone			S	Oral			Accord
	Rivotril			C	Oral	Strength : 2.5 Mg / Ml		Not Reported
	Depakin			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16082579	EXPEDITED (15-DAY)		DS	IT-ACCORD-112807		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral			Accord	
	Escitalopram			S	Oral			Not Reported	
	Rivotril			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16082859	EXPEDITED (15-DAY)		OT	ES-ZYDUS-034657		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Gabapentin			S	Oral			Zydus Pharm	
	Tramadol			S	Oral			Not Reported	
	Escitalopram			S	Oral	10 Mg 28 Tablets		Not Reported	
	Nebivolol			C	Oral	5 Mg 28 Tablets		Not Reported	
	Atorvastatin			C	Oral	40 Mg 28 Tablets		Not Reported	
	Acetylsalicylic Acid			C	Oral	Acetylsalicylic Acid 100 Mg 30 Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16083105	EXPEDITED (15-DAY)		HO	FR-ACCORD-113399		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Haematoma	Aripiprazole			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Zolpidem			S	Oral			Not Reported	
	Prazepam Arrow			S	Oral			Not Reported	
	Piroxicam			C				Not Reported	

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18-Mar-2019	16083128	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-113246		85 YR	Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage; Haematemesis	Clopidogrel			S	Oral	Morning, Suspended During Admission		Not Reported	
	Escitalopram			S	Oral	Morning, Continued During Admission With Proton Pump Inhibitor Protection		Not Reported	
	Fultium-D3			C				Not Reported	
	Alverine			C				Not Reported	
	Co-Beneldopa			C		25mg/100mg		Not Reported	
	Paracetamol			C				Not Reported	
	Amlodipine			C				Not Reported	
	Codeine Phosphate/Paracetamol			C		8mg/500mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16084548	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000238		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett	
	Diazepam			S	Oral	Unk		Lannett	
	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Propranolol			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Melatonin			S	Oral	Unk		Not Reported	
	Olanzapine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16086248	EXPEDITED (15-DAY)		DE	US-ALLERGAN- 1911233US			Female	USA

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Completed Suicide; Off Label Use	Hydrocodone			S	Oral			Allergan	
	Bitartrate;Acetaminophen Unk								
	Escitalopram			S	Oral			Not Reported	
	Oxycodone / Acetaminophen			S	Oral			Not Reported	
	Alprazolam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16086305	EXPEDITED (15-DAY)		DE, OT	US-LANNETT COMPANY, INC.-US-2019LAN000237		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett	
	Bupropion Hcl Er			S	Oral	Unk		Not Reported	
	Escitalopram Oxalate			S	Oral			Lannett	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16228182	DIRECT	Y	HO			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anhedonia; Apathy; Asthenia; Depression; Seizure; Serotonin Syndrome	Bupropion			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	11993343	EXPEDITED (15-DAY)		OT	GB-ACCORD-031871		43 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Restless Legs Syndrome	Quetiapine			S				Accord	
	Escitalopram			S				Accord	
	Fluoxetine			S				Accord	
	Dosulepin			S				Not Reported	

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Lofepramine		S		Not Reported					
Citalopram		S		Accord					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	14253950	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2017M1075619		45 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Escitalopram			S	Oral	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Sertraline			S	Oral	Unk		Not Reported	
	Sertraline			S	Unknown	Unk		Not Reported	
	Venlafaxine			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	15297841	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2018M1062706		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Atorvastatin			S	Oral	10 Mg, Qd		Not Reported	
	Bisoce 1,25 Mg, Comprimé Pelliculé			S	Oral	2 Df, Total		Mylan	
	Lactulose			S	Oral	2 Df, Qd		Not Reported	
	Amiodarone			S	Oral	Unk		Not Reported	
	Lansoprazole			S	Oral	15 Mg, Qd		Not Reported	
	Trimebutine			S	Oral	300 Mg, Qd		Not Reported	
	Repaglinide			S	Oral	2 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Driptane 5 Mg, Comprimé Sécable			S	Oral	3 Df, Qd		Mylan	
	Prograf			S	Oral	3 Mg, Qd		Mylan	
	Fungizone			S	Buccal	3 Df, Qd		Mylan	
	Amphotericin B W/Tetracycline			S	Buccal	3 Df, Qd		Mylan	

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19-Mar-2019	15493305	EXPEDITED (15-DAY)		DS	IT-JNJFOC-20181012555		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum Disorder; Dyskinesia; Off Label Use; Product Use In Unapproved Indication; Tremor	Risperidone			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Xanax			S	Oral			Not Reported	
	Zyprexa			S	Oral			Not Reported	
	Rivotril			C	Oral			Not Reported	
	Depakin			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16022658	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019092972		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Drug Interaction	Cordarone			S	Oral	Unk		Pfizer	
	Crestor			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Plavix			S	Oral	Unk		Not Reported	
	Previscan [Fluindione]			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16078892	EXPEDITED (15-DAY)		DE, HO, LT, OT	CZ-ALLERGAN-1910688US			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Cardiac Fibrillation; Intentional Overdose; Product Use In Unapproved Indication; Serotonin Syndrome; Suicide Attempt; Toxicity	Escitalopram Oxalate - Bp			S	Oral	Overdose: 250 Mg		Allergan	

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To Various Agents;
Ventricular Fibrillation

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19-Mar-2019	16087538	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR- APL-2019-014253			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram Levothyroxine			S C	Transplacental Transplacental	15 Milligram, Daily 50 Microgram, Daily		Aurobindo Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16087554	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-014324			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram Tablets			S	Unknown	20 Milligram, Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16087653	EXPEDITED (15-DAY)		DS, OT	PT-AUROBINDO-AUR- APL-2019-013996			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Stiff Person Syndrome	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16088283	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US- 2019ARB000385		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor	

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	Propranolol	S	Oral	Unk	Not Reported
	Levetiracetam	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Acetaminophen W/Chlorzoxazone	S	Oral	Unk	Not Reported

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19-Mar-2019	16088288	EXPEDITED (15-DAY)		DE	US-ARBOR PHARMACEUTICALS, LLC-US- 2019ARB000346		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Gabapentin Enacarbil			S	Oral	Unk		Arbor
	Tramadol			S	Oral	Unk		Not Reported
	Propranolol			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16089495	NON-EXPEDITED			US-SA-2019SA067973			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Glucophage "Hoechst"			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported
	Lantus			S	Unknown			Sanofi
	Sertraline Hydrochloride			S	Oral	1.5 For 1 Week Then 2 Tabs		Not Reported
	Victoza			S		Unk		Not Reported

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19-Mar-2019	16089710	EXPEDITED (15-DAY)		DE	US-HQ SPECIALTY-US- 2019INT000077		38 YR	Female	USA

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Completed Suicide; Toxicity To Various Agents	Levetiracetam In Sodium Chloride			S	Oral	Unk		Hq Specialty	
	Propranolol			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Gabapentin			S	Oral	Unk		Not Reported	
	Chlorzoxazone W/Paracetamol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16089941	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1024470		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Nausea; Vomiting	Escitalopram			S	Oral	7.5 Milliliter, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16090026	NON-EXPEDITED			US-SA-2019SA071592			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Myalgia; Nausea; Pruritus; Rash; Swelling; Urticaria; Vomiting	Leflunomide			S				Sanofi	
	Ofloxacin			S				Not Reported	
	Morphine Salt Not Specified			S				Not Reported	
	Metoprolol Succinate			S				Not Reported	
	Bupropion Hydrochloride			S				Not Reported	
	Talwin			S				Sanofi	
	Gabapentin			S				Not Reported	
	Atorvastatin			S				Not Reported	
	Olanzapine			S				Not Reported	
	Escitalopram Oxalate			S				Not Reported	
	Duloxetine Hydrochloride			S				Not Reported	
	Hydrocodone			S				Not Reported	
	Orencia			S				Not Reported	
	Oravig			S				Not Reported	
	Avandia			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16090314	NON-EXPEDITED			US-PERRIGO-18US013591		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Nicotine Polacrilex			S	Buccal	2 Mg, 9 To 10 Times Qd		Perrigo	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Gabapentin			C	Unknown	2100mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16091038	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD-US-2019NOV000099		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Toxicity To Various Agents	Quetiapine Fumarate			S	Oral	Unk		Novast	
	Propranolol			S	Oral	Unk		Not Reported	
	Amlodipine			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
	Trazodone			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16091451	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD-US-2019NOV000146		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Metoprolol Succinate			S	Oral	Unk		Novast	
	Quetiapine Fumarate			S	Oral	Unk		Novast	
	Amlodipine			S	Oral	Unk		Not Reported	
	Hydrochlorothiazide			S	Oral	Unk		Not Reported	
	Potassium Chloride			S	Oral	Unk		Not Reported	

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Escitalopram			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-Mar-2019	16091576	EXPEDITED (15-DAY)		DE	US-ASSERTIO THERAPEUTICS, INC.- US-2019DEP000221		38 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Assertio Therapeutics		
	Propranolol			S	Oral	Unk		Not Reported		
	Levetiracetam			S	Oral	Unk		Not Reported		
	Escitalopram			S	Oral	Unk		Not Reported		
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-Mar-2019	16091630	EXPEDITED (15-DAY)		DE	US-NOVAST LABORATORIES, LTD- US-2019NOV000172		60 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Metoprolol Succinate			S	Oral	Unk		Novast		
	Amlodipine			S	Oral	Unk		Not Reported		
	Hydrochlorothiazide			S	Oral	Unk		Not Reported		
	Clonazepam			S	Oral	Unk		Not Reported		
	Escitalopram			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-Mar-2019	16091959	EXPEDITED (15-DAY)		DE	US-ASSERTIO THERAPEUTICS, INC.- US-2019DEP000183		42 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Assertio Therapeutics		
	Tramadol			S	Oral	Unk		Not Reported		

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	Propranolol	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Ethanol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16092278	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911296US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S				Allergan	
	Bupropion			S				Not Reported	
	Verapamil			S				Not Reported	
	Escitalopram			S				Not Reported	
	Ethanol			S				Not Reported	
	Diphenhydramine			S				Not Reported	
	Lisinopril			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16092282	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1911228US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S	Oral			Allergan	
	Metoprolol			S	Oral			Not Reported	
	Amlodipine			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Potassium Chloride			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16092548	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000117		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide; Toxicity To Various Agents	Metoprolol Tartrate	S	Oral	Unk	Validus
	Amlodipine /00972402/	S	Oral	Unk	Not Reported
	Hydrochlorothiazide	S	Oral	Unk	Not Reported
	Clonazepam	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	12414524	EXPEDITED (15-DAY)		DS, OT	IT-ACCORD-040817		61 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Sertraline			S		50 Mg		Accord	
	Escitalopram			S				Accord	
	Quetiapine			S	Oral			Accord	
	Venlafaxine/Venlafaxine			S				Not Reported	
	Hydrochloride								
	Valproic Acid			S				Not Reported	
	Mirtazapine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	14305782	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1771196US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Carafate			S	Oral	1 Df, Tid		Allergan	
Abdominal Discomfort;	Carafate			S				Allergan	
Abdominal Pain;	Hydrochlorothiazide			S	Oral	1 Df, Qd		Allergan	
Abdominal Pain Upper;	Lexapro			S	Unknown	1 Df, Qd		Allergan	
Alopecia; Angiopathy;	Bentyl Tablets			S	Unknown	1 Df, Qid		Allergan	
Atrial Thrombosis;	Misoprostol			S	Oral	100 Mg, Qid		Not Reported	
Atrophic Vulvovaginitis;	Misoprostol			S				Not Reported	
Blister; Bronchitis; Chest	Norvasc			C	Oral	10 Mg, Qd		Not Reported	
Pain; Constipation;	Synthroid			C	Oral	Unk, Qd		Not Reported	
Constipation; Diarrhoea;	Zetia			C	Oral	1 Df, Bid		Not Reported	
Diarrhoea; Diplopia;									
Dizziness; Dyspnoea;									
Fatigue; Feeling									

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Abnormal; Gastroesophageal Reflux Disease; Limb Injury; Mass; Neck Pain; Neck Pain; Off Label Use; Pain In Extremity; Pollakiuria; Pulmonary Mass; Pulmonary Thrombosis; Sinusitis; Skin Discolouration; Thrombosis; Urinary Tract Infection; Vision Blurred	Klonopin	C	Oral	1 Df, Bid	Not Reported
	Premarin	C	Vaginal	Unk, Bi-Weekly	Not Reported
	Xanax	C	Oral	1 Df, Bid	Not Reported
	Avapro	C	Oral	1 Df, Qd	Not Reported
	Ambien	C	Oral	1 Df, Qhs (As Needed)	Not Reported
	Lipitor	C	Oral	1 Df, Qd	Not Reported
	Zoloft	C	Unknown	25 Mg, Qd	Not Reported
	Zoloft	C	Unknown	50 Mg, Qd	Not Reported
	Clonazepam	C	Oral	1 Df, Bid	Not Reported
	Celebrex	C	Unknown	1 Df, Qd	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported
	Vitamin B12	C	Intramuscular	1000 Mg, Single	Not Reported

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Ipratropium Bromide	C	Nasal	4 Df; 2-3 Times Daily	Not Reported
Fluzone	C	Unknown	Unk	Not Reported
Fluzone	C	Unknown	Unk	Not Reported
Valium	C	Oral	1 Df, Prn (Bid)	Not Reported
Xarelto	C	Oral	Unk	Not Reported
Prevnar 13	C	Unknown	0.5 Ml, Single	Not Reported
Tramadol	C	Oral	1 Df, Q6hr (Prn)	Not Reported
Tramadol	C	Oral	Unk Unk, Tid	Not Reported
Ciprofloxacin	C	Oral	1 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	14540063	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-007470			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Domperidone			S	Unknown	Unk		Not Reported
	Amiodarone			S	Unknown	Unk		Aurobindo
	Digoxin			S	Unknown	Unk		Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	14682526	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-016623			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Aurobindo
	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram Single Dose ; In Total		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

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20-Mar-2019	16007783	EXPEDITED (15-DAY)		HO, OT	NO-APOTEX-2019AP008092		21 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Aggression;	Olanzapine			S	Unknown	Unk		Apotex
Agitation; Alcohol Abuse;	Cipralext /01588501/			S	Unknown	Unk Unk, Qd		Not Reported
Bipolar Disorder;	Lamictal			S	Unknown	Unk		Not Reported
Depression; Derealisation;	Seroquel			S	Oral	Unk		Not Reported
Disturbance In Attention;	Seroquel			S	Oral	Unk		Not Reported
Disturbance In Social	Seroquel			S	Oral	Unk		Not Reported
Behaviour; Dizziness;	Seroquel			S	Oral	Unk		Not Reported
Drug Abuse; Drug Abuse;	Seroquel			S	Oral	Unk		Not Reported
Drug Ineffective;	Zyprexa			S	Unknown	Unk		Not Reported
Hypomania; Impaired	Cipramil /00582602/			S	Unknown	10 Mg, Qd Daily		Not Reported
Work Ability; Irritability;	Cipramil /00582602/			S	Unknown	60 Mg, Qd		Not Reported
Judgement Impaired;	Orfiril			S	Unknown	Unk		Not Reported
Logorrhoea; Malaise;	Valproate Sodium			S	Unknown	Increasing Dose		Not Reported
Mania; Mania; Memory	Seroxat			S	Unknown	Unk		Not Reported
Impairment; Personality	Seroxat			S	Unknown	20 Mg, Qd		Not Reported
Disorder; Quality Of Life	Efexor			S	Unknown	Unk		Not Reported
Decreased; Restlessness	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Efexor			S	Unknown	Unk		Not Reported
	Sobril			C	Unknown	Unk Unk, As Needed		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16093000	EXPEDITED (15-DAY)		HO	FR-ACCORD-113131		49 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Intentional Overdose; Miosis; Orthostatic Hypotension; Somnolence	Aripiprazole			S	Oral	Exact Dose When Unknown Imv		Not Reported	
	Olanzapine			S	Oral	Exact Dose When Unknown Imv		Not Reported	
	Escitalopram			S	Oral	Exact Dose When Unknown Imv		Not Reported	
	Bromazepam			S	Oral	Estimated Dose Of 20 Cp Bromazepam 6 Mg		Not Reported	
	Zolpidem			S	Oral	Exact Dose When Unknown Imv		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16093384	EXPEDITED (15-DAY)		HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2019-01659			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Malaise	Zartan 50 Mg			S	Oral	50 Milligram		Lupin	
	Bilocor 5 Mg			S	Oral	5 Milligram		Not Reported	
	Epleptin			S	Oral	100 Milligram		Not Reported	
	Rivotril			S	Oral	0.5 Milligram		Not Reported	
	Lexamil			S	Oral	10 Milligram		Not Reported	
	Ecotrin			S	Oral	81 Milligram		Not Reported	
	Spiractin /00006201/			S	Oral	25 Milligram		Not Reported	
	Prazoloc			S	Oral	40 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16093742	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-114242		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Mydriasis; Somnolence; Suicide	Escitalopram			S	Oral			Not Reported	

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Attempt; Toxicity To Various Agents; Vomiting	Paracetamol	S	Oral		Accord
	Hepatoum	S	Oral		Not Reported
	Azithromycin	S	Oral		Not Reported
	Arestal	S	Oral	Strength: 1 Mg	Not Reported
	Seresta	S	Oral	Strength: 10 Mg	Not Reported
	Prednisolone	S	Oral		Not Reported
	Inorial	S	Oral	Strength: 20 Mg	Not Reported
	Augmentin	S	Oral		Not Reported
	Cefpodoxime/Cefpodoxime	S	Oral		Not Reported
	Proxetil				
	Trimebutine	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16093795	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019020517			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram			S	Unknown	20 Milligram, Qd		Macleods	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16093832	EXPEDITED (15-DAY)		CA, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019020511			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 Milligram, Qd 0. - 38.2. Gestational Week, During 1 Trimester		Macleods	
	Levothyroxine			C	Transplacental	50 Microgram, Qd, 0. - 38.2. Gestational Week, During 1 Trimester		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094803	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019020533			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Escitalopram Oxalate			S	Oral	5 Milligram		Macleods	
	Escitalopram Oxalate			S	Oral	10 Milligram		Macleods	
	Olanzapin			C	Oral	15 Milligram, Qd, Daily Dose: 15 Mg Milligram(S) Every Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094901	EXPEDITED (15-DAY)		HO, LT, OT	CH- GLAXOSMITHKLINE- CH2019048598		56 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Reversible Cerebral Vasoconstriction Syndrome	Escitalopram			S	Oral	10 Mg, Qd		Glaxosmithkline	
	Seretide			S	Respiratory (inhalation)	2 Df, Qd		Glaxosmithkline	
	Salbutamol			C	Unknown	As Necessary		Glaxosmithkline	
	Mepolizumab			C	Unknown	Unk		Glaxosmithkline	
	Ipramol (Ipratropium + Salbutamol)			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Aliskiren			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096414	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB- 1026122		50 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram			S		20 Milligram Daily;		Ivax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096523	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1911805US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096559	EXPEDITED (15-DAY)		CA, OT	DE-ALLERGAN-1911810US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg/D, (0. - 38.2. Gestational Week)		Allergan	
	L-Thyroxin 50			C	Transplacental	50 [Mg/D] (0. - 38.2. Gestational Week)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096591	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1912025US			Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Vision Blurred	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Deanxit			S	Oral	125 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096617	NON-EXPEDITED			US-SA-2019SA066224			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Talwin Nx			S				Sanofi	
	Ambien			S				Sanofi	
	Amitriptyline Hydrochloride			S				Not Reported	
	Diphenhydramine Hydrochloride			S				Sanofi	
	Carbidopa/Levodopa			S				Not Reported	

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Ciprofloxacin	S	Not Reported
Codeine	S	Not Reported
Cortizone 10	S	Not Reported
Cymbalta	S	Not Reported
Daypro	S	Not Reported
Demerol	S	Sanofi
Donepezil Hydrochloride	S	Not Reported
Fentanyl	S	Not Reported
Gabapentin	S	Not Reported
Gabitril	S	Not Reported
Hycotuss	S	Not Reported
Indocin [Indometacin Sodium]	S	Not Reported
Keflex [Cefalexin]	S	Not Reported
Levetiracetam	S	Not Reported
Lamotrigine	S	Not Reported
Lexapro	S	Not Reported
Pramipexole Hydrochloride	S	Not Reported
Nabumetone	S	Not Reported
Paroxetine Hydrochloride	S	Not Reported
Promethazine	S	Not Reported
Provigil [Modafinil]	S	Not Reported
Requip	S	Not Reported
Trazodone Hydrochloride	S	Not Reported
Venlafaxine Hydrochloride	S	Not Reported
Zonisamide	S	Not Reported
Hydrocodone	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096889	EXPEDITED (15-DAY)		DE	US-VALIDUS PHARMACEUTICALS LLC-US- 2019VAL000134		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Metoprolol Tartrate			S	Oral	(Extended Release)		Validus
	Amlodipine			S	Oral	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral			Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported

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Escitalopram			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Mar-2019	16097107	EXPEDITED (15-DAY)		HO, OT	JP-AMNEAL PHARMACEUTICALS- 2019AMN00332		73 YR	Female	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Haemolytic Anaemia; Left Ventricle Outflow Tract Obstruction; Pulseless Electrical Activity	Escitalopram Oxalate			S	Unknown	Unk		Amneal		
	Lorazepam			S	Unknown	Unk		Amneal		
	Adrenaline			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Mar-2019	16098145	EXPEDITED (15-DAY)		DE	US-ALLERGAN- 1911289US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Off Label Use	Hydrochlorothiazide Unk			S	Oral	Unk		Allergan		
	Amlodipine			S	Oral	Unk		Not Reported		
	Metoprolol			S	Oral	Unk		Not Reported		
	Clonazepam			S	Oral	Unk		Not Reported		
	Escitalopram			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Mar-2019	16099969	DIRECT	Y				65 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Agitation	Lexapro			S	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	15484432	EXPEDITED (15-DAY)		DS	IT-ALLERGAN- 1848269US			Male	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

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Autism Spectrum Disorder	Escitalopram Oxalate - Bp	S	Oral	5 Gtt, Qd	Allergan
	Risperidone	S	Oral	1 Mg, Qd	Not Reported
	Depakin	C	Oral	100 Mg	Not Reported
	Rivotril	C	Oral	2.5 Mg/ML	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16098246	EXPEDITED (15-DAY)		OT	PHHY2019FR061712		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased; Gamma- Glutamyltransferase Increased; Rash; Transaminases Increased	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Clomipramine			S	Oral	75 Mg, Qd		Novartis
	Lamotrigine			C	Oral	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16098317	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1025479		56 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis	Escitalopram			S	Oral	"10-15mg" Daily		Ivax
	Sertraline			S	Oral	50 Milligram Daily;		Not Reported
	Lergigan [Promethazine Hydrochloride]			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16098455	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2019-DE-1026089		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile	Escitalopram			S	Transplacental	15 Milligram Daily; 15 [Mg/D]		Ivax

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Apnoea; Retrognathia	L-Thyroxin 50	C	Transplacental	50 Microgram Daily; 50 [Mg/D]	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099565	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK041997			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Drug Ineffective;	Lamotrigine			S				Glaxosmithkline	
Fibromyalgia; Pain;	Gabapentin			S				Not Reported	
Product Use In	Lexapro			S				Not Reported	
Unapproved Indication;	Bupirone			S				Not Reported	
Therapeutic Response									
Unexpected									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099578	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000386		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Doxepin Hydrochloride			S	Oral	Unk		Lannett	
Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Hydroxyzine Hydrochloride			S	Oral	Unk		Lannett	
	Ethanol			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099627	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000249		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Escitalopram Oxalate			S	Oral	Unk		Lannett	
Toxicity To Various Agents	Tramadol			S	Oral	Unk		Not Reported	
	Propranolol			S	Oral	Unk		Not Reported	
	Gabapentin			S	Oral	Unk		Not Reported	

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Ethanol			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099800	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000327		60 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Hydrochlorothiazide;			S	Oral	Unk		Lannett		
	Triamterene			S	Oral	Unk		Not Reported		
	Amlodipine			S	Oral	Unk		Not Reported		
	Metoprolol			S	Oral	Unk		Not Reported		
	Clonazepam			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099805	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000326		60 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Amlodipine			S	Oral	Unk		Not Reported		
	Zolpidem			S	Oral	Unk		Not Reported		
	Naproxen			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099806	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000325		88 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Amlodipine			S	Oral	Unk		Not Reported		
	Alprazolam			S	Oral	Unk		Not Reported		

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Lisinopril			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099808	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000328		39 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Hydrochlorothiazide; Triamterene			S	Oral	Unk		Lannett		
	Metoprolol			S	Oral	Unk (Extended Release)		Not Reported		
	Quetiapine			S	Oral	Unk		Not Reported		
	Potassium Chloride			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099811	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000330		35 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Bupropion			S	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Mar-2019	16099813	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000329		49 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett		
	Hydrochlorothiazide (50mg)			S	Oral	Unk		Lannett		
	Bupropion			S	Oral	Unk		Not Reported		
	Verapamil			S	Oral	Unk		Not Reported		
	Ethanol			S	Oral	Unk		Not Reported		

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		Diphenhydramine		S	Oral	Unk			Not Reported
		Lisinopril		S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099940	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000332		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Venlafaxine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099941	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000331		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Methylphenidate Hydrochloride			S	Oral	Unk		Lannett	
	Bupropion			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099954	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000333		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Acetaminophen			S	Oral	Unk		Lannett	
	Doxepin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099977	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2019NSR000040		42 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Ethanol			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16100113	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2019NSR000091		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Hydroxyzine Hydrochloride			S	Oral	Unk		Northstar
	Doxepin			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16100454	EXPEDITED (15-DAY)		OT	SE-PFIZER INC- 2019114897		56 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis	Sertraline Hcl			S	Oral	50 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	1 Df, 1x/Day (10-15 Mg)		Not Reported
	Lergigan [Promethazine Hydrochloride]			C		Unk, As Needed		Not Reported
	Imovane			C		Unk, As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16100627	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US- 2019LAN000274		51 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Toxicity To Various Agents	Primidone			S	Oral	Unk		Lannett
	Escitalopram Oxalate			S	Oral	Unk		Lannett
	Propranolol			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Trazodone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101177	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US- 2019NSR000048		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Propranolol Hydrochloride			S	Oral	Unk		Northstar
	Levetiracetam			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101372	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2019119444		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Urinary Retention	Gabapentin			S	Oral	300 Mg, 1x/Day For First Week 0-0-1		Pfizer
	Gabapentin			S	Oral	300 Mg, 2x/Day		Pfizer
	Gabapentin			S	Oral	300 Mg, 1x/Day		Pfizer
	Escitalopram			S	Oral	5 Mg, Once (Every 24 Hours) 1/2-0-0		Not Reported

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Zytram	S	Oral	75 Mg, 1x/Day For First Week 0-0-1	Not Reported
Zytram	S	Oral	75 Mg, 2x/Day (Every 12 Hours) 1-0-1. First Week 0-0-1 , Second Week 1-0-1 And Continue Till The Rev	Not Reported
Nebivolol	C	Oral	Unk	Not Reported
Atorvastatin	C	Oral	Unk	Not Reported
Acetylsalicylic Acid Enteric Coated	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101411	EXPEDITED (15-DAY)	HO		FR-ACCORD-114264		88 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rectal Haemorrhage	Escitalopram			S	Oral			Not Reported	
	Previscan (Fluindione)			S	Oral	1/2 Cp / D 1 Day / 2 Alternating With 3/4 Cp,Strength: 20mg, Scored Tablet		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101549	EXPEDITED (15-DAY)	OT		FR-MYLANLABS-2019M1025859		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Coma; Somnolence; Suicide Attempt; Toxicity To Various Agents	Zopiclone			S	Oral	14 Dosage Form, Total		Not Reported	
	Escitalopram			S	Oral	9 Dosage Form, Total		Not Reported	
	Diazepam			S	Oral	10 Dosage Form, Total		Mylan	
	Tercian /00759301/			S	Oral	5 Dosage Form, Total		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101954	EXPEDITED (15-DAY)	DE		US-LANNETT COMPANY, INC.-US-		38 YR	Female	USA

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2019LAN000898

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Levetiracetam			S	Oral	Unk		Lannett	
	Escitalopram Oxalate			S	Oral	Unk		Lannett	
	Propranolol			S	Oral	Unk		Not Reported	
	Gabapentin			S	Oral	Unk		Not Reported	
	Acetaminophen W/Chlorzoxazone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16102400	EXPEDITED (15-DAY)		OT	AU-ALLERGAN- 1912359US			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16102408	EXPEDITED (15-DAY)		OT	NL-ALLERGAN- 1912341US			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16105608	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Lexapro Zoloft			S				Not Reported	
				S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16060957	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX-2019AP009038		52 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown	Unk		Apotex	
	Metamizole			S	Unknown	1000 Mg, Qd, 2 Dosages 500 Mg Daily		Not Reported	
	Tramadol			S	Unknown	200 Mg, Qd (100 Mg , Bid)		Not Reported	
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported	
	Metoclopramide			S	Unknown	30 Mg, Qd, 3 Dosages 10 Mg Daily		Not Reported	
	Omeprazole			S	Unknown	20 Mg, Qd (In The Morning, Fasting)		Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Ketoprofen			S	Unknown	300 Mg, Qd (3 Dosages 100 Mg Daily)		Not Reported	
	Betametazona Fiterman			C	Unknown	Unk		Not Reported	
	Zoledronic Acid			C	Endocervical	Unk		Not Reported	
	Effentora			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	
	Morphine			C	Unknown	Unk		Not Reported	
	Valproic Acid			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16095481	EXPEDITED (15-DAY)		OT	US-009507513-1903USA007224			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section; Maternal Exposure During Pregnancy	Remeron			S		Unk		Merck	
	Buprenorphine Hydrochloride			S		16 Mg Daily (Two 8 Mg		Not Reported	

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Buprenorphine Hydrochloride	S	Films Once Daily)	Unk	Not Reported
Suboxone	S	8 Mg Twice Daily	Unk	Not Reported
Suboxone	S	Unk	Unk	Not Reported
Nicotine	S	Unk	Unk	Not Reported
Lexapro	S	Unk	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104038	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20190321142		31 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Neutropenia; Pleural Effusion	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Tylenol No.1 Forte Caplets			S	Unknown			Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)			Not Reported
	Cipralex			S	Unknown			Not Reported
	Ciprofloxacin			S	Oral			Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)			Not Reported
	Morphine			S	Unknown			Not Reported
	Piperacillin Sodium W/Tazobactam Sodium			S	Unknown			Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)			Not Reported
	Avastin			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			C	Unknown			Not Reported

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	Docusate	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Lactulose	C	Unknown	Not Reported
	Senna	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104406	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00013504		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Unknown	
	L-Thyroxin 50			C	Transplacental	50 [G/D]		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104463	EXPEDITED (15-DAY)		HO, OT	US-009507513-1903USA007895		1 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Infantile Vomiting	Remeron			S	Transplacental	Unk		Merck	
	Buprenorphine Hydrochloride			S	Transplacental	Unk		Not Reported	
	Buprenorphine Hydrochloride			S	Transmammary	Unk		Not Reported	
	Suboxone			S	Transplacental	Unk		Not Reported	
	Nicotine			S	Transplacental	Unk		Not Reported	
	Lexapro			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104762	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00020602			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Blood Potassium	Escitalopram			S	Oral			Unknown	

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Increased; Cough; Electrocardiogram Qt Prolonged; Gastroesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Fluoxetine	C	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16105289	EXPEDITED (15-DAY)		DE, HO	EG-JNJFOC-20190318682		16 YR	Female	EGY

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite;	Risperdal			S	Oral			Not Reported
Encephalitis; Inappropriate	Risperdal			S	Oral			Not Reported
Schedule Of Product	Cogentin			S	Oral			Not Reported
Administration; Off Label	Depakine			S	Oral			Not Reported
Use; Pneumonia	Depakine			S	Oral			Not Reported
Aspiration; Pneumonitis	Depakine			S	Oral			Not Reported
	Ciprallex			S	Oral			Not Reported
	Ciprallex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16106804	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1026235			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Titration Error; Feeling Abnormal; Multiple Sclerosis Relapse; Panic Attack	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16106957	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1912329US			Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Oxalate - Bp			S	Oral	40 Mg, Qd		Allergan	
	Fluoxetine			C	Unknown	20 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16106980	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1912335US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unknown		Allergan	
	Lavita			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16107914	NON-EXPEDITED			US-TEVA-2019-US-1019751			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Asthenia; Dizziness; Drug Ineffective; Pain	Escitalopram Oxalate			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16107916	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1912284US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Decreased Appetite; Loss Of Personal Independence In Daily	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

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Activities; Mental Status	Bupropion	S	Unknown	Unk	Not Reported
Changes; Psychomotor	Bupropion	S			Not Reported
Retardation; Urinary	Buspirone	S	Unknown		Not Reported
Incontinence	Buspirone	S			Not Reported
	Quetiapine	S	Unknown		Not Reported
	Quetiapine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16107944	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1912562US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
Phosphatase Increased; Gamma-	Clomipramine			S	Oral	75 Mg, Qd		Not Reported
Glutamyltransferase Increased; Rash; Transaminases Increased	Lamotrigine			C	Oral	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16107947	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1912343US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depersonalisation/Derealisation Disorder; Mydriasis; Product Use Issue; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2019	15284902	EXPEDITED (15-DAY)		DS, HO, LT, OT	PL-SA-2018SA153669		50 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Condition Aggravated; Depression; Drug Ineffective; Insomnia; Loss	Atorvastatin			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Meloxicam			S				Not Reported

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Of Consciousness; Suicide Attempt; Tinnitus	Meloxicam	S				Not Reported
	Zolpidem Tartrate	S	Unknown	10 Mg, Qd		Sanofi
	Bisoprolol Fumarate	S		Unidentified Dose		Not Reported
	Sertraline	S	Unknown	50 Mg, Qd		Not Reported
	Tramadol Hydrochloride	S	Unknown			Not Reported
	Tramadol Hydrochloride	S				Not Reported
	Tramadol Hydrochloride	S				Not Reported
	Escitalopram Oxalate	S	Unknown			Not Reported
	Perindopril	S	Unknown			Not Reported
	Clarithromycin	S	Unknown	Two 10-Day Cycles		Not Reported
	Clarithromycin	S	Unknown	Unk		Not Reported
	Doxepin	S	Unknown	25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	13428466	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-003667		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased;	Xyrem			S	Oral	3.5 G, Bid		Jazz
Condition Aggravated;	Xyrem			S	Oral	4 G, Bid		Jazz
Constipation; Dizziness;	Lexapro			S		Unk		Not Reported
Fatigue; Feeling	Adderall			S	Unknown			Not Reported
Abnormal; Helicobacter	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
Infection; Mast Cell								
Activation Syndrome;								
Mood Altered;								
Nasopharyngitis; Night								
Sweats; Pain; Pre-Existing								
Condition Improved;								
Sexual Dysfunction;								
Sinusitis Bacterial;								
Tachycardia; Therapeutic								
Response Unexpected								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	14721516	NON-EXPEDITED			US-PFIZER INC-2018139414		76 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Nitroglycerin			S		Unk		Pfizer
	Fexofenadine Hcl			S		Unk		Not Reported
	Irbesartan			S		Unk		Not Reported
	Duloxetine Hcl			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Fluoxetine Hcl			S		Unk		Not Reported
	Oxycodone And Acetaminophen			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	14893179	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1825609US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia; Thrombocytopenia	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Naftidrofuryl			C	Oral	200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16041082	EXPEDITED (15-DAY)		HO, OT	PL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-200662		52 YR	Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Omeprazole			S	Unknown	20 Milligram, Qd (In The Morning, Fasting)		Astrazeneca
	Escitalopram			S	Unknown	()		Not Reported
	Ketoprofen			S	Unknown	3 Dosages 100 Mg Daily		Not Reported
	Metoclopramide			S	Unknown	3 Dosages 10 Mg Daily		Not Reported
	Metamizole			S	Unknown	2 Dosages 500 Mg Daily		Not Reported
	Tramadol			S	Unknown	100 Milligram, Bid		Not Reported
	Alprazolam			S	Unknown	Unk ()		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Buprenorphine	S	Unknown	35 Ug/Hour Every 4 Days	Not Reported
Betametazon	C	Unknown	()	Not Reported
Zoledronic Acid	C	Unknown	Unk	Not Reported
Effentora	C	Unknown	()	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Valproic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16069212	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1910767US			Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety;	Escitalopram Oxalate - Bp			S	Unknown	Unk Unk, Unknown		Allergan
Disturbance In Attention;	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unknown		Allergan
Dizziness; Dizziness; Drug	Escitalopram Oxalate - Bp			S	Unknown	0.5 Df, Unknown		Allergan
Withdrawal Syndrome;	Thrombo Ass			C	Unknown	0.5 Df, Qd		Not Reported
Dyspnoea; Dyspnoea; Ear								
Discomfort; Fatigue;								
Fatigue; Fatigue; Impaired								
Work Ability; Impaired								
Work Ability; Irritability;								
Limb Discomfort; Limb								
Discomfort; Myalgia;								
Nausea; Panic Reaction;								
Restlessness;								
Restlessness; Rhinitis;								
Somnolence; Trance								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16109850	EXPEDITED (15-DAY)		OT	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-202862		56 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Autoimmune Hepatitis	Escitalopram	S	Oral	Unk Unk, Daily, 10-15mg (1)	Not Reported
	Sertraline	S	Oral	50 Milligram, Daily	Sun
	Lergigan [Promethazine Hydrochloride]	C	Unknown	Unk, Prn	Not Reported
	Imovane	C	Unknown	Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110084	EXPEDITED (15-DAY)	LT		FR-ACCORD-114648		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110714	EXPEDITED (15-DAY)	OT		ES-AUROBINDO-AUR-APL-2019-014964			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urinary Retention	Escitalopram 10 Mg			S	Oral	5 Milligram, Daily (1/2-0-0)		Aurobindo
	Gabapentin Hard Capsules 300mg			S	Oral	300 Milligram, At Every 8 Hour (1-1-1. 1st Week 0-0-1, 2nd Week 0-1-1, 3rd Wee		Aurobindo
	Zytram Bid			S	Oral	75 Milligram, Two Times A Day (1-0-1. 1st Week 0-0-1, 2nd Week 1-0-1 An		Not Reported
	Nebivolol			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	Unk		Not Reported
	Acetylsalicylic Acid			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110866	EXPEDITED (15-DAY)	OT		IT-ACCORD-114979		56 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Abuse; Toxicity To Various Agents	Escitalopram	S	Oral	Strength 10 Mg	Not Reported
	Metoprolol	S	Oral		Accord
	Xarelto	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110951	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2019-GB-1028338			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastroesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram			S	Oral	40 Milligram Daily;		Ivax
	Fluoxetine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16111039	EXPEDITED (15-DAY)		HO	FR-ACCORD-115509		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Not Reported
	Paracetamol			S	Oral	79 G, Total		Accord
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Inorial			S	Oral	120 Mg, Total		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Hepatoum			S	Oral	Unspecified		Not Reported
	Arestal			S	Oral	30 Mg, Total		Not Reported
	Seresta			S	Oral	310 Mg, Total		Not Reported
	Cefpodoxime/Cefpodoxime Proxetil			S	Oral	2000 Mg, Total		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Augmentin	S	Oral	6 G, 1 Day				Not Reported	
	Prednisolone	S	Oral	200 Mg, Total				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113199	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912514US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Contusion; Subcutaneous Haematoma	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Eliquis			S	Oral	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113210	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912521US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gingival Bleeding; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Kardegic			S	Oral	1 Df, Qd		Not Reported	
	Coumadine			S	Oral	1 Df, Qd		Not Reported	
	Pantoprazole Arrow			C	Oral	1 Df, Qd		Not Reported	
	Lasilix			C	Oral	3 Df, Qd		Not Reported	
	Colchicine Opocalcium			C	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113255	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1912527US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Behaviour Disorder; Congenital Anomaly; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Intra-uterine	Unk		Allergan	
	Mediator			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16115468	EXPEDITED (15-DAY)		OT	PHHY2019FR065429		19 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hidradenitis	Tafinlar			S	Oral	2 Df, Qd (Ug/Liter)		Novartis	
	Prazepam			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Melatonine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16087134	EXPEDITED (15-DAY)		OT	SE-AUROBINDO-AUR-APL-2019-013992			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis	Sertraline Film-Coated Tablet			S	Oral	50 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	1 Unk, Once A Day, 10-15mg		Not Reported	
	Lergigan [Promethazine Hydrochloride]			C	Unknown	As Necessary		Not Reported	
	Imovane			C	Unknown	As Necessary		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16099132	EXPEDITED (15-DAY)		CA, OT	DE-HETERO CORPORATE-HET2019DE00322		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Hetero	
	L-Thyroxin 50			S	Transplacental	50 [Mg/D]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16115906	NON-EXPEDITED			US-TEVA-2019-US-1029683			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Screen Positive	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	
	Ranitidine			C				Not Reported	
	Lamotrigine			C				Not Reported	
	Trazodone			C				Not Reported	
	Humira			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16116433	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR- APL-2019-015545			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Tablets			S	Oral	40 Milligram, Once A Day		Aurobindo	
	Fluoxetine			C	Unknown	20 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16116587	EXPEDITED (15-DAY)		OT	GB-ACCORD-114295		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Feeling Cold; Nausea	Escitalopram			S	Oral	Prescribed 10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16116952	NON-EXPEDITED			US-PFIZER INC- 2019125110		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Venlafaxine Hcl			S		Unk		Pfizer	

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Acetaminophen	S	Unk	Not Reported
Escitalopram Oxalate	S	Unk	Not Reported
Insulin Glargine	S	Unk	Not Reported
Metformin Hcl	S	Unk	Not Reported
Mirtazapine	S	Unk	Not Reported
Macrobid [Nitrofurantoin]	S	Unk	Not Reported
Oxcarbazepine	S	Unk	Not Reported
Nitrofurantoin Macrocrystalline	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16117817	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1029052		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Previscan 20 Mg			S	Oral	15 Milligram Daily; Scored		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16118359	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1025850		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Disturbance In Attention;	Cetirizine			S	Oral	50 Milligram, Total		Not Reported
Hypoglycaemia;	Zopiclone			S	Oral	30 Milligram, Total		Not Reported
Hypotension;	Escitalopram			S	Oral	140 Milligram, Total		Not Reported
Somnolence; Suicide Attempt; Toxicity To Various Agents	Mag 2 /00454301/			S	Oral	7 Dosage Form, Total		Mylan
	Xanax			S	Oral	49 Dosage Form, Total		Mylan
	Doliprane			S	Oral	3 Gram, Total		Mylan
	Flagyl /00012501/			S	Oral	9 Dosage Form, Total		Mylan
	Naproxene /00256201/			C		Unk		Mylan

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26-Mar-2019	16119036	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912760US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cephalhaematoma; Foetal Exposure During Pregnancy; Thrombocytopenia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	15 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16119156	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1027502		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Urinary Retention	Escitalopram 10 Mg 28 Comprimidos			S	Oral	5 Milligram Daily; 1/2-0-0		Ivax	
	Gabapentina 300 Mg Cápsulas Duras			S	Oral	1-1-1.1st Week 0-0-1, 2nd Week 0-1-1, 3rd Week 1-1-1 And Continue Until Further Review		Actavis	
	Zytram Bid 75 Mg Comprimidos De Liberacion Prolongada , 56 Comprimidos			S	Oral	1-0-1.1st Week 0-0-1, 2nd Week 1-0-1 And Continue To Review		Not Reported	
	Nebivolol 5 Mg 28 Comprimidos			C	Oral			Not Reported	
	Atorvastatina 40 Mg 28 Comprimidos			C	Oral			Not Reported	
	Ácido Acetilsalicílico 100 Mg 30 Comprimidos			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16119285	EXPEDITED (15-DAY)		DS	FR-TAKEDA-2019TUS017411		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Respiration Abnormal; Sleep Apnoea	Brintellix			S	Unknown	Unk		Takeda	

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Syndrome; Therapeutic Response Decreased	Seroplex	S	Oral	10 Milligram, Qd	Not Reported
	Seroplex	S	Oral	5 Milligram, Qd	Not Reported
	Seroplex	S			Not Reported
	Bilastine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16119488	NON-EXPEDITED			US-TEVA-2019-US-1018901			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Increased; Palpitations	Escitalopram Tablets			S	Unknown	For 2 Years		Ivax
	Escitalopram Tablets			S				Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16120154	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913364US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Bactrim			S	Oral	800 Mg Every 2 Days		Not Reported
	Doliprane			S	Oral	3 G		Not Reported
	Vfend			S	Oral	600 Mg		Not Reported
	Augmentin			S	Oral	3 G, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	12641225	NON-EXPEDITED			US-PFIZER INC-2016365727		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lincocin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Vimovo			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

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27-Mar-2019	15976643	NON-EXPEDITED			US-JAZZ-2019-US-000750		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Asthma; Chest Pain; Drug Hypersensitivity; Headache; Heart Rate Increased; Night Sweats; Obstructive Airways Disorder; Pain In Extremity; Seasonal Allergy; Sinusitis; Snoring; Upper Respiratory Tract Infection	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustments		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Cymbalta			S				Not Reported	
	Lexapro			S				Not Reported	
	Adderall			C				Not Reported	
	Evoxac			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	15987635	NON-EXPEDITED		HO, OT	US-NEUROCRINE BIOSCIENCES INC.-2019NBI00414			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Suicide Attempt	Ingrezza (Valbenazine)			S	Oral			Neurocrine Biosciences	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16044411	EXPEDITED (15-DAY)			US-ALLERGAN-1908458US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hallucination; Initial Insomnia; Mydriasis; Therapeutic Response Unexpected; Tinnitus	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qhs		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan	
	Advil Congestion Relief			S	Oral	Unk Unk, Bid (At Noon And At 5 Pm)		Not Reported	
	Advil Congestion Relief			S				Not Reported	
	Lexapro			C	Unknown	Unk		Not Reported	

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Centrum			C		Unknown	Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16110103	EXPEDITED (15-DAY)		HO	IT-ACCORD-114256		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Sensory Disturbance	Cipralext			S	Oral			Not Reported	
	Lamictal			C	Oral			Not Reported	
	Rivotril			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16121850	EXPEDITED (15-DAY)		CA	DE-ACCORD-115453			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	10 Mg/D / Dosage Reduction To 5mg/D Before Stop		Not Reported	
	Magnetrans			C	Transplacental			Not Reported	
	Ibuprofen			C	Transplacental	400 Mg/D / On Demand, Max Once Per Week		Not Reported	
	Cetirizine			C	Transplacental			Not Reported	
	Paracetamol			C	Transplacental	1500 Mg/D / 1000-1500 Mg/D, In Total 2-3 Times		Not Reported	
	Cytotec			C	Transplacental			Not Reported	
	Olynth			C	Transplacental	If Required		Not Reported	
	Folio Forte			C	Transplacental	0.8 Mg/D / From Week 14 0.4mg/D		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16121873	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-028716		89 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Contusion; Subcutaneous Haematoma	Eliquis			S	Oral	5 Milligram, Qd		Bristol Myers Squibb	
	Seroplex			S	Oral	5 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16122018	NON-EXPEDITED			US-PFIZER INC- 2019127854		59 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown	
	Lexapro			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16122258	EXPEDITED (15-DAY)		HO	FR-ACCORD-115951		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram			S	Oral			Not Reported	
	Kardegic			S	Oral	75 Mg In Sachet-Dose		Not Reported	
	Omexel			C		0.4 Mg Prolonged-Release Film-Coated Tablet		Not Reported	
	Candesartan			C				Not Reported	
	Seebri Breezhaler			C				Not Reported	
	Avodart			C		0.50mg		Not Reported	
	Seresta			C		10 Mg		Not Reported	
	Tenordate			C				Not Reported	
	Imovane			C		7.5 Mg		Not Reported	
	Spironolactone			C				Not Reported	
Lasilix			C		40 Mg, Scored Tablet		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16123454	EXPEDITED (15-DAY)		DE, HO	PHHY2019CH064575		47 YR	Female	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Cardiac Arrest; Cough; Dyspnoea; Oropharyngeal Pain; Pyrexia	Clopin Eco			S	Oral	Beginning At 25 Mg/Day On 04-Dec-2018 And Increased To 300 Mg/Day On 20-Dec-2018		Not Reported
	Clarithromycin			S	Oral			Not Reported
	Piperacillin+Tazobactam			S	Intravenous drip			Novartis
	Metfin			S	Oral	Since At Least 19-Nov-2018		Not Reported
	Betmiga			S	Oral	Since At Least April 2018		Not Reported
	Dafalgan			S	Oral	1g Maximum 3x/Day On Hand; As Necessary		Not Reported
	Cipralelex			S	Oral	Normal Long Term Treatment		Not Reported
	Haloperidol			S	Oral			Not Reported
	Temesta (Lorazepam)			S	Oral	2.5 Mg Maximum 2x/Day On Hand Since At Least May 2018; As Necessary		Not Reported
	Ventolin			S	Respiratory (inhalation)	100 Micrograms On Hand Maximum 4x/Day; As Necessary		Not Reported
	Inderal			S	Oral	Normal Treatment For Many Years		Not Reported
	Tranxilium			C	Oral			Not Reported
	Zolpidem			C	Oral	10 Mg/Day On Hand Since At Least 26-Nov-2018; As Necessary		Not Reported
	Atorvastatine			C	Oral	20 Mg/Day Since At Least 19-Nov-2018		Not Reported
	Eltroxin			C	Oral	Since At Least April 2018		Not Reported
	Calcium Sandoz + Vitamin D3			C	Oral			Not Reported
	Duspatalin			C	Oral	Since At Least 19-Nov-2018		Not Reported

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	Symbicort	C	Respiratory (inhalation)	2 Inhalations/Day		Not Reported			
	Spasmo-Urgenin Neo	C	Oral			Not Reported			
	Cerazette	C	Oral			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16123545	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1026592		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram			S	Oral	20 Gtt Drops, Total (1/12 Millilitre)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16123571	EXPEDITED (15-DAY)		HO	PHHY2019FR065142		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Hypotension; Tonic Clonic Movements	Cotareg			S	Oral	1 Df, Qd			Novartis
	Seroplex			S	Oral	2 Df, Qd			Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous drip	Unk			Not Reported
	Uvedose			C	Unknown	Unk			Not Reported
	Seresta			C	Unknown	Unk			Not Reported
	Imovane			C	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16123792	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1026781		23 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	50 Milligram, Total			Not Reported
	Delorazepam			S	Oral	Unk			Not Reported
	Tavor /00273201/			S	Oral	4 Dosage Form, Total			Mylan

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Okil	S	Oral	800 Milligram, Total	Mylan
Lamotrigine	S	Oral	4 Dosage Form, Total	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124017	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913393US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Hypotension; Tonic Clonic Movements	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Cotareg			S	Oral	1 Df, Qd (80 Mg/12,5 Mg)		Not Reported
	Loxen (Niacardipine Hydrochloride)			S	Intravenous drip	Unk, Single (10mg/10ml)		Not Reported
	Uvedose			C				Not Reported
	Seresta			C				Not Reported
	Imovane			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124047	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1913496US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Respiration Abnormal; Sleep Apnoea Syndrome; Therapeutic Response Decreased	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Brintellix			S	Unknown	Unk		Not Reported
	Bilastine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124048	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1913324US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hidradenitis	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Prazepam			S	Oral	Unk		Not Reported

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	Melatonin		S	Oral	Unk			Not Reported	
	Tafinlar		S	Oral	2 Df, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124071	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1913503US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Traumatic Intracranial Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Coumadine			S	Oral	Unk		Not Reported	
	Pregabaline			C	Oral	Unk		Not Reported	
	Bisoce			C	Oral	Unk		Not Reported	
	Inexium			C	Oral	Unk		Not Reported	
	Perindopril			C	Oral	Unk		Not Reported	
	Repaglinide			C	Oral	Unk		Not Reported	
	Seresta			C	Oral	Unk		Not Reported	
	Lasilix			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124753	NON-EXPEDITED			US-EISAI MEDICAL RESEARCH-EC-2019-053083			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Belviq			S	Oral			Not Reported	
	Belviq			S	Oral			Not Reported	
	Lexapro			S	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16125100	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1913608US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Loss Of Consciousness; Neurological Symptom; Parathyroid Disorder; Product Use Issue; Somnolence	Escitalopram Oxalate - Bp Calcium	S C	Oral Oral	5 Mg, Q12h	Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	13951821	EXPEDITED (15-DAY)		HO, OT	AT-ALLERGAN-1704413US			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Cognitive Disorder; Dyspnoea; Hyperhidrosis; Hyperreflexia; Malaise; Panic Attack; Restlessness; Serotonin Syndrome; Tachycardia; Tremor	Escitalopram Oxalate Unk			S		10 Mg, Qd		Allergan	
	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan	
	Wick			S	Oral	30 MI, Qd		Not Reported	
	Temesta			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	15597965	NON-EXPEDITED			US-PFIZER INC-2018443915		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Weight Increased	Desvenlafaxine Succinate Monohydrate			S		50 Mg, Daily (For 2 Weeks)		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Fetzima			S		Unk		Not Reported	
	Remeron			S		Unk		Not Reported	
	Trintellix			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Rexulti			C		Unk		Not Reported	
	Sonata [Zaleplon]			C		Unk		Not Reported	
	Ambien			C		Unk		Not Reported	

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Melatonin	C	Unk	Not Reported
Abilify	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	15602853	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1852425US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Lexapro			S	Oral	5 Df, Qd		Allergan
Blister; Cellulitis; Chills;	Lexapro			S	Oral	5 Mg, Q6hr		Allergan
Depression; Dyspnoea;	Gocovri			S	Oral	137 Mg, Qhs		Not Reported
Feeling Hot; Gait	Gocovri			S	Oral	274 Mg, Qhs		Not Reported
Disturbance; Headache;	Gocovri			S	Oral	137 Unk, Qhs		Not Reported
Heart Rate Increased;	Gocovri			S	Oral	274 Mg, Qhs		Not Reported
Hypertension;	Gocovri			S	Oral	137 Mg, Qhs		Not Reported
Hypoaesthesia; Insomnia;	Gocovri			S	Oral	274 Mg, Qhs		Not Reported
Intentional Overdose;	Gocovri			S	Oral	137 Mg, Qhs		Not Reported
Nausea; Neuropathy	Parcopa			C		25/1000 Mg Unk		Not Reported
Peripheral; Pain In	Clonazepam			C		0.5 Mg, Unk		Not Reported
Extremity; Panic Attack;	Allegra			C		60 Mg, "1x/Day, Sometimes 2x/Day And Sometimes None"		Not Reported
Peripheral Swelling; Skin								
Discolouration; Swelling;								
Tooth Abscess; Tremor;								
Urinary Incontinence;								
Vision Blurred	Hydrocortisone			C		5 Mg, Unk		Not Reported
	Metoprolol Succinate			C		0.5 Df, Qhs		Not Reported
	Motrin Ib			C		200 Mg, Prn		Not Reported
	Nyamyc			C		10000 Units, Unk		Not Reported
	Ranitidine			C		150 Mg, Unk		Not Reported
	Ropinirole			C		4 Mg, Unk		Not Reported
	Stalevo 200			C		Unk		Not Reported
	Bepreve			C				Not Reported
	Systane			C		Unk		Not Reported
	Preparation H			C		Unk		Not Reported
	Tums Smooth Dissolve			C		750 Mg, As Needed		Not Reported

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Tylenol	C	650 Mg, 2-3 Per Day	Not Reported
Miralax	C	Unk	Not Reported
Cranberry/D3	C		Not Reported
Vitamin B12	C	1000 Mg, Unk	Not Reported
Vitamin D2	C	400 Units, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	15995158	EXPEDITED (15-DAY)		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2019-01086		24 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Lupin
	Aripiprazole			S	Unknown	Unk Unk, Qd (10 To 30 Mg)		Not Reported
	Clozapine			C	Unknown	Unk		Not Reported
	Clozapine			C	Unknown	600 Milligram, Qd		Not Reported
	Clozapine			C	Unknown	350 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16125685	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1029539		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Rash; Transaminases Increased	Clomipramine (Chlorhydrate De)			S	Oral	75 Milligram Daily;		Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Lamotrigine			C	Oral	100 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16125726	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-015255			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Coronary Syndrome; Anaemia; Haematoma; Haematuria	Escitalopram Arrow Film-Coated Tablet 5mg	S	Oral	1 Dosage Form, Once A Day	Aurobindo
	Allopurinol Arrow Tablets 100 Mg	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Furosemide Arrow 40 Mg Tablets	S	Oral	40 Milligram, Once A Day	Not Reported
	Kardegic	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Pregabalin Teva	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Previscan (Fluindione)	S	Oral	1.5 Dosage Form, Once A Day	Not Reported
	Imovane	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Bisoprolol Hemifumarate	C	Unknown	Unk	Not Reported
	Levemir	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Levothyrox	C	Unknown	Unk	Not Reported
	Galvus	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Xatral	C	Unknown	Unk	Not Reported
	Umuline	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16125741	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-015913			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Partial Seizures	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Alprazolam			C	Oral	0.25 Milligram, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126071	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2019- BI-01		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Movement Disorder; Loss Of Consciousness	Pritor (Telmisartan) Escitalopram			S S	Unknown Unknown			Boehringer Ingelheim Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126475	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-016097			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram Previscan (Fluindione)			S S	Oral Oral	5 Milligram, Once A Day 15 Milligram, Once A Day		Aurobindo Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126614	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019020590			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Fluoxetine			S C	Oral Unknown	40 Milligram, Qd 20 Milligram		Macleods Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126795	EXPEDITED (15-DAY)		OT	ES-ACCORD-116108			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Medication Error	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126799	EXPEDITED (15-DAY)		HO	FR-ACCORD-115947		83 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Accord
	Imovane			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Omexel L.P.			S	Oral			Not Reported
	Candesartan			S	Oral			Not Reported
	Tenordate			S	Oral			Not Reported
	Seebri Breezhaler			C				Not Reported
	Avodart			C				Not Reported
	Kardegic			C				Not Reported
	Lovenox			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126859	EXPEDITED (15-DAY)		HO	IT-ACCORD-115361		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Omeprazole			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126860	EXPEDITED (15-DAY)		HO	IT-ACCORD-115597		84 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertension; Medication Error; Off Label Use	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16128357	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP010216		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Gabapentine			S	Oral	1-1-1. 1ª Semana 0-0-1 , 2ª Semana 0-1-1, 3ª Semana 1-1-1 Y Seguir Hasta Nueva Revisión		Apotex	
	Escitalopram			S	Oral	1/2-0-0		Apotex	
	Zytram Bid			S	Oral	1-0-1. 1ª Semana 0-0-1 , 2ª Semana 1-0-1 Y Seguir Hasta Revisión		Not Reported	
	Nebivolol			C	Oral			Not Reported	
	Atorvastatina /01326101/			C	Oral			Not Reported	
	Acetylsalicylic Acid			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16129408	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1028985		73 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Coronary Syndrome; Anaemia; Haematoma; Haematuria	Escitalopram Arrow 5 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms Daily;		Ivax	
	Pregabaline Teva 50 Mg, Gélule			S	Oral	3 Dosage Forms Daily;		Not Reported	
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Forms Daily;		Not Reported	

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	Allopurinol Arrow 100 Mg, Comprimé	S	Oral	1 Dosage Forms Daily;	Not Reported
	Imovane 3,75 Mg, Comprimé Pelliculé	S	Oral	1 Dosage Forms Daily;	Not Reported
	Furosemide Arrow 40 Mg, Comprimé Sécable	S	Oral	40 Milligram Daily;	Not Reported
	Previscan 20 Mg, Comprimé Sécable	S	Oral	1.5 Dosage Forms Daily;	Not Reported
	Bisoprolol (Hemifumarate De)	C			Not Reported
	Levemir	C			Not Reported
	Pantoprazole	C			Not Reported
	Levothyrox	C			Not Reported
	Galvus	C			Not Reported
	Amlodipine	C			Not Reported
	Xatral	C			Not Reported
	Umuline	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16130059	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1028192		36 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyramidal Tract Syndrome; Toxicity To Various Agents; Tremor	Escitalopram			S	Oral	600 Mg,Unk		Not Reported	
	Diazepam			S	Oral	30 Df,Unk		Mylan	
	Teralithe			S	Oral	Dose 2 Boxes Of 400 Mg Tabres		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16130834	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102300		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Oedema; Drug Interaction; Overdose; Pulmonary Congestion; Pulmonary Oedema; Toxicity To Various Agents	Percodan			S	Unknown	Unk Unknown, Unknown		Endo	
	Roxicodone			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Oxycontin			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Valium			S	Unknown	Unk Unknown, Unknown		Not Reported	

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	Flexeril /00428402/		S	Unknown	Unk Unknown, Unknown		Not Reported		
	Desyrel		S	Unknown	Unk Unknown, Unknown		Not Reported		
	Lexapro		S	Unknown	Unk Unknown, Unknown		Not Reported		
	Celexa /00582602/		S	Unknown	Unk Unknown, Unknown		Not Reported		
	Neurontin		S	Unknown	Unk Unknown, Unknown		Not Reported		
	Caffeine		S	Unknown	Unk Unknown, Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16131746	DIRECT		LT			25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Lexapro			S	Oral	Quantity:1 Capsule(S);		Not Reported	
	Norplaxon			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	15587155	EXPEDITED (15-DAY)		DE, HO, LT	CA-ASSERTIO THERAPEUTICS, INC.- CA-2018DEP001875		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Diclofenac Potassium			S	Oral	50 Mg, Bid		Assertio Therapeutics	
	Ciprallex /01588501/			S	Oral	10 Mg, Qd		Not Reported	
	Ibuprofen			S	Oral	400 Mg, Prn		Not Reported	
	Eliquis			C		Unk		Not Reported	
	Pantoprazole			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	15905999	NON-EXPEDITED		OT	US-JAZZ-2018-US- 018869		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Dizziness; Feeling Abnormal; Libido	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	3 G, Bid		Jazz	

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Decreased; Nausea	Xyrem	S	Oral	Unknown Decreased Dose	Jazz
	Xyrem	S	Oral	2.25 G, Bid	Jazz
	Xyrem	S	Oral	3 G, Bid	Jazz
	Lexapro	S			Not Reported
	Hydroxyzine Hcl	C			Not Reported
	Ritalin	C			Not Reported
	Marijuana	C			Not Reported
	Spironolactone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16055904	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2019IN01318			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Escitalopram			S	Unknown	Unk		Invagen
	Phenytoin			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16083537	EXPEDITED (15-DAY)		HO	JP-ALLERGAN- 1911070US			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcoholism; Condition Aggravated	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Antihypertensives			C	Oral			Not Reported
	Sulpiride			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16121596	NON-EXPEDITED			US-APOTEX- 2018AP026501		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Persistent Genital Arousal Disorder	Fluoxetine	S	Unknown	Unk	Apotex
	Paroxetine	S	Unknown	Unk	Apotex
	Sertraline	S	Unknown	Unk	Apotex
	Escitalopram	S	Unknown	Unk	Apotex
	Venlafaxine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133550	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2019020585			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Urinary Retention	Escitalopram Oxalate			S	Oral	5 Milligram, Qd		Macleods
	Zytram Bid			S	Oral	75 Milligram, Bid		Not Reported
	Gabapentin			S	Oral	300 Milligram, Tid		Not Reported
	Acetylsalicylic Acid			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133622	EXPEDITED (15-DAY)		HO	FR-ACCORD-116247		44 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Faeces; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Mg, Unk		Not Reported
	Selincro			S	Oral			Not Reported
	Seroplex			S	Unknown	20 Mg, Qd		Not Reported
	Loxen			C	Unknown	1 Df, Qd		Not Reported
	Salbutamol			C	Unknown			Not Reported
	Lexomil			C	Unknown	1 Df, Unk		Not Reported
	Methadone			C	Unknown	80 Mg, Qd		Not Reported
	Kardegic			C	Unknown			Not Reported

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	Theralene		C	Unknown	2 Df, Unk			Not Reported	
	Corgard		C	Unknown	80 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133639	EXPEDITED (15-DAY)		OT	SE-ACCORD-116314		36 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Persistent Genital Arousal Disorder	Escitalopram			S		One Tablet Daily			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133694	EXPEDITED (15-DAY)		OT	HR-ACCORD-116687			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Somnolence; Suicide Attempt	Clonazepam			S	Oral				Not Reported
	Escitalopram			S	Oral				Not Reported
	Caffetin			S	Oral				Not Reported
	[Aminophenazone\Caffeine\Cod eine \Phenacetin] Alprazolam			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133861	EXPEDITED (15-DAY)		HO, OT	IN-TORRENT-00002153		7 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Ineffective	Paracetamol			S					Unknown
	Amitriptyline			S		Unknown			Unknown
	Pregabalin			S		Unknown			Unknown
	Escitalopram			S		Unknown			Unknown
	Paracetamol			S		Unknown			Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16134888	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1027891		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral	Unk		Not Reported	
	Lercan			C	Oral	Unk		Mylan	
	Lormetazepam			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16135206	EXPEDITED (15-DAY)		DS	SE-ALLERGAN-1913939US			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16135357	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1913999US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Hypothermia; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	280 Mg Total		Allergan	
	Noctamide			S	Oral	70mg In Total (35 Of 2mg Tablets)		Not Reported	
	Prazepam			S	Oral	600mg In Total (60 Of 10 Mg)		Not Reported	
	Depakote			S	Oral	850000mg In Total (170 Of 500 Mg)		Not Reported	
	Mianserine			S	Oral	98 Tablets In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16135401	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102287		61 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Oedema; Contusion; Drug Abuse; Drug Diversion; Drug Interaction; Haemorrhage; Osteophyte Fracture; Pneumonia; Pulmonary Oedema; Scab; Skin Abrasion; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage
	Hydrocodone Bitartrate, Acetaminophen			S	Unknown	Unk Unknown, Unknown		Vintage
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported
	Risperdal			S	Unknown	Unk Unknown, Unknown		Not Reported
	Seroquel			S	Unknown	Unk Unknown, Unknown		Not Reported
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Gabapentin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Nicotine			S	Unknown	Unk Unknown, Unknown		Not Reported
	Acetaminophen			S	Unknown	Unk Unknown, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16132123	EXPEDITED (15-DAY)		CA	DE-ACCORD-116318		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Mg/D		Not Reported
	Levothyroxine			C	Transplacental	75 Ug/D		Not Reported
	Xanaflu			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138187	EXPEDITED (15-DAY)		OT	FR-ACCORD-116672		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Head Injury; Loss Of Consciousness; Rhabdomyolysis; Somnolence	Aripiprazole			S	Oral			Not Reported
	Seresta			S	Oral	1/2cp-1/2cp- /1cp,Strength:50 Mg, Scored Tablet		Not Reported

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Tercian	S	Oral	1/2cp-1/2cp- /1cp/J,Strength:25mg	Not Reported
Zyprexa	S	Oral	Strength:5mg	Not Reported
Dafalgan Codeine	S			Not Reported
Seroplex	S	Oral	Strength: 20mg	Not Reported
Oxycontin Lp	S	Oral	Strength:40 Mg Prolonged-Release Film- Coated Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138194	EXPEDITED (15-DAY)		HO	FR-ACCORD-116430		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral			Not Reported
	Kardegic			S	Oral	Strength : 160 Mg Powder For Oral Solution In Sachet		Not Reported
	Inegy			C	Oral	Strength : 10 Mg / 40 Mg		Not Reported
	Spironolactone			C	Oral			Not Reported
	Cardensiel			C	Oral	Strength : 1.25 Mg		Not Reported
	Lasilix			C	Oral			Not Reported
	Esomeprazole/Esomeprazole			C	Oral			Not Reported
	Magnesium/Esomeprazole Sodium							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138211	EXPEDITED (15-DAY)		HO	FR-ACCORD-116915			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138260	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-017053			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Furosemide			S	Oral	10 Milligram, Once A Day		Not Reported
	Candesartan			S	Oral	4 Milligram, Once A Day		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Alprazolam			C	Unknown	Unk		Not Reported
	Spagulax Mucilage Pur			C	Unknown	Unk		Not Reported
	Gaviscon			C	Unknown	Unk		Not Reported
	Voltarene (Diclofenac Diethylamine)			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Rilmenidine			C	Unknown	Unk		Not Reported
	Eupressyl			C	Unknown	Unk		Not Reported
	Loxen L P			C	Unknown	Unk		Not Reported
	Uvedose			C	Unknown	Unk		Not Reported
	Doliprane			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138266	EXPEDITED (15-DAY)		DS, OT	GB-ACCORD-117055		22 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Insomnia; Irritability; Tension	Escitalopram			S	Oral			Not Reported
	Kalms			C		Night		Not Reported
	Sleeppeezy Valerian			C				Not Reported
	Lansoprazole			C				Not Reported
	Diazepam			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16138646	EXPEDITED (15-DAY)		OT	DE-ACCORD-116426		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Stillbirth	Quetiapine			S	Oral	25 Mg/D		Not Reported	
	Escitalopram			S	Oral	20 Mg/D		Not Reported	
	Presinol			S	Oral	500 Mg/D (2x250)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14634733	NON-EXPEDITED			US-PFIZER INC-2018103433		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Toradol			S		Unk		Not Reported	
	Vioxx			S		Unk		Not Reported	
	Imitrex			S		Unk		Not Reported	
	Baclofen			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Ambien			S		Unk		Not Reported	
	Singulair			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14801319	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1025119		72 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulitis; Lower Gastrointestinal Haemorrhage	Escitalopram			S		Unk		Not Reported	
	Xarelto			S		20 Mg, Unk		Mylan	
	Zofenil			C		Unk		Mylan	

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Carbidopa/Levodopa	C	Unk	Mylan
Androtardyl	C	Unk	Mylan
Amoxicillin Sodium And Potassium Clavulanate	C	Unk	Mylan
Requip	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14873407	NON-EXPEDITED			US-PFIZER INC- 2018193089		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Buspar			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	15211691	EXPEDITED (15-DAY)		HO, OT	PHHY2018ES053974			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Omeprazole			S	Oral	Unk		Novartis	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Bendamustine			S	Intravenous (not otherwise specified)	149 Mg, Unk		Not Reported	
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unk		Not Reported	
	Cotrimoxazol			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported	
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported	
	Obinutuzumab			S				Not Reported	
	Obinutuzumab			S				Not Reported	

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Atorvastatin	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	15686835	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1090125		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Bisocel 1,25 Mg, Comprimé Pelliculé			S	Oral	1.25 Milligram, Qd		Mylan
	Lamotrigine			S	Oral	100 Milligram, Qd		Not Reported
	Exemestane			S	Oral	2.5 Milligram, Qd		Not Reported
	Exemestane			S	Oral	25 Unk		Not Reported
	Ramipril			S	Oral	2.5 Milligram, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Milligram, Qd		Not Reported
	Seroplex			S	Oral	5 Milligram, Qd		Mylan
	Gabapentine Winthrop			S	Oral	200 Milligram, Qd		Mylan
	Lasilix /00032601/			S	Oral	20 Milligram, Qd		Mylan
	Levothyroxine Sodium			C	Oral	30 Gtt Drops, Qd		Mylan
	Potassium Gluconate			C	Oral	1 Dosage Form, Qd		Mylan
	Fluidabak			C	Ophthalmic	3 Gtt Drops, Qd		Mylan
	Gluconate Sodium W/Potassium Chloride/Sodium			C	Oral	1 Cs Par Jour		Mylan
	Transipeg /00754501/			C	Oral	11.8 Gram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16069203	EXPEDITED (15-DAY)			SE-ALLERGAN-1910995US			Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event	Escitalopram Oxalate - Bp			S	Oral	10-15 Mg		Allergan
	Sertraline			S	Oral	50 Mg		Not Reported
	Lergigan [Promethazine			C	Unknown	Unk Unk, Prn		Not Reported

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Hydrochloride]
Imovane

C

Unknown

Unk, Prn

Not Reported

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01-Apr-2019	16136935	EXPEDITED (15-DAY)		HO, LT	HU-ACCORD-117289		27 YR	Female	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperthermia; Intentional Overdose; Muscle Rigidity; Myoglobin Blood Increased; Serotonin Syndrome; Suicidal Ideation; Suicide Attempt; Tremor	Escitalopram			S				Not Reported
	Sertraline			S				Accord
	Moclobemide			S		Unk		Not Reported
	Cyproheptadine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16138378	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2016-05975		21 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Delivery	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Levofloxacin /01278901/			C	Unknown	500 Milligram, Qd		Not Reported
	Cefprozil			C	Unknown	1000 Milligram, Qd		Not Reported
	Etodolac			C	Unknown	300 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16141463	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2019M1028600		53 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Intentional Self-Injury; Sluggishness	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Pariet			S	Oral	240 Milligram, Qd		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16142573	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019132467		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Vfend			S	Oral	600 Mg, Unk		Pfizer	
	Bactrim			S	Oral	800 Mg, Alternate Day		Not Reported	
	Doliprane			S	Oral	3 G, Unk		Not Reported	
	Seroplex			S	Oral	20 Mg, 1x/Day		Not Reported	
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Oral	3 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16142739	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1914002US			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Impaired Work Ability	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145583	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-09249		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Gastrointestinal Disorder; Restlessness; Somnolence	Citalopram			S	Unknown	5 Mg, Unk		Not Reported	
	Citalopram			S				Not Reported	
	Sertraline			S	Unknown	12.5 Mg, Unk		Lupin	
	Sertraline			S				Lupin	
	Fluoxetine			S	Unknown	5 Mg, Unk		Lupin	
	Fluoxetine			S				Lupin	
	Escitalopram			S	Unknown	2.5 Mg, Unk		Lupin	
	Escitalopram			S				Lupin	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145590	NON-EXPEDITED			CN-LUPIN PHARMACEUTICALS INC.-2018-09146		15 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypomania; Insomnia	Escitalopram Tablets			S	Unknown	10 Mg, Qd (Tablets)		Lupin	
	Sertraline			S	Unknown	50 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145970	EXPEDITED (15-DAY)		OT	DE-ACCORD-117761		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 Mg/D		Not Reported	
	Tetanus Vaccine			C	Transplacental			Not Reported	
	Levothyroxine			C	Transplacental	5 Mg/D		Not Reported	
	Femibion [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145974	EXPEDITED (15-DAY)		OT	DE-ACCORD-117639			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145985	EXPEDITED (15-DAY)		DS	FR-ACCORD-117236		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral			Not Reported	

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Eliquis	S	Oral	Strength 2.5 Mg	Not Reported
Digoxin	C			Not Reported
Loxen Lp	C		Strength 50 Mg	Not Reported
Lopressor Lp	C		Strength 200 Mg, Breakable Sustained Release Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16146081	EXPEDITED (15-DAY)		HO	IT-ACCORD-117457		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Loss Of Consciousness; Nuchal Rigidity; Pupillary Reflex Impaired; Suicide Attempt	Escitalopram			S	Oral			Not Reported
	Felison			S	Oral	Strength : 30 Mg		Not Reported
	Seroquel			S	Oral	Strength : 100 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral	Strength : 2.5 Mg		Not Reported
	Zoloft			S	Oral	Strength : 100 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16146139	EXPEDITED (15-DAY)		HO	IT-ACCORD-116935		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Wall Haematoma; Cerebral Haemorrhage; Drug Interaction; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral			Not Reported
	Plavix			S	Oral			Not Reported
	Warfarin			S	Oral			Not Reported
	Doxazosin			C				Not Reported
	Esomeprazole			C				Not Reported
	Pregabalin			C				Not Reported
	Furosemide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16147035	NON-EXPEDITED			PHEH2019US014245			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Crying; Diarrhoea; Hot Flush; Myalgia; Upper Respiratory Tract Infection; Weight Increased	Letrozole			S	Unknown			Novartis
	Ibrance			S	Unknown			Not Reported
	Taxol			S	Unknown			Not Reported
	Lexapro			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16149459	EXPEDITED (15-DAY)		DE	FR-NAPPMUNDI-GBR- 2019-0065408		79 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bedridden; Malaise; Pain	Oxynormoro			S	Oral	4 Df, Daily (5mg Strength; Si Douleur)		Purdue
	Alprazolam			S	Oral	1 Df, Daily		Not Reported
	Levodopa-Carbidopa			S	Oral	1 Df, Daily (1 Cp Au Coucher)		Not Reported
	Modopar			S	Oral	4 Df, Daily (2cp A 16h Et 2cp Le Soir)		Not Reported
	Clozapine			S	Oral	1 Df, Daily (1 Cp Le Soir)		Not Reported
	Acupan			S	Sublingual	4 Df, Daily		Not Reported
	Doliprane			S	Oral	Unk		Not Reported
	Sinemet Plus			S	Oral	2 Df, Daily (1cp Matin Et 1cp Midi)		Not Reported
	Dutasteride			S	Oral	1 Df, Daily		Not Reported
	Escitalopram Oxalate			S	Oral	1 Df, Daily (1 Cp Matin)		Not Reported
	Monocrixo			S	Oral	Unk		Not Reported
	Rivastigmine			S	Transdermal	1 Df, Daily (9.5 Mg/24 Heures)		Not Reported
	Tramadol And Acetaminophen			S	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	15680050	EXPEDITED (15-DAY)		OT	PT-MACLEODS PHARMACEUTICALS US LTD- MAC2018018939			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown	20 Milligram		Macleods	
	Insulin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	15995716	EXPEDITED (15-DAY)		HO	FR-009507513- 1902FRA006378		92 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Leukopenia; Thrombocytopenia	Invanz			S	Subcutaneous	1 Gram, Qd		Merck	
	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported	
	Ceftriaxone Sodium			S	Subcutaneous	1 Gram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16043750	NON-EXPEDITED			US-SUNOVION- 2019SUN000793		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Myalgia; Off Label Use	Latuda			S	Oral	40 Mg		Sunovion	
	Latuda			S	Oral	20 Mg		Sunovion	
	Lexapro			S		20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16150407	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE- 1032127		44 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Genital Haemorrhage; Paraesthesia	Escitalopram Teva 10 Mg Filmragerad Tablett	S	Oral	10 Milligram Daily;	Ivax
	Escitalopram Teva 10 Mg Filmragerad Tablett	S			
	Montelukast	C			
	Symbicort Turbuhaler	C			Inhalator

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16151324	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2019-017143			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram			S	Oral	10 Microgram, Daily		Aurobindo

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16152444	EXPEDITED (15-DAY)		CA	DE-ACCORD-118170		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 Mg/D (5)		Not Reported
	Skinoren			C	Transplacental			Not Reported
	Folic Acid			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16153191	EXPEDITED (15-DAY)		HO	FR-ACCORD-117372		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Escitalopram			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Xgeva			S	Subcutaneous			Not Reported
	Aromasine			C	Oral	25 Mg, Coated Tablet		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16153621	EXPEDITED (15-DAY)		OT	GB-ACCORD-116825		37 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dry Skin; Dyspnoea; Fatigue; Hypoaesthesia; Nausea; Paraesthesia; Urticaria	Amitriptyline			S	Oral			Accord	
	Ciprallex			S	Oral			Not Reported	
	Calcium Gluconate			C				Not Reported	
	Zinc			C				Not Reported	
	Vitamin B Complex			C				Not Reported	
	Magnesium Hydroxide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16154179	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1032860		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram Oxalate			S	Oral	10 Microgram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16154318	EXPEDITED (15-DAY)		DE, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2019-02934		40 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Amlodipine Besylate			S	Unknown	Unk		Alkem	
	Duloxetine Hydrochloride			S	Unknown	Unk		Alkem	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Atenolol			S	Unknown	Unk		Not Reported	
	Trazodone			S	Unknown	Unk		Not Reported	
	Losartan			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16154726	EXPEDITED (15-DAY)		DS	SE-TEVA-2019-SE-1031897		61 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16155399	EXPEDITED (15-DAY)		DE	FR-009507513-1903FRA011015		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Malaise; Pain	Sinemet L.P.			S	Oral	1 Tablet In The Morning And 1 Tablet At Lunch		Merck	
	Alprazolam			S	Oral	1 Dosage Form, Qd		Not Reported	
	Carbidopa (+) Levodopa			S	Oral	One Tablet At Bedtime		Not Reported	
	Modopar			S	Oral	Two Tablets At 4 Pm And 2 Tablets In The Evening		Not Reported	
	Clozapine			S	Oral	1 Tablet In The Evening		Not Reported	
	Acupan			S	Sublingual	4 Dosage Form, Qd		Not Reported	
	Doliprane			S	Oral	Formulation: Powder For Oral Solution In Single-Dose		Not Reported	
	Dutasteride			S	Oral	1 Dosage Form, Qd. Formulation: Soft Capsule		Not Reported	
	Escitalopram			S	Oral	1 Tablet In The Morning. Formulation: Scored Film Coated Tablet		Not Reported	
	Oxynormoro			S	Oral	If Pain		Not Reported	
	Monocrixo			S	Oral	Unk		Not Reported	
	Rivastigmine			S	Transdermal	1 Dosage Form, Qd. Strength: 9.5 Mg/24 Hours		Not Reported	
	Acetaminophen (+) Tramadol Hydrochloride			S	Oral	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	14108082	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1064740			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Product Misuse; Intentional Self-Injury; Sopor	Delorazepam			S	Oral	Unk		Not Reported	
	Losartan			S	Oral	Unk		Not Reported	
	Haldol			S	Oral	Unk		Mylan	
	Escitalopram			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	15196839	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-932723			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia; Ventricular Tachycardia	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4 Mg, Cyclic		Cephalon	
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Ivax	
	Omeprazole			S	Oral	Unk Unk, Unknown Freq.		Teva	
	Obinutuzumab			S	Intravenous (not otherwise specified)			Not Reported	
	Cotrimoxamol			S	Unknown			Not Reported	
	Atorvastatin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Valsartan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	15543065	EXPEDITED (15-DAY)		OT	EE-PFIZER INC-2018430237		27 YR	Female	EST
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agoraphobia; Akathisia; Anger; Anxiety; Autophobia; Derealisation; Fatigue; Fear Of Death;	Efexor Xr			S		37.5 Mg, 1x/Day, Qd		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Valdoxan			S		25 Mg, 1x/Day, Qd		Not Reported	

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Impaired Quality Of Life;	Valdoxan	S		12.5 Mg, 1x/Day, Qd	Not Reported
Insomnia; Nightmare;	Valdoxan	S	Oral	Unk, 1x/Day	Not Reported
Palpitations; Panic	Oxazepam	C		Unk	Not Reported
Disorder; Paraesthesia;	Diazepam	C		Unk	Not Reported
Product Use Issue;					
Product Use Issue;					
Restlessness; Suicidal					
Ideation; Visual					
Impairment; Vomiting;					
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16007373	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1015354		92 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Leukopenia; Thrombocytopenia	Escitalopram Arrow 5 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms Daily;		Ivax
	Invanz 1 G, Poudre Pour Solution À Diluer Pour Perfusion			S	Subcutaneous	1 Gram Daily;		Not Reported
	Triacefan			S	Subcutaneous	1 Gram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16070927	EXPEDITED (15-DAY)		HO	DE-TORRENT-00013501		44 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy	Escitalopram			S	Oral			Unknown
	Olanzapin			C	Oral	Daily Dose: 15 Mg Milligram(S) Every Days, 7.5 Mg 2x		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16155898	EXPEDITED (15-DAY)		HO	GB-ACCORD-117613		56 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyarrhythmia;	Escitalopram			S	Oral			Not Reported

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Circulatory Collapse		Elleste-Solo		C	Transdermal		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16156800	EXPEDITED (15-DAY)		HO, OT	US-TAKEDA-2019TUS019364		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Macular Degeneration	Trintellix			S	Unknown	5 Milligram		Takeda	
	Trintellix			S	Unknown	10 Milligram		Takeda	
	Nortriptyline			S	Unknown	Unk		Not Reported	
	Seroquel			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Donepezil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16157823	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1032580		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan Cilexetil			S	Oral	4 Milligram Daily;		Not Reported	
	Pantoprazole			S	Oral	40 Milligram Daily;		Teva	
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Furosemide			S	Oral	10 Milligram Daily;		Actavis	
	Alprazolam			C				Not Reported	
	Spagulax Mucilage Pur, Granulés			C				Not Reported	
	Gaviscon			C				Not Reported	
	Voltarene Emulgel 1 %, Gel			C				Not Reported	
	Levothyrox			C				Not Reported	
	Rilmenidine			C				Not Reported	
	Eupressyl			C				Not Reported	
	Loxen L P 50 Mg, Gélule À Libération Prolongée			C				Not Reported	
	Uvedose 100 000 Ui, Solution Buvable En Ampoule			C		In Ampoule		Not Reported	
	Doliprane			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158036	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1030667		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Product Substitution Error	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Idaptan			S	Oral	20 Milligram, Bid		Mylan	
	Nifedipino			C	Oral	20 Milligram, Bid		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158299	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE48629		58 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Quetiapine Fumarate			S	Oral	1.0df Once/Single Administration		Zeneca	
	Escitalopram Oxalate			S	Oral	1.0df Once/Single Administration		Not Reported	
	Lorazepam			C				Not Reported	
	Depakin Chrono			C				Not Reported	
	Clonazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158319	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1030535		66 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Escitalopram			S	Oral	20 Mg, Unk		Not Reported	
	Iberogast			S	Oral	20 Gtt Drops, Tid (60 Drop, Qd)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158749	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1031949		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bedridden; Malaise; Pain	Levodopa Carbidopa Teva	S	Oral	1 Dosage Forms Daily; 1 Cp At Bedtime	Not Reported				
	Alprazolam Mylan 0,25 Mg, Comprimé Sécable Modopar	S	Oral	1 Dosage Forms Daily;	Not Reported				
		S	Oral	4 Dosage Forms Daily; 2cp At 16h And 2cp In The Evening	Not Reported				
	Clozapine Merck 25 Mg, Comprimé Sécable	S	Oral	1 Dosage Forms Daily; 1 Cp In The Evening	Not Reported				
	Acupan, Solution Injectable	S	Sublingual	4 Dosage Forms Daily;	Not Reported				
	Doliprane 1000 Mg, Poudre Pour Solution Buvable En Sachet-Dose	S	Oral		Not Reported				
	Sinemet 250 Mg/25 Mg, Comprimé Sécable	S	Oral	2 Dosage Forms Daily; 1cp Morning And 1cp Noon	Not Reported				
	Dutasteride Sandoz 0,5 Mg, Capsule Molle	S	Oral	1 Dosage Forms Daily;	Not Reported				
	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable	S	Oral	1 Dosage Forms Daily; 1 Morning Cp	Not Reported				
	Oxynormoro 5 Mg, Comprimé Orodispersible	S	Oral	1 Dosage Forms Daily; If Pain	Not Reported				
	Monocrixo	S	Oral		Not Reported				
	Rivastigmine Mylan Pharma 9,5 Mg/24 Heures, Dispositif Transdermique	S	Transdermal	1 Dosage Forms Daily;	Not Reported				
	Tramadol Paracetamol Mylan Generiques	S	Oral		Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158825	EXPEDITED (15-DAY)		OT	BR-SA-2019SA072678		40 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dengue Fever; Dermatitis; Drug Hypersensitivity; Erythema; Malaise;	Stilnox Cr			S	Oral	1 Df, Qd		Sanofi	
	Escitalopram Oxalate			S	Oral	,Half Tablet Before		Not Reported	

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Urticaria; White Blood Cell Count Decreased	Araceli	C	Oral	Sleeping 1 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	13991608	EXPEDITED (15-DAY)		HO, OT	PHHY2017NO134618		21 YR	Male	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Aggression;	Olanzapine			S	Unknown	Unk		Novartis
Agitation; Alcohol Abuse;	Valproate Sodium			S	Unknown	Unk		Not Reported
Bipolar Disorder;	Seroxat			S	Unknown	Unk		Not Reported
Depression; Derealisation;	Seroxat			S	Unknown	20 Mg, Qd		Not Reported
Disturbance In Attention;	Efexor			S	Unknown	Unk		Not Reported
Disturbance In Social	Efexor			S	Unknown	Unk		Not Reported
Behaviour; Dizziness;	Efexor			S	Unknown	Unk		Not Reported
Drug Abuse; Drug Abuse;	Efexor			S	Unknown	Unk		Not Reported
Drug Ineffective; Head	Efexor			S	Unknown	Unk		Not Reported
Injury; Hypomania;	Cipramil (Citalopram Hydrobromide)			S	Unknown	10 Mg, Qd		Not Reported
Impaired Work Ability;	Cipramil (Citalopram Hydrobromide)			S	Unknown	60 Mg, Qd		Not Reported
Irritability; Judgement	Lamictal			S	Unknown	Unk		Not Reported
Impaired; Logorrhoea;	Seroquel			S	Oral	Unk		Not Reported
Malaise; Mania; Mania;	Seroquel			S	Oral	Unk		Not Reported
Memory Impairment;	Seroquel			S	Oral	Unk		Not Reported
Personality Disorder;	Cipralext			S	Unknown	Unk Unk, Qd		Not Reported
Product Complaint; Quality	Orfiril			S	Unknown	Unk		Not Reported
Of Life Decreased;	Zyprexa			S	Unknown	Unk		Not Reported
Restlessness	Lithionit			C	Unknown	Unk		Not Reported
	Lithionit			C	Unknown	Unk		Not Reported
	Sobril			C	Unknown	Unk, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15207475	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS			Unknown	ESP

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US LTD-
MAC2018015689

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Omeprazole			S	Oral			Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Obinutuzumab			S				Not Reported
	Co-Trimoxazole			S	Unknown			Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Milligram		Not Reported
	Bendamustine Incb050465			S	Oral	20 Milligram, Tablet		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15667410	EXPEDITED (15-DAY)		DE, HO, OT	FR-009507513-1811FRA010604		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Mirtazapine			S	Oral	Unk		Merck
	Lysanxia			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported
	Seroplex			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15993212	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-008805			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Leukopenia; Thrombocytopenia	Escitalopram Arrow Film-Coated Tablet 5mg			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Triacefan			S	Subcutaneous	1 Gram, Once A Day		Not Reported	
	Invanz			S	Subcutaneous	1 Gram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15993329	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR- APL-2019-009079			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Herbal Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo	
	Ginseng			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Ginkgo Biloba			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16133582	EXPEDITED (15-DAY)		OT	FR-ACCORD-116710		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Drug Interaction; Drug Withdrawal Syndrome; Hyperhidrosis; Hypertensive Crisis; Insomnia; Malaise; Panic Attack; Tachycardia; Tremor	Escitalopram			S	Unknown	15 Mg, Once A Day		Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Bromazepam			S				Not Reported	
	Thiocolchicoside			S	Unknown	8 Mg, Two Times A Day, Also Received Unk Dose From Apr-2016		Not Reported	
	Bromazepam			C	Unknown	4.5 Mg, Unk		Not Reported	
	Amlodipine			C		Also Received Additionally Unk Dose		Not Reported	
	Perindopril/Perindopril Erbumine			C				Not Reported	
	Escitalopram			C				Not Reported	

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05-Apr-2019	16136376	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1914003US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram Oxalate Unk			S	Oral	1 Df, In Total		Allergan	
	Quetiapine Fumarate			S	Oral	1 Df, In Total		Not Reported	
	Lorazepam			C	Unknown			Not Reported	
	Depakin Chrono			C	Unknown	1500 Mg		Not Reported	
	Clonazepam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16160472	NON-EXPEDITED			US-TEVA-2019-US-1025851			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram Oxalate			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16160652	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.-2019IN01674			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Resistance; Treatment Failure	Escitalopram			S	Unknown	Unk		Invagen	
	Venlafaxine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16160672	EXPEDITED (15-DAY)		OT	TR-MACLEODS PHARMACEUTICALS US LTD-MAC2016003593			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During	Escitalopram Oxalate			S	Unknown	10 Mg, Qd		Macleods	

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Pregnancy	Nifedipine	C	Unknown	30 Mg, Qd	Not Reported
	Trimetazidine	C	Unknown	40 Mg, Qd	Not Reported
	Zofenopril	C	Unknown	30 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161448	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-017512			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram			S	Unknown	20 Milligram		Aurobindo
	Minerals Nos;Vitamins Nos			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161734	NON-EXPEDITED			US-PFIZER INC-2019143339			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161875	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2019-018042			Unknown	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram Film-Coated Tablets			S	Oral	1 Dosage Form, Daily		Aurobindo

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16165207	EXPEDITED (15-DAY)		HO	EG-TAKEDA-2019TUS019045		56 YR	Female	EGY
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressive Symptom; Drug Ineffective; Hypomania; Irritability; Product Use In Unapproved Indication; Social Avoidant Behaviour; Suicidal Ideation	Brintellix			S	Unknown	10 Milligram		Takeda	
	Ciprallex /01588501/			S	Unknown	10 Milligram		Not Reported	
	Lithium			S	Unknown	400 Milligram		Not Reported	
	Lithium			S	Unknown	600 Milligram		Not Reported	
	Tegretol Cr			S	Unknown	Unk		Not Reported	
	Tegretol Cr			S	Unknown	600 Milligram		Not Reported	
	Seroquel			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	5 Milligram, Bid		Not Reported	
	Cymbalta			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	0.5 Milligram, Bid		Not Reported	
	Prozac			S	Unknown	Unk		Not Reported	
	Effexor			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16133806	EXPEDITED (15-DAY)		HO	FR-ACCORD-116846		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Paroxetine			S	Oral			Not Reported	
	Prazepam			S	Oral			Not Reported	
	Cocaine			S	Unknown	0.5g		Not Reported	
	Tercian			S	Oral			Not Reported	
	Atarax			S	Oral			Not Reported	

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	Valium		S	Oral				Not Reported	
	Alcool		S	Oral	Unspecified			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16165851	NON-EXPEDITED			US-VIIV HEALTHCARE LIMITED-US2019GSK060618		31 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Muscular Weakness	Juluca			S		Unk		Viiv	
	Wellbutrin			S		Unk		Glaxosmithkline	
	Gabapentin			S		Unk		Glaxosmithkline	
	Finasteride			S		Unk		Glaxosmithkline	
	Lexapro			S		Unk		Not Reported	
	Mirtazapine			S		Unk		Not Reported	
	Strattera			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16165852	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK060618		31 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Muscular Weakness	Juluca			S		Unk		Viiv	
	Wellbutrin			S		Unk		Glaxosmithkline	
	Gabapentin			S		Unk		Glaxosmithkline	
	Finasteride			S		Unk		Glaxosmithkline	
	Lexapro			S		Unk		Not Reported	
	Mirtazapine			S		Unk		Not Reported	
	Strattera			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16165883	EXPEDITED (15-DAY)		CA	DE-ACCORD-118269			Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 (Mg/D)		Not Reported	
	Levothyroxine			C	Transplacental	112 (Ug/D (Bis 75 Ug/D))		Not Reported	
	Femibion Pregnancy 1			C	Transplacental	0.8 (Mg/D)		Not Reported	
	Progestan			C	Transplacental	600 (Mg/D (3 X 200 Mg/D))		Not Reported	
	Dekristol			C	Transplacental	2000 (I.E./D (Bis 1000 I.E./D))		Not Reported	
	Progynova			C	Transplacental	3 (Mg/D (3 X 1 Mg/D))		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16165993	EXPEDITED (15-DAY)		CA	NL-ACCORD-118605			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16166157	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-118938		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Logorrhoea; Seizure; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
	Lithium			S	Oral			Not Reported	
	Tercian			S	Oral			Not Reported	
	Valium			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16166201	EXPEDITED (15-DAY)		OT	IE-ACCORD-119106			Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hallucination; Product Substitution Issue	Escitalopram Accord	S	Oral	Strength 5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	12316100	NON-EXPEDITED			US-JAZZ-2015-US-012071		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anxiety; Panic Attack; Stress	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	3.75 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Ritalin			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Vortioxetine			S				Not Reported	
	Sumatriptan			C		Unk		Not Reported	
	Klonopin			C		Unk		Not Reported	
	Norco			C		10-325		Not Reported	
	Verapamil			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	14332694	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2017M1082248		19 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Parkinsonism	Aripiprazole			S	Oral	2.5 Mg, Qd		Not Reported	
	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported	
	Cipralext /01588502/			S	Oral	5 Mg, Qd		Mylan	
	Cipralext /01588502/			S	Oral	10 Mg, Qd		Mylan	

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Ciprallex /01588502/	S	Oral	15 Mg, Qd	Mylan
Methylprednisolone	C	Unknown	Unk	Mylan
Probiotics /07325001/	C	Unknown	Unk, Qd	Mylan
Zoldem	C	Oral	Unk	Mylan
Zoldem	C	Oral	5 Mg, Qd	Mylan
Zoldem	C	Oral	10 Mg, Qd	Mylan
Zoldem	C		Unk	Mylan
Zoldem	C		Unk	Mylan
Zolpidem	C	Oral	10 Mg, Unk	Mylan
Atarax /00058401/	C	Unknown	Unk	Mylan
Atarax /00058401/	C	Oral	1 Df, Qd,25-50 Mg 1 Df, Qd	Mylan
Atarax /00058401/	C	Oral	25 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	50 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	25 Mg, Qd	Mylan
Atarax /00058401/	C	Oral	50 Mg, Unk	Mylan
Atarax /00058401/	C		25 Mg, Unk	Mylan
Sertraline Hydrochloride	C	Unknown	50 Mg, Qd	Mylan
Sertraline Hydrochloride	C	Unknown	Unk	Mylan
Sertraline Hydrochloride	C	Unknown	25 Milligram, Qd	Mylan
Seroquel	C	Unknown	75 Mg, Qd	Mylan
Seroquel	C	Unknown	50 Mg, Qd	Mylan
Hova	C	Unknown	1 Df, Unk	Mylan
Temesta /00273201/	C	Unknown	1 Df, Qd, 1-2 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg, Unk	Mylan
Mexalen	C	Oral	500 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg ,Qd	Mylan
Mexalen	C	Oral	500 Mg, Qd	Mylan
Mexalen	C	Oral	500 Mg, Unk	Mylan

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Aerius /01009701/	C	Unknown	5 Mg, Qd	Mylan
Praxiten	C	Oral	15 Mg, Qd	Mylan
Praxiten	C	Oral	7.5 Mg, Qd	Mylan
Praxiten	C	Oral	15 Mg, Qd	Mylan
Praxiten	C	Unknown	Unk	Mylan
Praxiten	C	Oral	15 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	14972719	NON-EXPEDITED			US-PFIZER INC-2018225421		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Advil			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Bystolic			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Paxil [Paroxetine Hydrochloride]			S		Unk		Not Reported
	Coreg Cr			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	15340180	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1064798		44 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Malaise; Tremor; Vertigo	Leponex			S	Oral	150 Mg, Qd		Mylan
	Escitalopram			S	Oral	15 Mg, Qd		Not Reported
	Deniban			S	Oral	25 Mg, Qd		Mylan
	Valium			S	Oral	16 Gtt, Qd		Mylan
	Arlevertan			S	Oral	3 Df, Qd		Mylan
	Resilient			S	Oral	1 Df, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	15800258	EXPEDITED (15-DAY)		DE, HO, OT	FR-ALLERGAN-1900871US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Norset			S	Oral	Unk		Not Reported
	Lysanxia			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	15960041	EXPEDITED (15-DAY)		HO	IT-ACCORD-106763		85 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Medication Error; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported
	Glyceryl Trinitrate			C	Transdermal			Not Reported
	Formodual			C	Respiratory (inhalation)			Not Reported
	Annister			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16166956	EXPEDITED (15-DAY)		HO, LT, OT	GB-SA-2019SA093597		84 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypotension	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Furosemide			S	Oral	20 Mg, Qd		Sanofi	
	Irbesartan			S	Oral	75 Mg, Qd		Sanofi	
	Braltus			C				Not Reported	
	Seretide			C		125		Not Reported	
	Simvastatin			C		40 Mg		Not Reported	
	Zapain			C		1-2 Four Times Daily		Not Reported	
	Salbutamol			C		Unk		Not Reported	
	Sando K [Potassium Bicarbonate;Potassium Chloride]			C		Various Acute Scripts		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16166972	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-204299		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan			S	Oral	4 Milligram, Daily		Not Reported	
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported	
	Pantoprazole			S	Oral	40 Milligram, Daily		Sun	
	Furosemide			S	Oral	10 Milligram, Daily		Not Reported	
	Alprazolam			C	Unknown	()		Not Reported	
	Spagulax Mucilage Pur, Granules			C	Unknown	()		Not Reported	
	Gaviscon			C	Unknown	()		Not Reported	
	Voltarene Emulgel 1 %, Gel			C	Unknown	()		Not Reported	
	Levothyrox			C	Unknown	()		Not Reported	

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Rilmenidine	C	Unknown	()	Not Reported
Eupressyl	C	Unknown	()	Not Reported
Loxen L P 50 Mg, Gelule A Liberation Prolongee	C	Unknown	()	Not Reported
Uvedose 100 000 Ui, Solution	C	Unknown	()	Not Reported
Buvable En Ampoule	C	Unknown	()	Not Reported
Doliprane	C	Unknown	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16167373	EXPEDITED (15-DAY)		OT	NL-ACCORD-118852		61 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthyroidism	Escitalopram			S		1dd,Strength:10 Mg		Not Reported	
	Propylthiouracil			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16167456	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1034906		24 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown			Ivax	
	Clozapine			C	Unknown	Dose Was Gradually Increased To 600mg Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16168898	EXPEDITED (15-DAY)		HO, LT, OT	GB-TORRENT-00020752		84 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypotension	Furosemide			S	Oral			Unknown	
	Irbesartan Hydrochloride			S	Oral	Unknown		Unknown	
	Braltus			C		Unknown		Unknown	
	Seretide			C		125		Unknown	
	Simvastatin			C		Unknown		Unknown	

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Zapain	C	As Necessary, 1-2 Four Times Daily	Unknown
Escitalopram	S	Oral	Unknown
Salbutamol	C		Unknown
Sando-K	C	Various Acute Scripts	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16169329	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK034221			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Wellbutrin			S				Glaxosmithkline	
	Ativan			S				Not Reported	
	Lexapro			S				Not Reported	
	Pamelor			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16171199	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1032221		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence	Alprazolam			S	Unknown	Non Renseignee		Not Reported	
	Escitalopram			S	Unknown	Non Renseignee		Not Reported	
	Dafalgan Codeine			S	Unknown	Non Renseignee		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16173143	DIRECT		OT			44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Product Substitution Issue	Escitalopram			S	Oral	Quantity:30 Tablet(S);		Cipla	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	14923451	EXPEDITED (15-DAY)		HO, OT	ES-ALLERGAN-1826240US			Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram Oxalate Unk			S	Unknown	Unk, Unknown		Allergan
	Omeprazol			S	Oral	Unk, Unknown		Not Reported
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown		Not Reported
	Cotrimoxazol			S	Unknown	Unk Unk, Unknown		Not Reported
	Atorvastatin			C		Unk Unk, Unknown		Not Reported
	Valsartan			C	Unknown	Unk Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	15708617	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP026139		64 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Escitalopram			S	Unknown	Unk, Unknown		Apotex
	Omeprazole			S	Oral	Unk Unk, Unknown		Apotex
	Obinutuzumab			S	Intravenous (not otherwise specified)	)1000 Mg, Unknown (1000 Mg, Unknown)		Not Reported
	Bendamustine			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown (149.4 Mg, Unknown)		Not Reported
	Cotrimoxazol			S	Unknown	Unk, Unknown		Not Reported
	Atorvastatin			C	Unknown	Unk, Unknown		Not Reported
	Valsartan "Nichi Iko"			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	15977322	NON-EXPEDITED			US-SUNOVION-2019SUN000555			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Somnolence; Weight Increased	Latuda			S	Oral	40 Mg		Sunovion

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Lexapro			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Apr-2019	16093936	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP009688		45 YR	Female	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Libido Decreased; Loss Of Libido; Sexual Dysfunction	Escitalopram			S	Unknown	10 Mg, Qd (10 Milligram, Daily)		Apotex		
	Sertraline			S	Oral	50 Mg, Qd (50 Milligram, Daily)		Apotex		
	Sertraline			S	Oral	100 Mg, Qd (100 Milligram, Daily)		Apotex		
	Enalapril			C	Oral	20 Mg, Qd (20 Milligram)		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Apr-2019	16120551	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01535		56 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Erectile Dysfunction; Sexual Dysfunction	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	1.5 Dosage Form, Qd		Lupin		
	Escitalopram Oxalate Tablets Usp, 10 Mg			S	Oral	1.5 Dosage Form, Qd		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Apr-2019	16171954	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-017991			Unknown	POL	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Haemorrhage; Herbal Interaction	Escitalopram			S	Unknown	Unk		Aurobindo		
	Ginkgo Biloba			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Apr-2019	16173353	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-017892			Unknown	ITA	

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	1 Dosage Form, In Total		Aurobindo
	Quetiapine			S	Oral	1 Dosage Form, In Total		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported
	Depakin Chrono			C	Unknown	1500 Milligram		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16174079	EXPEDITED (15-DAY)		HO	CR-GLAXOSMITHKLINE-CR2019062785		38 YR	Male	CRI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Migraine	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Escitalopram			S	Unknown	50 Mg, Qd		Glaxosmithkline
	Sertraline			S	Unknown	50 Mg, Qd		Glaxosmithkline
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline
	Sumatriptan			S	Unknown	Unk		Glaxosmithkline
	Celecoxib			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	50 Mg, Qd		Not Reported
	Valproic Acid			S	Unknown	500 Mg, Qd		Not Reported
	Desvenlafaxine			S	Unknown	50 Mg, Qd		Not Reported
	Propranolol			S	Unknown	40 Mg, Bid		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Eletriptan			S	Unknown	Unk		Not Reported
	Rizatriptan			S	Unknown	Unk		Not Reported
	Frovatriptan			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16176748	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1915629US			Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Movement Disorder; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan	
	Pritor (Telmisartan)			S	Unknown	40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	14228105	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1767805US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Motor Developmental Delay; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder; Speech Disorder Developmental	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
	Xanax			S	Transplacental			Not Reported	
	Stilnox			S	Transplacental			Not Reported	
	Seresta			S	Transplacental			Not Reported	
	Donormyl (Doxylamine Succinate)			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15325509	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1841350US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual; Intentional Overdose; Product Use Issue; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 40mg; In Total		Allergan	
	Seresta			S	Oral	10 Mg; In Total		Not Reported	
	Paracetamol			S	Oral	2 G; In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15562774	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1080835		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Loss Of	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported	
	Escitalopram			S				Not Reported	

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Libido	Escitalopram	S	Unknown	22.5 Mg, Qd/Every Bedtime	Not Reported
	Mirtazapine	S			Not Reported
	Mirtazapine	S	Unknown	1 Mg/Tid When Necessary	Not Reported
	Mirtazapine	S			Not Reported
	Alprazolam	S			Not Reported
	Alprazolam	S	Unknown	100 Mg, Tid	Not Reported
	Alprazolam	S			Not Reported
	Lamotrigine	S			Not Reported
	Lamotrigine	S	Unknown	20 Mg, Qd/Every Morning	Not Reported
	Lamotrigine	S			Not Reported
	Enalapril	S			Not Reported
	Lansoprazole	S	Unknown	30 Mg, Qd/Every Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15566692	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20181028115		86 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Electrocardiogram Qt Prolonged	Apalutamide			S	Oral			Not Reported
	Seroplex			S	Unknown			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Decapeptyl [Gonadorelin]			C	Unknown			Not Reported
	Cotareg			C	Unknown			Not Reported
	Lercan			C	Unknown			Not Reported
	Tahor			C	Unknown			Not Reported
	Escitalopram			C	Oral			Not Reported
	Valsartan			C	Oral			Not Reported
	Lercanidipine			C				Not Reported
	Rabeprazole			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15629042	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1853816US			Female	JPN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15752886	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1858509US			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ankle Fracture; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15968465	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-1906475US			Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Disorder; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Clozapine			C	Unknown	600 Mg, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177239	EXPEDITED (15-DAY)		HO	FR-ACCORD-120278		40 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Libido Disorder; Priapism	Escitalopram			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177944	NON-EXPEDITED			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-02513		29 YR	Male	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Emotional Poverty; Libido Decreased; Off Label Use	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Quetiapine Fumarate			S	Unknown	12.5 Mg, At Night		Alkem	

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Quetiapine Fumarate			S			Alkem			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16178002	EXPEDITED (15-DAY)		OT	FR-ACCORD-120090		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Dependence	Escitalopram			S	Oral			Not Reported	
	Diazepam			S	Oral			Accord	
	Imovane			S	Oral			Not Reported	
	Theralene			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16178009	EXPEDITED (15-DAY)		OT	IT-ACCORD-120233		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Incorrect Dose Administered; Sopor	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16178182	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-019307			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16178329	EXPEDITED (15-DAY)		HO, LT, OT	GB-LUPIN PHARMACEUTICALS INC.-2019-02153		84 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypotension	Irbesartan			S	Oral	75 Milligram, Qd		Lupin	

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Escitalopram	S	Oral	10 Milligram, Qd	Lupin
Furosemide	S	Oral	20 Milligram, Qd	Not Reported
Zapain	C	Unknown	Unk Unk, Prn (1-2 Four Times Daily)	Not Reported
Simvastatin	C	Unknown	40 Milligram	Not Reported
Seretide	C		Unk (125)	Not Reported
Salbutamol	C	Unknown	Unk	Not Reported
Braltus	C	Unknown	Unk	Not Reported
Sando K /00031402/	C	Unknown	Unk (Various Acute Scripts)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16180926	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1915608US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Macular Degeneration	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Trintellix			S	Unknown	10 Mg		Not Reported
	Trintellix			S	Unknown	5 Milligram		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported
	Seroquel			S	Unknown	Unk		Not Reported
	Donepezil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181104	EXPEDITED (15-DAY)		HO, OT	PHHY2018FR085207		10 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol			S	Oral	2 G, Total		Not Reported
	Seroplex			S	Oral	40 Mg, Total		Not Reported
	Seresta			S	Oral	10 Mg, Total		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181623	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1033063		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Liver Disorder	Escitalopram			S	Oral	10 Milligram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181712	EXPEDITED (15-DAY)		OT	NP-DSJP-DSU-2019-112814			Unknown	NPL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenia Gravis	Olmesartan Medoxomil			S	Unknown	Unk		Daiichi	
	Amlodipine			S	Unknown	Unk		Not Reported	
	Carvedilol			S	Unknown	Unk		Not Reported	
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Aspirin /00002701/			S	Unknown	Unk		Not Reported	
	Hydralazine			S	Unknown	Unk		Not Reported	
	Losartan			S	Unknown	Unk		Not Reported	
	Finasteride			S	Unknown	Unk		Not Reported	
	Niacin			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Pantoprazole			S	Unknown	Unk		Not Reported	
	Simvastatin			S	Unknown	Unk		Not Reported	
	Nitroglycerin			S	Unknown	Unk		Not Reported	
	Acetaminophen			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16182042	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1915634US			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Drug Interaction; Dry Mouth; Hyperhidrosis; Sleep Disorder	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
	Omeprazole	S	Oral	40 Mg, Qd	Not Reported
	Tranxilium	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16182045	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1915771US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram Oxalate - Bp			S	Unknown	15 Mg		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16183856	DIRECT	Y	OT			33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Nausea	Lexapro			S	Oral		3 WEEK	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16182341	EXPEDITED (15-DAY)		OT	GB-ROCHE-2157437			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Klonopin			S	Unknown			Not Reported	
	Prozac			S	Unknown			Not Reported	
	Zoloft			S	Unknown			Not Reported	
	Celexa			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Effexor			S	Unknown			Not Reported	

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	Ambien		S	Unknown				Not Reported	
	Adderall		S	Unknown				Not Reported	
	Desipramine		S	Unknown				Not Reported	
	Zyprexa		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16182462	NON-EXPEDITED			US-APOTEX-2019AP009750		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Rash; Rash Papular; Rash Pruritic	Escitalopram			S	Unknown	5 Mg, Qd		Apotex	
	Escitalopram			S				Apotex	
	Loratadine			C	Unknown	Unk		Not Reported	
	Albuterol /00139501/			C	Unknown	Unk		Not Reported	
	Budesonide W/Formoterol			C	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16183108	EXPEDITED (15-DAY)		OT	US-ACCORD-119872		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dysuria; Eye Irritation; Malaise	Escitalopram Accord			S				Not Reported	
	Ativan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16183222	NON-EXPEDITED			US-SHIRE-US201911842			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Concussion; Disturbance In Attention	Vyvanse			S	Unknown	50 Milligram, 1x/Day:Qd		Shire	
	Adderall Xr			S	Unknown	Unk, 1x/Day:Qd		Shire	
	Lexapro			S	Unknown	10 Milligram		Not Reported	

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11-Apr-2019	16184129	NON-EXPEDITED			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM- 2018-02932		58 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Partial Responder	Quetiapine Fumarate			S	Unknown	25 Mg, Unk		Alkem	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184177	NON-EXPEDITED			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM- 2018-01462		71 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dyskinesia	Quetiapine Fumarate			S	Unknown	50 Mg, Qd		Alkem	
	Quetiapine Fumarate			S	Unknown	100 Mg, Qd		Alkem	
	Escitalopram			S	Unknown	10 To 15 Mg/Qd For 6 Months		Not Reported	
	Risperidone			S	Unknown	1 Mg, Qd		Not Reported	
	Sertraline			C	Unknown	80 Mg, Unk		Not Reported	
	Venlafaxine			C	Unknown	150 Mg, Qd		Not Reported	
	Mirtazapine			C	Unknown	45 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184193	NON-EXPEDITED			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM- 2018-01410		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Escitalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S				Not Reported	
	Quetiapine Fumarate			S	Unknown	Unk		Alkem	

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Quetiapine Fumarate	S			Alkem
Risperidone	S	Unknown	Unk	Not Reported
Risperidone	S			Not Reported
Aripiprazole	S	Unknown	Unk	Not Reported
Aripiprazole	S			Not Reported
Cyamemazine	S	Unknown	Unk	Not Reported
Cyamemazine	S			Not Reported
Propericiazine	S	Unknown	Unk	Not Reported
Propericiazine	S			Not Reported
Fluoxetine	S	Unknown	Unk	Not Reported
Fluoxetine	S			Not Reported
Benzodiazepine	S	Unknown	Unk	Not Reported
Benzodiazepine	S			Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
Carbamazepine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184212	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2018-04468		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rash; Sedation	Lamotrigine			S	Unknown	Unk		Alkem
	Quetiapine Fumarate			S	Unknown	Unk		Alkem
	Citalopram			S	Oral	30 Mg, Qd		Not Reported
	Citalopram			S				Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Lithium			S	Oral	750 Mg, Qd		Not Reported
	Lithium			S				Not Reported
	Ziprasidone Hydrochloride			S	Oral	20 Mg, Bid		Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Ziprasidone Hydrochloride			S				Not Reported
	Bupropion Hydrochloride			S	Oral	75 Mg, Qd		Not Reported
	Bupropion Hydrochloride			S				Not Reported

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Guanfacine	C	Oral	1 Mg, Bid	Not Reported
Fluvoxamine Maleate	C	Oral	Un50 Mg, Qd	Not Reported
Amphetamine–Dextroamphetamine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184309	NON-EXPEDITED			US-PFIZER INC-2019144950		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Phenergan [Promethazine]			S		Unk		Not Reported
	Zofran [Ondansetron]			S		Unk		Not Reported
	Oxycodone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16185358	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1034073		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Atenolol			S	Oral	25 Milligram		Not Reported
	Tramadol			S	Oral	Inconnue		Not Reported
	Seroplex			S	Oral	1 Dosage Form		Mylan
	Exforge			S	Oral	0.5 Dosage Form		Mylan
	Hemigoxine Nativelle			S	Oral	1 Dosage Form		Mylan
	Macrogol Stearate			C	Oral	2 Dosage Form		Mylan
	Caltrate /00944201/			C	Oral	1 Dosage Form		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16186813	EXPEDITED (15-DAY)		DE, OT	DK-ALLERGAN-1915784US			Female	DNK

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Hypertrophy; Confusional State; Constipation; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension; Hyperventilation; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Overdose; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)Overdose: 30 Mg		Allergan	
	Zeldox			S	Oral	80 Mg, Qd		Not Reported	
	Litarex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported	
	Mirtazapine			S	Oral	30 Mg, Qd		Not Reported	
	Mirtazapine			S				Not Reported	
	Ferro Duretter			C	Unknown	100 Mg, Qd		Not Reported	
	Alprazolam			C	Unknown	0.5 Mg, Qd		Not Reported	
	Centyl Med Kaliumklorid			C	Unknown	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16186817	EXPEDITED (15-DAY)		LT	FR-ALLERGAN- 1915793US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperreflexia; Intentional Overdose; Mydriasis; Poisoning Deliberate; Product Use Issue	Escitalopram Oxalate - Bp			S	Oral	Overdose 25 Dosage Forms; In Total		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16324559	DIRECT	N				43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Libido Decreased; Sexual Dysfunction; Therapy Cessation; Vulvovaginal Hypoaesthesia	Escitalopram Lexapro			S	Oral		1 DAY	Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	13935159	EXPEDITED (15-DAY)		HO, OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM- 2017-00575		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypomagnesaemia; Seizure Like Phenomena; Ventricular Tachycardia	Quetiapine Fumarate Escitalopram			S S	Unknown Unknown	50 Mg, Qid 20 Mg, Qd		Alkem Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	15982382	EXPEDITED (15-DAY)		DE, HO, OT	FR-TEVA-2019-FR- 1012958		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Death; Agitation; Delirium; Dissociative Amnesia; Drug Intolerance; Psychotic Disorder; Suicidal Ideation; Withdrawal Syndrome	Venlafaxine Hydrochloride Norset Seroplex Lysanxia Mirtazapine			S S S S S	Unknown Oral Unknown Unknown Oral	 Unk Unk		Teva Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16021036	NON-EXPEDITED			US-PFIZER INC- 2019085867		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Sertraline Hcl Escitalopram			S S		Unk Unk		Pfizer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16103509	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE- 1026757		44 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy	Escitalopram			S	Oral			Ivax
	Escitalopram			S	Oral			Ivax
	Olanzapin			C	Oral	15 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16183252	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1034741		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram Oxalate			S	Oral			Ivax
	Quetiapine Fumarate			S	Oral			Teva
	Lorazepam			C				Not Reported
	Depakin Chrono 500 Mg			C				Not Reported
	Comprese A Rilascio Prolungato							
	Clonazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16187440	EXPEDITED (15-DAY)		HO	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-07142		79 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Gait Disturbance; Hallucination; Overdose; Somnolence	Quetiapine Fumarate			S	Oral	100 Mg, 0-0-0-1, Tabletten		Alkem
	Valproinsaeure			S	Oral	500 Mg, 0-0-0-1, Tabletten		Not Reported
	Cipralext 10 Mg			S	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Levothyroxine			C	Oral	75 Mg, 1-0-0-0, Tabletten		Not Reported
	Torasemide			C	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported
	Felodipine			C	Oral	10 Mg, 1-0-0-0, Tabletten		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16187459	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES			Unknown	DEU

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2018-08294

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Quetiapine Fumarate			S	Oral	50 Mg, Od		Alkem
	Ciprallex			S	Oral	20 Mg, 10 Mg And 5 Mg Od		Not Reported
	Lamictal			S	Oral	125 Mg, Od		Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C	Oral	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16187546	EXPEDITED (15-DAY)		HO, LT, OT	GB-AUROBINDO-AUR- APL-2019-019129			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypotension	Furosemide			S	Oral	20 Milligram, Daily		Not Reported
	Irbesartan			S	Oral	75 Milligram, Daily		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Braltus			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	125		Not Reported
	Simvastatin			C	Unknown	40 Milligram		Not Reported
	Zapain			C	Unknown	1-2 Four Times Daily		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Sando K			C	Unknown	Various Acute Scripts		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16188006	EXPEDITED (15-DAY)		OT	TW-ALKEM LABORATORIES LIMITED-TW-ALKEM- 2019-01138		42 YR	Female	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Bradykinesia; Electrocardiogram Qt Prolonged; Muscle Rigidity	Escitalopram	S	Unknown	5 Mg, Qd	Not Reported
	Escitalopram	S			Not Reported
	Quetiapine Fumarate	S	Unknown	75 Mg, Qd	Alkem
	Valproate	S	Unknown	1000 Mg, Qd	Not Reported
	Lorazepam	C	Unknown	Unk	Not Reported
	Clonazepam	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16188112	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2019-019016			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Movement Disorder; Loss Of Consciousness	Escitalopram			S	Unknown	15 Milligram		Aurobindo	
	Pritor (Telmisartan)			S	Oral	40 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16188710	EXPEDITED (15-DAY)		HO	GB-APOTEX- 2019AP011429		82 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronic Acid			S	Oral	70 Mg, Q.Wk.		Apotex	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Acetylsalicylic Acid			S	Oral	75 Mg, Qd		Not Reported	
	Felodipine			C	Unknown			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
	Adcal D3			C	Unknown			Not Reported	
	Doxazosin			C	Unknown			Not Reported	
	Simvastatin			C	Unknown			Not Reported	
	Salbutamol			C	Unknown			Not Reported	
	Seretide			C	Unknown			Not Reported	
	Dymista			C	Unknown			Not Reported	
	Montelukast			C	Unknown			Not Reported	

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Gabapentin	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16188712	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2019AP011616		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Quetiapine			S	Oral	1 Df, Unk (In Total)		Apotex
	Escitalopram Oxalate			S	Oral	1 Df, Unk (In Total)		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Depakin Chrono /00228502/			C	Unknown	1500 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16189526	NON-EXPEDITED			US-PFIZER INC-2019154119		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16190845	NON-EXPEDITED			US-PFIZER INC-2019157476		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S	Oral	50 Mg, 1x/Day (1 Capsule Orally At Bedtime)		Pfizer
	Lyrica			S	Oral	25 Mg, 2x/Day (1 Capsule		Pfizer

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Atorvastatin Calcium	S	Orally Bid(Twice A Day))	Unk	Pfizer
Gabapentin	S		Unk	Pfizer
Gemfibrozil	S		Unk	Pfizer
Crestor	S		Unk	Not Reported
Cymbalta	S		Unk	Not Reported
Dyazide	S		Unk	Not Reported
Keflex [Cefalexin]	S		Unk	Not Reported
Lexapro	S		Unk	Not Reported
Norco	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		Unk	Not Reported
Amitriptyline	S		Unk	Not Reported
Cefdinir	S		Unk	Not Reported
Chlorthalidone	S		Unk	Not Reported
Prednisone	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16191517	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1035597		75 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Erythematous	Serpentil [Escitalopram Oxalate]			S	Oral	5 Milligram Daily;		Ivax
	Tulip			C	Oral	10 Milligram Daily;		Not Reported
	Brunoq			C	Oral	10 Milligram Daily;		Not Reported
	Valsacor			C	Nasal	160 Milligram Daily;		Not Reported
	Praxiten			C	Oral			Not Reported
	Peptoran			C	Oral	150 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16192452	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1915806US			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Drug Abuse; Overdose; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	30 Mg, Single		Allergan	
	Cocaine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16196452	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Fluoxetine			S				Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2019	15973610	NON-EXPEDITED			US-009507513-1902USA005780		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Belsomra			S	Oral	Unk, Nightly		Merck	
	Lexapro			S	Oral	5 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2019	16193499	EXPEDITED (15-DAY)		HO, LT, OT	GB-TEVA-2019-GB-1036446		84 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypotension	Furosemide			S	Oral	20 Milligram Daily;		Ivax	
	Irbesartan Hydrochloride			S	Oral	75 Milligram Daily;		Teva	
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Braltus			C				Not Reported	
	Seretide			C		125		Not Reported	
	Simvastatin			C				Not Reported	
	Zapain			C		1-2 Four Times Daily		Not Reported	
	Salbutamol			C				Not Reported	
Sando-K			C		Various Acute Scripts		Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	15983294	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-199588		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Death;	Venlafaxine			S	Unknown	Unk ()		Sun	
Agitation; Delirium;	Venlafaxine			S	Unknown	Unk ()		Sun	
Dissociative Amnesia;	Mirtazapine			S	Oral	Unk ()		Sun	
Drug Intolerance;	Norset			S	Oral	Unk ()		Not Reported	
Psychotic Disorder;	Seroplex			S	Unknown	Unk ()		Not Reported	
Suicidal Ideation;	Lysanxia			S	Unknown	Unk ()		Not Reported	
Withdrawal Syndrome									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16169409	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019146750		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia;	Pantoprazole			S	Oral	40 Milligram, Qd		Pfizer	
Inappropriate Antidiuretic	Candesartan			S	Oral	4 Milligram		Not Reported	
Hormone Secretion	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Furosemide			S	Oral	10 Milligram		Not Reported	
	Alprazolam			C		Unk		Not Reported	
	Spagulax			C		Unk		Not Reported	
	Gaviscon [Alginic Acid;Aluminium Hydroxide Gel, Dried;Magnesium Trisil			C		Unk		Not Reported	
	Voltarene [Diclofenac Sodium]			C		Unk		Not Reported	
	Levothyrox			C		Unk		Not Reported	
	Rilmenidine			C		Unk		Not Reported	
	Eupressyl [Urapidil]			C		Unk		Not Reported	
	Loxen L P			C		Unk		Not Reported	

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Uvedose	C	Unk	Not Reported
Doliprane	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16196703	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102406		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Oedema; Completed Suicide; Drug Interaction; Pain In Extremity; Pneumonia; Pulmonary Congestion; Pulmonary Oedema; Skin Abrasion; Toxicity To Various Agents	Opana			S	Unknown	Unk Unknown, Unknown		Endo
	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage
	Ultram /00599202/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported
	Seroquel			S	Unknown	Unk Unknown, Unknown		Not Reported
	Cardizem /00489701/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Caffeine			S	Unknown	Unk Unknown, Unknown		Not Reported
	Fentanyl			S	Unknown	Unk Unknown, Unknown		Not Reported
	Gabapentin			C	Unknown	Unk Unknown, Unknown		Not Reported
	Isosorbide Dinitrate			C	Unknown	Unk Unknown, Unknown		Par

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197522	EXPEDITED (15-DAY)		HO, OT	BH- GLAXOSMITHKLINE- BH2019GSK061603		18 YR	Female	BHR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bulimia Nervosa; Drug Intolerance; Intentional Overdose; Intentional Product Misuse; Suicide Attempt; Weight Increased	Escitalopram			S		20 Mg, Unk		Glaxosmithkline
	Escitalopram			S				Glaxosmithkline
	Bupropion			S		150 Mg, Qd		Glaxosmithkline
	Fluoxetine			S		20 Mg, Qd		Not Reported
	Fluoxetine			S		40 Mg, Qd		Not Reported

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	Mirtazapine		S			15 Mg, Unk			Not Reported
	Mirtazapine		S						Not Reported
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15-Apr-2019	16198186	EXPEDITED (15-DAY)		DE, OT	US-ENDO PHARMACEUTICALS INC-2019-102414		40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Oedema; Cardiac Failure Acute; Contusion; Hypertensive Heart Disease; Pulmonary Oedema; Skin Abrasion; Toxicity To Various Agents	Opana			S	Unknown	Unk Unknown, Unknown		Endo	
	Oxycodone Hydrochloride			S	Unknown	Unk Unknown, Unknown		Vintage	
	Numorphan			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Klonopin			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Celexa /00582602/			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Lexapro			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Abilify			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Desyrel			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Caffeine			S	Unknown	Unk Unknown, Unknown		Not Reported	
	Warfarin			S	Unknown	Unk Unknown, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16198902	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2019M1035340		80 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hyperhidrosis; Malaise	Escitalopram			S	Oral	20 Milligram, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16199942	EXPEDITED (15-DAY)		OT	ES-ALLERGAN- 1916159US			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Escitalopram Oxalate - Bp			S	Oral	10 Mg Q24hr		Allergan	

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	Lixiana	S	Oral	60 Mg Q24hr	Not Reported
	Paracetamol	C	Oral	Unk	Not Reported
	Combiprasal	C	Respiratory (inhalation)	0.5 Mg / 2.5 Mg	Not Reported
	Seguril	C	Oral	Unk	Not Reported
	Sebiprox	C	Cutaneous	15 Mg/G	Not Reported
	Omeprazol	C	Oral	Unk	Not Reported
	Omnice Ocas	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	15651338	EXPEDITED (15-DAY)		CA, HO	CA-ALLERGAN-1854400US			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan	
	Benzotropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported	
	Benzotropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported	
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported	
	Methadose			S	Transplacental	70 Mg, Qd		Not Reported	
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported	
	Quetiapine			S	Transplacental	300 Mg, Q12h		Not Reported	
	Rabeprazole			S	Transplacental	Unk		Not Reported	
	Zopiclone			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	15720344	EXPEDITED (15-DAY)		HO, LT	US-009507513-1812USA003811		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Prinivil			S	Oral	20 Milligram, Qd		Merck	
	Metformin			S	Oral	1000 Milligram, Bid		Not Reported	

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				(2x/Day)	
Lexapro	S	Oral	10 Milligram, Qd		Not Reported
Trazodone Hydrochloride	S	Oral	50 Milligram, Qd		Not Reported
Trazodone Hydrochloride	S	Oral	100 Milligram, Qd		Not Reported
Glyburide	C		Unk		Not Reported
Gemfibrozil	C		Unk		Not Reported
Pravachol	C		Unk		Not Reported
Pantoprazole	C		Unk		Not Reported
Combivent	C		Unk		Not Reported
Gabapentin	C		Unk		Not Reported
Valium	C		Unk		Not Reported
Victoza	C		Unk		Not Reported
Lunesta	C		Unk		Not Reported
Anoro	C		Unk		Not Reported
Proair (Albuterol Sulfate)	C		Unk		Not Reported
Cyclizine	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16170908	EXPEDITED (15-DAY)		OT	PHHY2019FR076011		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Loss Of Consciousness; Malaise; Syncope; Withdrawal Syndrome	Telmisartan			S	Unknown	Unk		Novartis
	Citalopram			S	Oral	15 Mg, Qd		Not Reported
	Seroplex			S	Oral	15 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16200453	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01407		28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Sedation; Therapeutic Product Effect Incomplete	Escitalopram	S	Unknown	10 Milligram	Lupin
	Lorazepam	S	Unknown	0.5 Milligram, Qd	Lupin
	Clonazepam	S	Unknown	0.5 Milligram, Qd	Not Reported
	Clobazam	C	Unknown	Unk Unk, Tid (15 Mg In The Morning, 15mg In The)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16200626	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US02039			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia	Gabapentin			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Mirtazapine			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk, Low Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16201819	EXPEDITED (15-DAY)		HO, OT	IN-MACLEODS PHARMACEUTICALS US LTD-MAC2019020871			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Olanzapine			S	Unknown	10 Milligram		Macleods
	Escitalopram Oxalate			S	Unknown	5 Milligram		Macleods
	Escitalopram Oxalate			S	Unknown	20 Milligram		Macleods
	Fluoxetine			S	Unknown	20 Milligram		Not Reported
	Valproate Semisodium			C	Unknown	500 Milligram		Not Reported

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16-Apr-2019	16202016	EXPEDITED (15-DAY)		HO, OT	BH-LUPIN PHARMACEUTICALS INC.-2019-02312		18 YR	Female	BHR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bulimia Nervosa; Impulsive Behaviour; Intentional Product Misuse; Overdose; Paradoxical Drug Reaction; Suicide Attempt; Weight Increased	Escitalopram			S	Unknown	Unk		Lupin	
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin	
	Mirtazapine			S	Unknown	15 Milligram, Qd		Not Reported	
	Bupropion Hydrochloride Extended-Release Tablets			S	Unknown	150 Milligram, Qd		Lupin	
	Bupropion Hydrochloride Extended-Release Tablets			S	Unknown	30 Dosage Form		Lupin	
	Bupropion Hydrochloride Extended-Release Tablets			S				Lupin	
	Fluoxetine			S	Unknown	20 Milligram, Qd		Lupin	
	Fluoxetine			S	Unknown	40 Milligram, Qd, Dose Increased		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16202636	EXPEDITED (15-DAY)		HO, OT	IN- ELI_LILLY_AND_COMP ANY-IN201904003481		45 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Olanzapine			S	Unknown	10 Mg, Unknown		Eli Lilly And Co	
	Fluoxetine Hydrochloride			S	Unknown	20 Mg, Unknown		Eli Lilly And Co	
	Escitalopram			S	Unknown	5 Mg, Unknown		Not Reported	
	Escitalopram			S	Unknown	20 Mg, Unknown		Not Reported	
	Divalproex Sodium			C	Unknown	500 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16203251	EXPEDITED (15-DAY)		OT	ES-DSJP-DSE-2019- 113378			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Pruritus; Rash	Lixiana	S	Oral	1 Cada 24 Horas	Daiichi
	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
	Paracetamol	C	Oral	Unk	Not Reported
	Omeprazol /00661201/	C	Oral	Unk	Not Reported
	Combiprasal	C	Respiratory (inhalation)	0.5mg/2.5mg	Not Reported
	Sebiprox	C	Cutaneous	Unk	Not Reported
	Seguril	C	Oral	Unk	Not Reported
	Omnice Ocas	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16203382	EXPEDITED (15-DAY)		DE, OT	SE-GLAXOSMITHKLINE-SE2019067745		28 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Toxicity To Various Agents	Lamictal			S	Oral	200 Mg, Qd		Glaxosmithkline	
	Voxra			S	Oral	150 Mg, Qd		Glaxosmithkline	
	Elvanse			S	Oral	40 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Melatonin			C	Unknown	4 Mg, Prn (Max 2 Per Day)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16205106	EXPEDITED (15-DAY)		OT	US-009507513-1904USA004119		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anger; Breast Enlargement; Condition Aggravated; Constipation; Deafness; Dependence; Disturbance In Attention; Drug Ineffective; Ear Disorder; Erection Increased; Fatigue;	Remeron			S		Unk		Merck	
	Risperdal			S		Unk		Not Reported	
	Seroquel			S		Unk		Not Reported	
	Zyprexa			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

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Gastric Ulcer; Influenza	Lamictal	S	Unk	Not Reported
Like Illness; Insomnia;	Tegretol	S	Unk	Not Reported
Memory Impairment;	Wellbutrin	S	Unk	Not Reported
Mood Swings; Muscle	Buspar	S	Unk	Not Reported
Spasms; Rash; Rectal	Valium	S	Unk	Not Reported
Haemorrhage; Suicidal	Valium	S	Unk	Not Reported
Ideation; Therapeutic	Valium	S	Unk	Not Reported
Product Effect Increased;	Valium	S	Unk	Not Reported
Weight Increased	Valium	S	Unk	Not Reported
	Trazodone Hydrochloride	S	Unk	Not Reported
	Trazodone Hydrochloride	S	Unk	Not Reported
	Paxil	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Elavil (Amitriptyline	S	Unk	Not Reported
	Hydrochloride)	S	Unk	Not Reported
	Klonopin	S	Unk	Not Reported
	Ritalin	S	Unk	Not Reported
	Pamelor	S	Unk	Not Reported
	Zoloft	S	Unk	Not Reported
	Skelaxin	S	Unk	Not Reported
	Effexor	S	37.5 Mg, Unk	Not Reported
	Effexor Xr	S	Unk	Not Reported
	Celebrex	S	Unk	Not Reported
	Geodon	S	Unk	Not Reported
	Depakote	S	Unk	Not Reported
	Zomig	S	Unk	Not Reported
	Imitrex (Sumatriptan Succinate)	S	Unk	Not Reported
	Soma (Carisoprodol)	S	Unk	Not Reported
	Lithium	S	Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16338532	DIRECT					69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Agitation; Irritability; Nightmare; Product Substitution Issue; Sleep Disorder	Escitalopram Oxalate			S	Oral	Quantity:1 Df Dosage Form;		Aurobindo	
	Probiotic			C				Not Reported	
	Atorvastatin Calcium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	15722727	EXPEDITED (15-DAY)		HO, LT	US-EMD SERONO- 9057702		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Metformin			S	Oral			Not Reported	
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported	
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported	
	Placebo			S	Intramuscular	Daily Dose: Single Dose		Not Reported	
	Lisinopril			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
	Lexapro			S	Oral	Restarted At Lower Dose		Not Reported	
	Trazodone			S	Oral			Not Reported	
	Trazodone			S	Oral			Not Reported	
	Gemfibrozil			C				Not Reported	
	Glyburide			C				Not Reported	
	Pravachol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Combivent			C				Not Reported	
	Valium			C				Not Reported	
	Victoza			C				Not Reported	
	Lunesta			C				Not Reported	
	Anoro			C				Not Reported	
	Gabapentin			C				Not Reported	
	Proair /00139502/			C				Not Reported	

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Medicine			C			Not Reported			
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17-Apr-2019	16017286	NON-EXPEDITED		OT	US-NEUROCRINE BIOSCIENCES INC.- 2019NBI00447		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Fatigue;	Ingrezza (Valbenazine)			S	Oral			Neurocrine	
Influenza; Migraine;	Ingrezza (Valbenazine)			S	Oral			Biosciences	
Somnolence; Swollen	Ciprofloxacin			S				Neurocrine	
Tongue; Therapeutic	Medrol Dp (Methylprednisolone)			S				Biosciences	
Product Effect Decreased	Divalproex			S				Not Reported	
	Lorazepam			S				Not Reported	
	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16205829	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-020592			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Amlodipine			S	Unknown	2.5 Milligram, Daily		Aurobindo	
Balance Disorder;	Escitalopram			S	Unknown	10.0 Milligram, Daily		Aurobindo	
Bradycardia; Dizziness;	Escitalopram			S				Aurobindo	
Drug Ineffective; Fall;	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
Headache; Hypotension;	Escitalopram Tablets			S				Aurobindo	
Mobility Decreased;	Ramipril			S	Unknown	5.0 Milligram, Daily		Aurobindo	
Nausea; Orthostatic	Codeine			S	Unknown	30.0 Milligram, Two Times		Not Reported	
Hypotension; Pain; Panic						A Day			
Attack; Sleep Disorder	Furosemide			S	Unknown	40.0 Milligram, Daily		Not Reported	
	Furosemide			S	Unknown	20.0 Milligram, Daily		Not Reported	
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, Two Times		Not Reported	
						A Day			
	Metoprolol			S	Unknown	25.0 Milligram, Daily		Not Reported	

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Oxazepam	S	Unknown	10.0 Milligram, Two Times A Day	Not Reported
Zopiclone	S	Unknown	2.5 Milligram, Daily	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Clopidogrel	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Macrogol	C	Unknown	Unk	Not Reported
Rabeprazole	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16205947	EXPEDITED (15-DAY)	OT		IT-ACCORD-122086		37 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Nausea; Vomiting	Escitalopram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16205950	EXPEDITED (15-DAY)	OT		IT-ACCORD-122467		23 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Delorazepam			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Oki			S	Oral	Strength 80 Mg		Not Reported
	Tavor (Lorazepam)			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16206210	EXPEDITED (15-DAY)		OT	IT-ACCORD-121964		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Abuse; Nausea	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16207198	EXPEDITED (15-DAY)		DE	US-TORRENT-00008034		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown	
	Hydrochlorothiazide			S	Oral	Unknown		Unknown	
	Clonazepam			S	Oral	Unknown		Unknown	
	Metoprolol			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16207204	EXPEDITED (15-DAY)		DE	US-TORRENT-00008049		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown	
	Naproxen			S	Oral	Unknown		Unknown	
	Zolpidem			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16207448	NON-EXPEDITED			US-PFIZER INC-2019162129		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Venlafaxine Hcl	S	Unk	Pfizer
	Tagamet [Cimetidine]	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported
	Hydrocodone	S	Unk	Not Reported
	Nabumetone	S	Unk	Not Reported
	Nortriptyline	S	Unk	Not Reported
	Vioxx	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16209772	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1916485US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Interstitial Lung Disease	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Duloxetine Teva			S	Unknown	15 Mg		Not Reported	
	Venlafaxine			S	Unknown	37.5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16209827	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1916574US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Pantoprazole			S	Oral			Not Reported	
	Tinzaparine Sodique			S	Subcutaneous			Not Reported	
	Spironolactone			S	Oral			Not Reported	
	Trileptal			S	Oral			Not Reported	
	Lacosamide			S	Oral			Not Reported	
	Diltiazem			S	Oral			Not Reported	
	Bactrim			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16209855	EXPEDITED (15-DAY)		OT	TR-ALLERGAN-1916571US			Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16209863	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1916593US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematemesis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Pentasa			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Marijuana			S	Unknown	Unk		Not Reported	
	Premarin			S	Oral	0.625 Mg, Qd		Not Reported	
	Propanolol Hydrochloride			S	Oral	40 Mg, Q12h		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16211702	DIRECT		DS, HO, OT			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar I Disorder; Hypomania; Insomnia; Therapy Change	Escitalopram; Generic For: Lexapro			S	Oral	Quantity:100 Tablet(S);		Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16180946	EXPEDITED (15-DAY)			TR-ALLERGAN-1915661US			Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Decreased; Nausea; Visual	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan	

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Impairment	Escitalopram Oxalate - Bp	S	Unknown	5 Mg, Unknown	Allergan
	Dideral	C	Unknown	50 Mg, Unknown	Not Reported
	Dideral	C	Unknown	25 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16210442	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-020672			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo
	Cimzia			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	50 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	1000 Milligram, Daily		Not Reported
	Nortriptyline			S	Oral	25 Milligram, Daily		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Voltaren			S	Topical	Unk, Daily		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16211201	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX- 2019AP011722		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug	Citalopram			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex

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Interaction;	Escitalopram	S	Unknown	Unk	Apotex
Electrocardiogram Qt	Escitalopram	S	Unknown		Apotex
Prolonged; Heart Rate	Oxazepam	S	Oral		Not Reported
Increased; Irritability;	Oxazepam	S	Oral		Not Reported
Miosis; Overdose; Oxygen	Quetiapine	S	Oral	Unk	Apotex
Saturation Decreased;	Quetiapine	S	Unknown	Unk	Apotex
Respiratory Alkalosis;	Temazepam	S	Oral	Unk	Not Reported
Sinus Tachycardia;	Topiramate	S	Unknown	Unk	Apotex
Somnolence; Suicide	Topiramate	S	Oral	Unk	Apotex
Attempt; Toxicity To	Quetiapine Mylan	S	Oral	Unk	Not Reported
Various Agents	Naloxone	S	Intramuscular	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Fluticasone W/Salmeterol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown		Not Reported
	Ramipril	C	Endocervical		Not Reported
	Salbutamol	C		Unk	Not Reported
	Salbutamol	C	Other	Unk	Not Reported
	Spironolactone	C	Unknown		Not Reported
	Spironolactone	C	Unknown		Not Reported
	Advair	C	Unknown		Not Reported

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18-Apr-2019	16211262	EXPEDITED (15-DAY)		OT	FR-ACCORD-122627		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Weight Decreased; Xerophthalmia	Escitalopram			S	Oral			Not Reported	
	Lercan			C	Oral	Strength: 20 Mg		Not Reported	
	Lormetazepam			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16211372	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020685			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Milligram		Aurobindo	
	Gabapentin			S	Oral	600 Milligram, Two Times A Day		Aurobindo	
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported	
	Domperidone			S	Oral	10 Milligram, Two Times A Day		Not Reported	
	Ferrous Sulfate			S	Oral	300 Milligram, 3 Times A Day		Not Reported	
	Temazepam			S	Oral	30 Milligram, Daily		Not Reported	
	Tylenol With Codeine			S	Oral	2 Dosage Form, 3 Times A Day		Not Reported	
	Vitalux			S	Oral	Unk Unk, Two Times A Day		Not Reported	
	Wellbutrin			S	Oral	150 Milligram, Two Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16211409	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-020679			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Gabapentin			S	Oral	300 Milligram, Daily		Aurobindo
	Gabapentin Capsules			S	Oral	600 Milligram, Two Times A Day		Aurobindo
	Clonazepam			S	Unknown	0.5 Milligram, Three Times A Day		Not Reported
	Domperidone			S	Unknown	10 Milligram, Two Times A Day		Not Reported
	Ferrous Sulphate			S	Unknown	300 Milligram, 3 Times A Day		Not Reported
	Temazepam			S	Oral	30 Milligram, Daily		Not Reported
	Tylenol With Codein #3			S	Oral	2 Dosage Form, 3times A Day		Not Reported
	Vitalux			S	Oral	Unk, Two Times Daily		Not Reported
	Wellbutrin			S	Oral	150 Milligram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16212023	EXPEDITED (15-DAY)		LT, OT	FR- GLAXOSMITHKLINE- FR2019069701		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Glaxosmithkline
	Racecadotril			S	Oral	Unk		Glaxosmithkline
	Escitalopram			S	Oral	Unk		Glaxosmithkline
	Levothyrox			S	Oral	Unk		Glaxosmithkline
	Mirtazapine			S	Oral	Unk		Not Reported
	Coveram			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16212140	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008080		39 YR	Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown	
	Metoprolol			S	Oral	Extended Release		Unknown	
	Hydrochlorothiazide			S	Oral	Unknown		Unknown	
	Quetiapine			S	Oral	Unknown		Unknown	
	Potassium Chloride			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212164	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008200		51 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown	
	Propranolol			S	Oral	Unknown		Unknown	
	Quetiapine			S	Oral	Unknown		Unknown	
	Primidone			S	Oral	Unknown		Unknown	
	Trazodone			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212213	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008164		19 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Completed Suicide; Toxicity To Various Agents	Venlafaxine			S	Oral	Extended Release		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16100332	NON-EXPEDITED			US-APOTEX-2019AP008942			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Drug Hypersensitivity; Muscle Twitching	Paxil	S	Unknown	Unk	Apotex
	Wellbutrin	S	Unknown	Unk	Not Reported
	Bactrim Ds	S	Unknown		Not Reported
	Lexapro	S	Unknown		Not Reported
	Macrobid /00024401/	S	Unknown		Not Reported
	Nubain	S	Unknown		Not Reported
	Prozac	S	Unknown		Not Reported
	Zoloft	S	Unknown		Not Reported
	Ranitidine	C	Oral	1 Df, Bid	Not Reported
	Gabapentin	C	Oral	1 Df, Tid	Not Reported
	Lorazepam	C	Oral	Unk, Prn (1-2 Tablets Every 6 Hours As Needed Orally Daily)	Not Reported
	Neurontin	C	Oral	2 Df, Tid	Not Reported
	Hydrocodone/Acetaminophen	C	Oral	1 Df, Q.4h. (As Needed)	Not Reported
	Lisinopril	C	Oral	1 Df, Bid	Not Reported
	Tylenol With Codeine	C	Oral	Unk, Q.6h (1 To 2 Tablets As Needed Orally Every 6 Hrs)	Not Reported
	Prednisone	C	Oral	4 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	3 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	2 Df, Qd (For 2 Days) As Directed	Not Reported
	Prednisone	C	Oral	1 Df, Qd (For 2 Days) As Directed	Not Reported
	Lovastatin	C	Oral	1 Df, Qd (With A Meal Orally)	Not Reported
	Azithromycin	C	Oral	2 Df, Qd (On The First Day)	Not Reported
	Azithromycin	C	Oral	1 Df, Qd (Daily For 4	Not Reported

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Celexa /00582602/			C	Unknown	Days) 1 Df, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216373	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-020327			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Quetiapine			S	Unknown	150 Milligram		Aurobindo	
	Teva Escitalopram			S	Unknown	15 Milligram		Not Reported	
	Teva Escitalopram			S				Not Reported	
	Teva Escitalopram			S				Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216933	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008100		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown	
	Acetaminophen			S	Oral	Unknown		Unknown	
	Doxepin			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216979	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008269		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown	
	Alprazolam			S	Oral	Unknown		Unknown	
	Acetaminophen And Hydrocodone 300 Mg / 10 Mg			S	Oral	Unknown		Unknown	
	Acetaminophen And Oxycodone			S	Oral	Unknown		Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16217290	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED- 2019SP003246			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Zolpidem			S	Unknown	Unk		Strides	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	Unk		Not Reported	
	Citalopram			S	Unknown	Unk		Not Reported	
	Zoloft			S	Unknown	Unk		Not Reported	
	Desipramine			S	Unknown	Unk		Not Reported	
	Adderall			S	Unknown	Unk		Not Reported	
	Wellbutrin			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Effexor			S	Unknown	Unk		Not Reported	
	Zyprexa			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16218136	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008243		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown	
	Doxepin			S	Oral	Unknown		Unknown	
	Hydroxyzine			S	Oral	Unknown		Unknown	
	Ethanol			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16218764	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008186		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide; Toxicity To Various Agents	Escitalopram	S	Oral	Unknown	Unknown
	Bupropion	S	Oral	Extended Release	Unknown
	Methylphenidate	S	Oral	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16219250	EXPEDITED (15-DAY)	LT		PHHY2019FR091323		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral			Novartis
	Mirtazapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Racecadotril Biogaran 100 Mg			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16219268	EXPEDITED (15-DAY)	OT		PHHY2019GB085858			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Escitalopram			S	Unknown	Unk (Reduce To 12.5 Mg Over 8 Weeks)		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	Unk (Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks)		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported

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Mirtazapine	S	Unknown	Unk	Not Reported
Mirtazapine	S	Unknown	15 Mg, Unk	Not Reported
Lorazepam	S	Unknown	Unk	Novartis
Lorazepam	S			Novartis
Lorazepam	S			Novartis
Lorazepam	S			Novartis
Lorazepam	S			Novartis
Buspirone	S	Unknown	Unk	Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported
Buspirone	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16219306	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1037339		38 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Off Label Use	Paroxetine			S	Oral	30 Mg, Once Daily (Qd)		Not Reported
	Candesartan			S	Oral	16 Mg, Once Daily (Qd)		Not Reported
	Escitalopram			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Levetiracetam			S	Oral	1500 Mg, Once Daily (Qd)		Not Reported
	Nepresol /00017902/			S	Oral	25 Mg, Once Daily (Qd)		Mylan
	L-Thyroxin /00068001/			C	Oral	Unk		Mylan
	Cytotec			C		Unk		Mylan
	Folic Acid			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16219570	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-021092			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral	25 Dosage Form, Total		Aurobindo

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16219820	EXPEDITED (15-DAY)		OT	IN-HETERO CORPORATE- HET2019IN00483		45 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Escitalopram			S	Unknown	05 Mg		Hetero	
	Escitalopram			S		20 Unk		Hetero	
	Fluoxetine			S	Unknown	20 Mg		Not Reported	
	Valproate Semisodium			C	Unknown	Unk		Not Reported	
	Olanzapine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16219863	EXPEDITED (15-DAY)		OT	SE-ACCORD-122801		19 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngeal Haemorrhage	Escitalopram			S	Oral			Not Reported	
	Citalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16220327	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008361		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown		Unknown	
	Tramadol			S	Oral	Unknown		Unknown	
	Propranolol			S	Oral	Unknown		Unknown	
	Gabapentin			S	Oral	Unknown		Unknown	
	Ethanol			S		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16220372	EXPEDITED (15-DAY)		DE, HO	US-TORRENT- 00008245		35 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Bupropion			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16220442	EXPEDITED (15-DAY)		LT	PHHY2019FR091335		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Paracetamol			S	Oral	12 G, Unk		Not Reported	
	Tramadol			S	Oral	Unk		Not Reported	
	Diazepam			S	Oral	100 Mg, Unk		Not Reported	
	Seroplex			S	Oral	560 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2019	16220601	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008120		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Propranolol			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
	Methylphenidate			S	Oral	Unknown		Unknown	
	Lamotrigine			S	Oral	Unknown		Unknown	
	Diazepam			S	Oral	Unknown		Unknown	
	Melatonin			S	Oral	Unknown		Unknown	
	Olanzapine			S	Oral	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2019	16220613	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008325		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Completed Suicide; Toxicity To Various Agents	Bupropion	S	Oral	Unknown	Unknown
	Verapamil	S	Oral	Unknown	Unknown
	Escitalopram	S	Oral	Unknown	Unknown
	Ethanol	S	Oral	Unknown	Unknown
	Diphenhydramine	S	Oral	Unknown	Unknown
	Hydrochlorothiazide	S	Oral	Unknown	Unknown
	Lisinopril	S	Oral	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2019	16220620	EXPEDITED (15-DAY)		DE	US-TORRENT-00008081		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
	Lisinopril			S	Oral	Unknown		Unknown	
	Alprazolam			S	Oral	Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2019	16220899	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00008276		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Propranolol			S	Oral	Unknown		Unknown	
	Levetiracetam			S	Oral	Unknown		Unknown	
	Escitalopram			S	Oral	Unknown		Unknown	
	Gabapentin			S	Oral	Unknown		Unknown	
	Acetaminophen/Chlorzoxazone			S	Oral	Unknown		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	15734485	EXPEDITED (15-DAY)		HO, LT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-116064		65 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Metformin Hydrochloride			S	Oral	1000 Mg, Bid		Bristol Myers Squibb	
	Lisinopril			S	Oral	20 Mg, Qd		Not Reported	
	Trazodone			S	Oral	50 Mg, Qd		Not Reported	
	Trazodone			S	Oral	100 Mg, Qd		Not Reported	
	Lexapro			S	Oral	10 Mg, Qd		Not Reported	
	Glyburide			C	Unknown	Unk		Not Reported	
	Gemfibrozil			C	Unknown	Unk		Not Reported	
	Pravachol			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Combivent			C	Unknown	Unk		Not Reported	
	Valium			C	Unknown	Unk		Not Reported	
	Victoza			C	Unknown	Unk		Not Reported	
	Lunesta			C	Unknown	Unk		Not Reported	
	Anoro			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Proair /00139502/			C	Unknown	Unk		Not Reported	
	Medizine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	15991597	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019074542		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Psychomotor Skills Impaired	Lorazepam			S	Oral	250 Mg, Single		Pfizer	
	Quetiapine Fumarate			S	Oral	500 Mg, Single		Not Reported	
	Escitalopram Oxalate			S	Oral	100 Mg, Single		Not Reported	
	Trittico			S	Oral	10 Df, Single		Not Reported	

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22-Apr-2019	16003746	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-009338			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Anxiety; Cardiac Disorder; Drug Ineffective; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Thinking Abnormal	Escitalopram			S	Unknown	Unk		Aurobindo	
	Aripiprazole Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Aripiprazole Tablets			S	Unknown	30 Milligram, Once A Day		Aurobindo	
	Clozapine			C	Unknown	600 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16052814	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2019M1020954		58 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Olanzapine			S	Unknown	Unk Unk,Unk		Not Reported	
	Escitalopram			S	Unknown	Unk Unk,Unk		Not Reported	
	Aripiprazole			S		Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Ziprasidone			S		Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Citalopram			S		Series Of Citalopram Infusions		Mylan	
	Risperidone			S	Unknown	Unk Unk,Unk		Mylan	
	Clomipramine			S		Unk		Mylan	
	Tiapride			C		Unk		Mylan	
	Melperone			C		Unk		Mylan	
	Clonazepam			C		Unk		Mylan	
	Propofol			C		Unk		Mylan	
	Memantine			C		Unk		Mylan	
	Haloperidol			C		Unk		Mylan	

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22-Apr-2019	16138359	EXPEDITED (15-DAY)		HO, OT	PL-ACCORD-116599		52 YR	Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Medication Error; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown			Not Reported
	Metoclopramide			S	Unknown	3 Dosages 10 Mg Daily		Accord
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported
	Tramadol			S	Unknown	100 Mg, Bid (200 Mg)		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Metamizole Sodium			S	Unknown	2 Dosages 500 Mg Daily		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd (In The Morning Fasting)		Not Reported
	Ketoprofen/Ketoprofen Arginate/Ketoprofen Lysine/Ketoprofen Sodium			S	Unknown	3 Dosages 100 Mg Daily		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown			Not Reported
	Valproic Acid			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Zoledronic Acid			C	Unknown			Not Reported
	Betamethasone Effentora			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16222032	EXPEDITED (15-DAY)		OT	FR-ACCORD-123456		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Drug Dependence	Escitalopram			S	Unknown	Unspecified		Not Reported
	Alprazolam			S	Unknown	Unspecified		Not Reported
	Dafalgan Codeine			S	Unknown	Unspecified		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16223283	NON-EXPEDITED			US-PFIZER INC-2019162079			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Effexor Xr			S		37.5 Mg, Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16223798	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1036546		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Dysgraphia; Dyskinesia; Tremor	Quetiapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported	
	Sertraline			S		200 Milligram, Qd		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Valproic Acid			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224388	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1036720		81 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Cerebral Haemorrhage; Ecchymosis; Subdural Haematoma	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Plavix			S	Oral	75 Milligram, Qd		Mylan	
	Coumadin			S	Oral	5 Milligram		Mylan	
	Pregabalin			C		Unk		Mylan	
	Furosemide			C		Unk		Mylan	
	Doxazosin			C		Unk		Mylan	

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Esomeprazole Sodium			C		Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224451	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1036751		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Haematoma	Escitalopram			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	10 Milligram, Qd		Not Reported	
	Aripiprazole			S	Oral	5 Milligram, Qd		Not Reported	
	Prazepam Arrow			S	Oral	10 Milligram, Qd		Mylan	
	Piroxicam			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224944	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1037021		65 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Respiratory Tract Infection	Sertraline			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Brintellix			S	Oral	5 Milligram, Qd		Mylan	
	Brintellix			S	Oral	10 Milligram, Qd		Mylan	
	Brintellix			S	Oral	15 Milligram, Qd		Mylan	
	Cipramil /00582602/			S	Unknown	Unk		Mylan	
	Cipralext /01588501/			S	Unknown	Unk		Mylan	
	Mirtazapin			C	Unknown	Unk		Mylan	
	Stesolid			C	Unknown	20 Milligram, Qd		Mylan	
	Stilnoct			C	Unknown	10 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16225505	EXPEDITED (15-DAY)		OT	SG-ALLERGAN-1917168US			Female	SGP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16225668	EXPEDITED (15-DAY)		OT	PHHY2019FR088499		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Trileptal			S	Oral	Unk		Novartis	
	Pantoprazole			S	Oral	Unk		Not Reported	
	Spironolactone			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Lacosamide			S	Oral	Unk		Not Reported	
	Diltiazem			S	Oral	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Tinzaparine Sodique			S	Subcutaneous	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	14213348	EXPEDITED (15-DAY)		CA, DS, HO	FR-PFIZER INC-2017493671		273 DAY	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Maternal Exposure During Pregnancy; Motor Developmental Delay; Neonatal Behavioural Syndrome; Neurodevelopmental Disorder; Speech Disorder Developmental	Xanax			S	Transplacental	Unk		Pfizer	
	Seroplex			S	Transplacental	10 Mg, 1x/Day		Not Reported	
	Stilnox			S	Transplacental	Unk		Not Reported	
	Seresta			S	Transplacental	Unk		Not Reported	
	Donormyl (Doxylamine Succinate)			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	15351216	NON-EXPEDITED			US-PFIZER INC-2018354224		71 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Metoprolol Tartrate			S		Unk		Unknown	
	Catapres [Clonidine Hydrochloride]			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16044404	EXPEDITED (15-DAY)		DE, HO, OT	SG-ALLERGAN-1908607US			Male	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antisocial Behaviour; Compulsive Shopping; Depressed Mood; Mood Swings; Product Use Issue; Seizure; Suicide Attempt; Underdose	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	2.5 Mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16076780	NON-EXPEDITED			US-TAKEDA-2019TUS013412			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Diabetes Mellitus	Trintellix			S	Oral	Unk		Takeda	
	Lexapro			S	Oral	Unk		Not Reported	
	Rexulti			S	Oral	0.5 Milligram, Qd		Not Reported	
	Rexulti			S	Oral	3 Milligram, Qd		Not Reported	
	Prozac			C	Oral	20 Milligram, Qd		Not Reported	
	Lamictal			C	Oral	200 Milligram, Qd		Not Reported	
	Trazodon			C	Oral	150 Milligram, Qd		Not Reported	
	Deplin			C	Oral	15 Milligram, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16226909	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1040900		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16230314	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019164650		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Besilate			S	Unknown	1.5 Df, 1x/Day		Pfizer	
	Apo Escitalopram			S	Unknown	Unk		Not Reported	
	Apo Tamsulosin			S	Unknown	1 Df, 1x/Day		Not Reported	
	Apo-Trazodone			S	Unknown	1 Df, 1x/Day		Not Reported	
	Brilinta			S	Unknown	1 Df, 2x/Day		Not Reported	
	Ciclopirox Olamine			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	1 Df, 3x/Day		Not Reported	
	Delatestryl			S	Unknown	0.5 MI, 1 Every 2 Weeks		Not Reported	
	Dexilant			S	Unknown	1 Df, 1x/Day		Not Reported	
	Diltiazem			S	Unknown	1 Df, 1x/Day		Not Reported	
	Emo Cort			S	Topical	Unk Unk, 1x/Day		Not Reported	
	Escitalopram			S	Unknown	1 Df, 1x/Day		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Jamp Asa			S	Unknown	1 Df, 1x/Day		Not Reported	
	Metonia			S	Unknown	1 Df, 3x/Day		Not Reported	
	Mylan Nitro SI			S	Oral	Unk		Not Reported	
	Mylan Nitro SI			S	Oral	Unk		Not Reported	
	Nasonex			S	Nasal	Unk Unk, 1x/Day		Not Reported	

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	Nitro-Dur	S	Unknown	1 Df, 1x/Day	Not Reported
	Ratio-Zopiclone	S	Unknown	1 Df, Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	1 Df, 1x/Day	Not Reported
	Synthroid	S	Unknown	1 Df, 1x/Day	Not Reported
	Tevabisoprol	S	Unknown	1 Df, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16230495	EXPEDITED (15-DAY)	LT		FR-ALLERGAN-1917196US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan
	Lamotrigine			S	Oral	Unk, Unknown		Not Reported
	Racecadotril Bgr			S	Oral	Unk, Unknown		Not Reported
	Levothyrox			S	Oral	Unk, Unknown		Not Reported
	Mirtazapine			S	Oral	Unk, Unknown		Not Reported
	Coveram			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16231791	EXPEDITED (15-DAY)	OT		GB-ACCORD-123735		50 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Headache; Tongue Biting	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16231840	EXPEDITED (15-DAY)	HO, OT		GB-CIPLA LTD.-2019GB02132			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt	Escitalopram			S	Oral	40 Milligram, Per Day		Invagen
	Fluoxetine			C	Unknown	20 Milligram (Capsules)		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Prolonged;
Gastroesophageal Reflux
Disease; Lethargy;
Malaise; Product
Dispensing Error;
Somnolence

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16235351	EXPEDITED (15-DAY)		LT	FR-009507513-1904FRA009494		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Mirtazapine			S	Oral			Merck
	Lamotrigine			S	Oral			Not Reported
	Racecadotril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coveram			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16235488	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1917372US			Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy; Syncope; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	Titrated 10 Mg Till 12,5 Mg Under Terapitiden.		Allergan
	Alfuzosin			C	Unknown			Not Reported
	Mirtazapin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16235489	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1917155US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Agitation; Bradypnoea; Intentional Overdose; Off Label Use; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Escitalopram Oxalate - Bp	S	Oral	Actual: Overdose: 560 Mg	Allergan
	Tramadol	S	Oral	Unk	Not Reported
	Paracetamol	S	Oral	12 G	Not Reported
	Diazepam	S	Oral	100 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	15597623	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-972702		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anorgasmia; Ejaculation Failure; Erectile Dysfunction; Erectile Dysfunction; Loss Of Libido; Male Sexual Dysfunction	Escitalopram			S	Unknown	40 Milligram Daily;		Ivax
	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Mirtazapine			S	Unknown	22.5 Milligram Daily; Every Bedtime		Teva
	Mirtazapine			S				Teva
	Mirtazapine			S				Teva
	Alprazolam			S	Unknown	Tid When Necessary		Actavis
	Alprazolam			S				Actavis
	Alprazolam			S				Actavis
	Lamotrigine			S	Unknown	Tid		Teva
	Lamotrigine			S				Teva
	Enalapril			S	Unknown	20 Milligram Daily; Every Morning		Teva
	Lansoprazole			S	Unknown	30 Milligram Daily; Every Morning		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	15675033	EXPEDITED (15-DAY)		DS, OT	PT-AUROBINDO-AUR-APL-2018-057308			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dystonia; Gait Disturbance; Gait Inability; Posture Abnormal; Stiff	Escitalopram 20 Mg			S	Unknown	20 Milligram		Aurobindo
	Escitalopram 20 Mg			S				Aurobindo
	Insulin			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Person Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16236323	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2019GB02145			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram			S	Unknown	20 Milligram, Per Day, Tablet		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16237021	EXPEDITED (15-DAY)		CA, OT	DE-ACCORD-123927		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 Mg/D		Not Reported	
	L-Thyroxin 50			C	Transplacental	50 Mg/D		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16237073	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.- 2019GB02377			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Invagen	
	Elleste-Solo			C	Transdermal	80 Microgram, Qd (Every 24 Hrs), Transdermal Patch		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16237259	EXPEDITED (15-DAY)		OT	NO-TEVA-2019-NO- 1042888			Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Hypomania	Escitalopram Actavis			S	Oral	20 Milligram Daily;		Ivax	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16237451	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2019073865		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Zelitrex			S	Oral	6 Df, Qd		Glaxosmithkline	
	Seroplex			S	Oral	1 Df, Qd		Glaxosmithkline	
	Fludex (Indapamide)			S	Oral	Unk		Not Reported	
	Ditropan			S	Oral	2 Df, Qd		Not Reported	
	Perindopril			S	Oral	8 Mg, Qd		Not Reported	
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported	
	Paracetamol			C	Oral	3 Df, Qd		Glaxosmithkline	
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported	
	Movicol			C	Oral	2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16238201	NON-EXPEDITED			US-PFIZER INC-2019176876		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16240547	NON-EXPEDITED			US-TAKEDA-2019TUS023465			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Dry Mouth; Headache; Initial Insomnia; Nausea; Paraesthesia; Poor Quality	Trintellix			S	Unknown	Unk		Takeda	
	Lexapro			S	Unknown	Unk		Not Reported	
	Lexapro			S				Not Reported	
	Celexa /00582602/			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sleep; Restlessness; Therapy Partial Responder	Abilify	S	Unknown	Unk		Not Reported
	Abilify	S				Not Reported
	Gabapentin	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	15481816	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2018-027084		29 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Gastric Haemorrhage; Hypoxia; Intentional Overdose; Seizure; Suicide Attempt	Salbutamol			S	Unknown			Bausch And Lomb	
	Trimipramine Beta			S	Unknown	100		Not Reported	
	Tramadol			S	Unknown			Not Reported	
	Metoprolol			S	Unknown			Not Reported	
	Cipralex			S	Unknown	10		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16241742	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-022644			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram			S	Unknown	5 Milligram		Aurobindo	
	Escitalopram			S	Unknown	15 Milligram		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16242520	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-206381		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Sun	
	Escitalopram			S	Oral	Unk		Not Reported	
	Spironolactone			S	Oral	Unk		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tinzaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))	S	Subcutaneous	Unk	Not Reported
Trileptal	S	Oral	Unk	Not Reported
Lacosamide	S	Oral	Unk	Not Reported
Diltiazem (Chlorhydrate De)	S	Oral	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16242606	EXPEDITED (15-DAY)	HO		IT-ACCORD-124176		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S				Not Reported	
	Coaprovel 300 / 12.5			S	Oral			Not Reported	
	Urbason			C				Not Reported	
	Paracetamol			C				Not Reported	
	Alprazolam			C				Not Reported	
	Eutirox			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Alendronic Acid/Cholecalciferol			C	Oral			Not Reported	
	Colecalciferol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16243716	NON-EXPEDITED			US-PFIZER INC- 2019173755		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Apriso			S		Unk		Not Reported	
	Calcium			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Norco			S		Unk		Not Reported	
	Pravastatin			S		Unk		Not Reported	
	Singulair			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vit D	S	Unk	Not Reported
Zyloprim	S	Unk	Not Reported
Folic Acid	S	Unk	Not Reported
Baby Aspirin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16244202	EXPEDITED (15-DAY)		OT	GB- ELI_LILLY_AND_COMP ANY-GB201904008235			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Prozac			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Zoloft			S	Unknown	Unk, Unknown		Not Reported
	Desipramine			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	Unk, Unknown		Not Reported
	Adderall			S	Unknown	Unk, Unknown		Not Reported
	Wellbutrin			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Effexor			S	Unknown	Unk, Unknown		Not Reported
	Ambien			S	Unknown	Unk, Unknown		Not Reported
	Celexa [Citalopram Hydrobromide]			S	Unknown	Unk Unk, Unknown		Not Reported
	Zyprexa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16244577	EXPEDITED (15-DAY)		OT	US-APOTEX- 2019AP012786		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Drug Ineffective; Electrocardiogram Qt Prolonged; Paraesthesia	Buspirone			S	Unknown	Unk		Apotex
	Sertraline			S	Unknown	Unk		Apotex
	Escitalopram			S	Unknown	Unk		Apotex
	Citalopram			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aripiprazole	S	Unknown	Unk	Apotex
Albuterol	S	Unknown	Unk	Apotex
Montelukast	S	Unknown		Apotex
Clonazepam Auden	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16246178	EXPEDITED (15-DAY)		DE, OT	SE-SHIRE- SE201913147			Unknown	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death; Toxicity To Various Agents	Elvanse			S	Oral	40 Milligram, 1x/Day:Qd		Shire
	Lamictal			S	Oral	200 Milligram, 1x/Day:Qd		Not Reported
	Escitalopram Accord			S	Oral	10 Milligram, 1x/Day:Qd		Not Reported
	Voxra			S	Oral	150 Milligram, 1x/Day:Qd		Not Reported
	Melatonin Agb			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2019	16246785	EXPEDITED (15-DAY)		DE	BE-ACCORD-124115		38 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2019	16246854	EXPEDITED (15-DAY)		OT	SE-ACCORD-124226		56 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis	Escitalopram			S	Oral	10-15mg		Not Reported
	Sertraline			S	Oral			Accord
	Lergigan [Promethazine Hydrochloride]			C				Not Reported
	Imovane			C				Not Reported

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28-Apr-2019	16247640	EXPEDITED (15-DAY)		HO, OT	LU-APOTEX-2019AP012363		47 YR	Female	LUX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral	Unk		Apotex	
	Gilenya			S	Oral	1 Df, Qd		Not Reported	
	Lyrice			C	Oral	100 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2019	16248048	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1918189US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram Hydrobromide - Bp			S	Unknown			Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	7.5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported	
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported	
	Trintellix			S	Unknown	10 Mg, Qd (Once Every 24 Hours)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2019	16251644	DIRECT		LT			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Facial Paralysis; Headache; Heart Rate Increased; Pain In Extremity; Pyrexia;	Lexapro			S	Oral			Not Reported	

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Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	14370638	NON-EXPEDITED			US-PFIZER INC-2018005289		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Interaction; Inhibitory Drug Interaction	Xeljanx Xr			S	Oral	11 Mg, 1x/Day		Pfizer	
	Xeljanx Xr			S		11 Mg, 1x/Day		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Plaquenil			C		200 Mg, 1x/Day (Two Pills In The Evening)		Not Reported	
	Plaquenil			C		Unk		Not Reported	
	Prednisone			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	15993802	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-108376			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Bendamustine/Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149.4 Mg, Unknown		Not Reported	
	Escitalopram			S				Not Reported	
	Cotrimoxamol			S				Not Reported	
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported	
	Omeprazole			S				Not Reported	
	Rituximab			S				Not Reported	
	Valsartan Nichi Iko			C				Not Reported	
	Atorvastatin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16186388	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR054397		49 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Alanine Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Creatinine Increased; Death; Diarrhoea; Gamma-Glutamyltransferase Increased; Urinary Retention	Votrient Seroplex	S S	Oral Unknown	800 Mg, Daily 15 Ot, Unk	Novartis Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16248572	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR-APL-2019-023150			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol			S	Oral	Unk		Aurobindo
	Paracetamol			S	Oral	12 Gram		Aurobindo
	Diazepam			S	Oral	100 Milligram		Not Reported
	Seroplex			S	Oral	560 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16248832	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-124339			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram			S	Oral			Not Reported
	Fluoxetine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16248932	EXPEDITED (15-DAY)		OT	ES-ACCORD-124567		66 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Urinary Retention	Escitalopram			S	Oral	Strength: 10 Mg 28 Tablets, 1/2-0-0		Not Reported	
	Gabapentin			S	Oral	1-1-1. 0-0-1 1st Week, 2nd Week 0-1-1, 1-1-1 3rd Week And Continue To Further Review		Not Reported	
	Zytram Bid			S	Oral	Strength: 75 Mg, 56 Tablets, 1-0-1. 1st Week 0-0-1, 2nd Week 1-0-1 And Continue Until Revision		Not Reported	
	Nebivolol			C	Oral	Strength: 5 Mg 28 Tablets		Not Reported	
	Atorvastatin			C	Oral	Strength: 40 Mg 28 Tablets		Not Reported	
	Acetylsalicylic Acid			C	Oral	Strength: 100 Mg 30 Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16249312	EXPEDITED (15-DAY)		HO	FR-ACCORD-124554		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral			Not Reported	
	Previscan (Fluindione)			S	Oral	Strength 20 Mg, Scored Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16249944	EXPEDITED (15-DAY)		LT	FR-MARINA BIOTECH, INC.- 2019MARINA000566			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Coveram Nos			S	Oral	Unk		Unknown	
	Lamotrigine			S	Oral	Unk		Not Reported	

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	Racecadotril	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Levothyroxine Sodium	S	Oral	Unk	Not Reported
	Mirtazapine	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16250823	NON-EXPEDITED			US-TEVA-2019-US-1041720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Escitalopram Tablets, USP Teva			S	Unknown			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16251989	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1039316			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Prescription Form Tampering	Escitalopram			S	Unknown	Non Renseign�e		Not Reported	
	Quetiapine			S	Unknown	Non Renseign�e		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16252613	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1039434		40 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma;	Escitalopram			S	Unknown	Unk		Not Reported	
Hypermetropia; Migraine;	Cipralex /01588501/			S		20 Gram, Qd (Started With 1 Drop Daily)		Mylan	
Optic Nerve Injury; Visual Field Defect	Cipralex /01588501/			S		Unk		Mylan	

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29-Apr-2019	16253358	EXPEDITED (15-DAY)		LT	FR-ZYDUS-036083		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine	S	Oral	()	Not Reported
	Racecadotril	S	Oral	()	Not Reported
	Escitalopram	S	Oral		Cadila
	Levothyroxine	S	Oral	()	Not Reported
	Mirtazapine	S	Oral		Zydus Pharm
	Coveram	S	Oral	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	15375512	EXPEDITED (15-DAY)		OT	CZ-ACCORD-071688		58 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Mental Disorder; Suicide Attempt	Aripiprazole			S				Not Reported
	Escitalopram			S	Unknown			Not Reported
	Citalopram			S		Series Of Citalopram Infusions		Not Reported
	Risperidone			S	Unknown	Unk Unk,Unk		Not Reported
	Olanzapine			S	Unknown			Not Reported
	Venlafaxine			S	Unknown	Unk Unk,Unk		Not Reported
	Ziprasidone/Ziprasidone Hydrochloride/Ziprasidone Mesilate			S		Unk		Not Reported
	Mirtazapine			S	Oral	Unk Unk,Unk		Not Reported
	Clomipramine			S				Not Reported
	Tiapride			C		Unk		Not Reported
	Memantine/Memantine Hydrochloride			C				Not Reported
	Propofol			C		Unk		Not Reported
	Melperone/Melperone Hydrochloride			C				Not Reported
	Haloperidol			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported

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30-Apr-2019	15876530	EXPEDITED (15-DAY)		OT	PHHY2019GB004960		46 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Clozaril			S	Oral	175 Mg, Qd (50 Mg Am And 125 Mg Pm)		Not Reported	
	Clozaril			S	Oral	Unk		Not Reported	
	Clozaril			S	Oral	Unk		Not Reported	
	Clozaril			S	Oral	Unk		Not Reported	
	Olanzapine			S	Oral	20 Mg, Qd		Novartis	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	15900047	EXPEDITED (15-DAY)		HO, OT	JP-SUNOVION-2019SUN000331		30 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Glossoptosis; Overdose; Serotonin Syndrome; Tonic Convulsion	Lunesta			S	Oral	15 Df, 2mg Tablets		Sunovion	
	Lexapro			S	Oral	15 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16073573	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1023573		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral	Unk		Not Reported	
	Medrol /00049601/			C				Mylan	
	Plavix			C				Mylan	
	Omeprazen /00661201/			C				Mylan	
	Desloratadine			C				Mylan	

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Pregabalin			C			Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16108610	EXPEDITED (15-DAY)		OT	IT-ACCORD-114238		74 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyperpyrexia; Hyponatraemia	Escitalopram			S	Oral			Not Reported	
	Medrol			C				Not Reported	
	Plavix			C				Not Reported	
	Desloratadine			C				Not Reported	
	Omeprazen			C				Not Reported	
	Pregabalin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16239131	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019172513		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Pfizer	
	Spironolactone			S	Oral	Unk		Pfizer	
	Tinzaparine Sodique			S	Subcutaneous	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Trileptal			S	Oral	Unk		Not Reported	
	Lacosamide			S	Oral	Unk		Not Reported	
	Diltiazem			S	Oral	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253460	NON-EXPEDITED			US-TEVA-2019-US-1039868			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Escitalopram			S	Unknown			Ivax	

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30-Apr-2019	16253462	NON-EXPEDITED			US-TEVA-2019-US-1045292			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gluten Sensitivity	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253819	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-023151			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral	Unk		Aurobindo	
	Escitalopram			S	Oral	Unk		Aurobindo	
	Mirtazapine			S	Oral	Unk		Aurobindo	
	Levothyrox			S	Oral	Unk		Not Reported	
	Racecadotril			S	Oral	Unk		Not Reported	
	Coveram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253831	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE090529			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Novartis	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported	
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16254093	EXPEDITED (15-DAY)		HO, LT	PHHY2019FR096102		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral	10 Mg, Qd		Novartis	
	Perindopril			S	Oral	8 Mg, Qd		Not Reported	
	Fludex (Indapamide)			S	Oral	Unk (Inconnue)		Not Reported	
	Zelitrex			S	Oral	6 Df, Qd		Not Reported	
	Ditropan			S	Oral	2 Df, Qd		Not Reported	
	Seroplex			S	Oral	1 Df, Qd		Not Reported	
	Movicol			C	Oral	2 Df, Qd		Not Reported	
	Paracetamol			C	Oral	3 Df, Qd		Not Reported	
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255104	EXPEDITED (15-DAY)		OT	PT-ACCORD-124718		27 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown			Not Reported	
	Insulin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255112	EXPEDITED (15-DAY)		HO	SE-BIODELIVERY SCIENCES INTERNATIONAL-2019BDSI0338		69 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Fentanyl Citrate			S	Unknown			Not Reported	
	Mirtazapine			S	Unknown			Not Reported	

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Tapentadol Hydrochloride	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255530	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1039862		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Rectal Haemorrhage	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Previscan /00789001/			S	Oral	1/2 Cp/J 1 Jours/2 En Alternance Avec 3/4 Cp		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255959	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2018AMN00435			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Rash Pruritic	Escitalopram Oxalate			S	Unknown	Unk		Amneal
	Escitalopram Oxalate			S				Amneal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255962	NON-EXPEDITED		OT	US-AMNEAL PHARMACEUTICALS-2018AMN00396			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dysgeusia; Dyspnoea; Headache; Hypersensitivity; Neck Pain; Pharyngeal Swelling; Pruritus; Throat Irritation	Escitalopram Oxalate			S		5 Mg, 1x/Day		Amneal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16256122	EXPEDITED (15-DAY)		HO, OT	DE-HORMOSAN PHARMA GMBH-2019-02631			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Deep Vein Thrombosis; Pulmonary Embolism	Quetiapine	S	Oral	Unk	Lupin
	Escitalopram	S	Unknown	Unk	Lupin
	Bisoprolol	S	Unknown	1.25 Milligram	Not Reported
	Trigoa	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16256865	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1039954			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Treatment Failure	Diazepam			S	Unknown			Not Reported	
	Flurazepam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	Unk		Not Reported	
	Acetylsalicylic Acid			S	Unknown	Unk		Mylan	
	Lamotrigine			S	Unknown	Unk		Mylan	
	Epclusa			S	Unknown	Unk		Mylan	
	Chlorpromazine			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16257402	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1918363US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Citalopram Hydrobromide - Bp			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16257561	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019178552			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dizziness; Drug Ineffective; Fatigue; Hypoaesthesia; Indifference; Myalgia; Oropharyngeal Pain; Seizure	Efexor XL Zoloft Prozac Desipramine Klonopin Adderall Wellbutrin Lexapro Ambien Celexa [Citalopram Hydrobromide] Zyprexa	S S S S S S S S S S S C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk	Pfizer Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16258355	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1918457US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Product Use In Unapproved Indication; Restlessness; Tremor	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	14114520	NON-EXPEDITED			US-PFIZER INC-2017454452		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer	
	Erythrocin			S		Unk		Unknown	
	Clindamycin Hcl			S		Unk		Pfizer	
	Relpax			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	

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Mobic	S	Unk	Not Reported
Elavil	S	Unk	Not Reported
Levbid	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Allegra	S	Unk	Not Reported
Ambien	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Ditropan	S	Unk	Not Reported
Flexeril	S	Unk	Not Reported
Januvia	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Metformin	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Zantac	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	15839133	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1001820		46 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Clozaril			S	Oral	50 Milligram, Am		Mylan
	Clozaril			S	Oral	125 Milligram, Pm		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Clozaril			S	Oral	Unk		Mylan
	Olanzapine			S	Oral	20 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Mylan
	Omeprazole			C	Oral	20 Milligram, Qd		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16180947	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1915639US			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressive Symptom; Weight Decreased	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Lithium Carbonate			C	Oral			Not Reported	
	Lithium Carbonate			C	Oral	200 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16242839	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1039557		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Azithromycin			S	Oral	1500 Milligram, Total		Not Reported	
	Escitalopram			S	Oral	140 Milligram, Qd		Not Reported	
	Prednisolone			S	Oral	200 Milligram, Total		Not Reported	
	Paracetamol			S	Oral	79 Gram, Total		Not Reported	
	Cefpodoxime			S	Oral	2000 Milligram, Total		Not Reported	
	Trimebutine			S	Oral	14000 Milligram, Total		Not Reported	
	Amoxicillin/Clavulanic Acid			S	Oral	6 Gram, Qd		Not Reported	
	Loperamide			S	Oral	30 Milligram, Total		Not Reported	
	Arestal			S	Oral	30 Milligram, Total		Mylan	
	Seresta			S	Oral	310 Milligram, Total		Mylan	
	Inorial			S	Oral	120 Milligram, Total		Mylan	
	Augmentin /00756801/			S	Oral	6 Gram, Qd		Mylan	
	Oxazepam			S	Oral	310 Milligram, Total		Mylan	
	Bilastine			S	Oral	120 Milligram, Total		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16259321	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1043381		64 YR	Male	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Syncope	Escitalopram			S	Oral	Titrated 10 Mg To 12.5 Mg During The Therapy Period.		Ivax	
	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Alfuzosin			C				Not Reported	
	Mirtazapin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16259378	EXPEDITED (15-DAY)		DS	SE-ACCORD-125307		61 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Escitalopram			S	Oral	10mg 1x1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16259541	EXPEDITED (15-DAY)		HO, OT	US-ASTELLAS-2019US017878		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Tamsulosin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
Acrophobia; Alopecia;	Solifenacin			S	Unknown			Astellas	
Amnesia; Anxiety; Anxiety;	Atorvastatin			S	Unknown			Not Reported	
Arthritis; Back Disorder;	Teriflunomide			S	Oral			Not Reported	
Balance Disorder;	Teriflunomide			S	Oral			Not Reported	
Decreased Appetite;	Teriflunomide			S	Oral			Not Reported	
Depression; Diarrhoea;	Teriflunomide			S	Oral			Not Reported	
Diverticulitis; Fatigue; Gait	Teriflunomide			S	Oral			Not Reported	
Disturbance; Gastric	Teriflunomide			S	Oral			Not Reported	
Ulcer; Hypersomnia;	Teriflunomide			S	Oral			Not Reported	
Hypoaesthesia; Multiple	Teriflunomide			S	Oral			Not Reported	
Sclerosis Relapse;	Teriflunomide			S	Oral			Not Reported	
Myalgia; Nasopharyngitis;	Teriflunomide			S	Oral			Not Reported	
Nausea; Pain; Pain;	Teriflunomide			S	Oral			Not Reported	
Paraesthesia; Product Use	Teriflunomide			S	Oral			Not Reported	
In Unapproved Indication;	Morniflumate			S	Unknown	Unk Unk, At Bedtime		Not Reported	
Product Use Issue;									
Pruritus; Pruritus									

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Generalised; Temperature Intolerance; Tinnitus; Vertigo; Vision Blurred; Vomiting	Escitalopram Oxalate	S	Unknown		Not Reported
	Metformin Hydrochloride	S	Unknown		Not Reported
	Vitamin B-Complex /00228301/	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Colecalciferol	S	Unknown		Not Reported
	Calcium	S	Unknown		Not Reported
	Calcium	S	Unknown	Unk, Unknown Freq.	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Mirtazapine	C	Unknown	Unk Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260399	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1045002		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Spironolactone			S	Oral			Actavis
	Lacosamide			S	Oral			Not Reported
	Diltiazem (Chlorhydrate De)			S	Oral			Teva
	Trileptal			S	Oral			Not Reported
	Tinzaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			S	Subcutaneous			Not Reported
	Bactrim			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260644	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1918478US			Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Lymphocytic Leukaemia; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	5 Mg, Qd		Allergan
	Ladose			S	Transplacental			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16262200	EXPEDITED (15-DAY)		HO	CA-BAUSCH-BL-2019-012772			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin XI			S	Oral			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Ferrous Sulphate			S	Unknown			Not Reported	
	Gabapentin			S	Oral			Not Reported	
	Gabapentin			S	Oral			Not Reported	
	Temazepam			S	Oral			Not Reported	
	Tylenol With Codeine No.3			S	Oral			Not Reported	
	Vitalux			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16262218	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1918323US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Citalopram Hydrobromide - Bp			S	Unknown	Unk, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unknown		Allergan	
	Acetaminophen W/Oxycodone			S	Unknown	Unk, Unknown		Not Reported	
	Diazepam			S	Unknown	Unk, Unknown		Not Reported	
	Lorazepam			S	Unknown	Unk, Unknown		Not Reported	
	Morphine			S	Unknown	420 Mg, Unknown		Not Reported	
	Morphine			S	Unknown	30 Mg, Unknown		Not Reported	
	Morphine			S	Unknown	30 Mg, Unknown		Not Reported	
	Oxycodone			S	Unknown	Unk, Unknown		Not Reported	
	Zopiclone			S	Oral	Unk, Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16262219	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1918186US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16264340	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zoloft 25mg			S				Not Reported	
	Lexapro 20mg			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	15030176	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1040164		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Prescribed Underdose	Tramadol			S	Oral	Unk		Not Reported	
	Esomeprazole			S	Oral	Unk		Not Reported	
	Lipanthyl			S	Oral	145 Mg, Qd		Mylan	
	Decapeptyl /00975902/			S	Intramuscular	1 Df, Cycle		Mylan	
	Innohep			S	Subcutaneous	1 Df, Qd		Mylan	
	Amlor			S	Oral	Unk		Mylan	
	Amlor			S	Oral	Unk		Mylan	
	Novonorm			S	Oral	Unk		Mylan	
	Novonorm			S	Oral	Unk		Mylan	
	Xtandi			S	Oral	120 Mg, Qd		Mylan	
	Xtandi			S	Oral	40 Mg, Qd		Mylan	
	Seroplex			S	Oral	10 Mg, Qd		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16262578	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2019TUS026516			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Trintellix			S	Unknown	10 Milligram, Qd		Takeda	
	Trintellix			S				Takeda	
	Trintellix			S				Takeda	
	Citalopram			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	10 Milligram		Not Reported	
	Escitalopram			S	Unknown	7.5 Milligram		Not Reported	
	Escitalopram			S	Unknown	5 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16262773	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1043519		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol Base			S	Oral			Teva	
	Paracetamol			S	Oral	12 Gram		Not Reported	
	Diazepam			S	Oral	100 Milligram		Barr	
	Seroplex 20 Mg, Comprimé Pelliculé Sécable			S	Oral	560 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16262787	EXPEDITED (15-DAY)		LT	FR-PROVELL PHARMACEUTICALS-2066517		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Euthyrox			S	Oral			Provell	
	Racecadotril Bgr			S	Oral			Pharmaceuticals	
	Coveram			S	Oral			Not Reported	

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	Mirtazapine		S	Oral				Not Reported	
	Escitalopram		S	Oral				Not Reported	
	Lamotrigine		S	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16263384	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1045352		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine			S	Oral			Teva	
	Escitalopram			S	Oral			Ivax	
	Mirtazapine			S	Oral			Teva	
	Levothyrox			S	Oral			Not Reported	
	Racecadotril Bgr			S	Oral			Not Reported	
	Coveram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16263412	EXPEDITED (15-DAY)		OT	IT-ACCORD-125513		80 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hyperhidrosis; Malaise	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16266222	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2019-012774		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Wellbutrin XI			S	Oral			Not Reported	
	Clonazepam			S	Oral			Not Reported	
	Domperidone			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

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	Ferrous Sulfate	S	Oral	Not Reported
	Gabapentin	S	Oral	Not Reported
	Temazepam	S	Oral	Not Reported
	Tylenol With Codeine	S	Oral	Not Reported
	Vitalux	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16266605	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20190441815		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Paracetamol			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16267041	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1918614US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Dislocation; Device Malfunction; Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan	
	Amlodipine Besilate			S	Unknown	1.5 Df, Qd		Not Reported	
	Apo-Escitalopram			S	Unknown			Not Reported	
	Apo Tamsulosin			S	Unknown	1 Df, Qd		Not Reported	
	Apo-Trazodone			S	Unknown	1 Df, Qd		Not Reported	
	Brilinta			S	Unknown	1 Df, Q12h		Not Reported	
	Ciclopirox Olamine			S	Unknown			Not Reported	
	Clonazepam			S	Unknown	1 Df, Q8hr		Not Reported	
	Delatestryl			S	Unknown	0.5 MI, Q2weeks		Not Reported	
	Dexilant			S	Unknown	1 Df, Qd		Not Reported	
	Diltiazem			S	Unknown	1 Df, Qd		Not Reported	

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Emo Cort	S	Topical	Unk, Qd	Not Reported
Jamp Asa	S	Unknown	1 Df, Qd	Not Reported
Metonia	S	Unknown	1 Df, Q8hr	Not Reported
Mylan Nitro	S	Oral		Not Reported
Mylan Nitro	S	Oral	Unk	Not Reported
Nasonex	S	Nasal	Unk, Qd	Not Reported
Nitro-Dur	S	Unknown	1 Df, Qd	Not Reported
Ratio-Zopiclone	S	Unknown	1 Df	Not Reported
Rosuvastatin Calcium	S	Unknown	1 Df, Qd	Not Reported
Synthroid	S	Unknown	1 Df, Qd	Not Reported
Tevabisoprol	S	Unknown	1 Df, Qd	Not Reported
Triatec (Acetaminophen)\Codeine Phosphate)	S	Unknown	1 Df, Q6hr	Not Reported
Escitalopram	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16269058	DIRECT		OT			14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Kelnor			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16269393	NON-EXPEDITED			US-TEVA-2019-US-1044604			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Emotional Disorder; Palpitations	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16269432	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019GSK078975			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Wellbutrin XL			S	Oral	150 Mg, Bid (150 Mg,2 In 1 D)		Glaxosmithkline
	Domperidone			S	Unknown	10 Mg, Bid (10 Mg,2 In 1 D)		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline
	Ferrous Sulphate			S	Unknown	300 Mg, Tid (300 Mg,3 In 1 D)		Glaxosmithkline
	Gabapentin			S	Oral	300 Mg, 1d (300 Mg,1 In 1 D)		Glaxosmithkline
	Gabapentin			S	Oral	600 Mg, Bid (600 Mg,2 In 1 D)		Glaxosmithkline
	Clonazepam			S	Unknown	0.5 Mg, Tid (0.5 Mg,3 In 1 D)		Not Reported
	Temazepam			S	Oral	30 Mg, 1d (30 Mg,1 In 1 D)		Not Reported
	Tylenol # 3 (Codeine + Acetaminophen)			S	Oral	2 Df, Tid (2 Dosage Forms,3 In 1 D)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16269530	NON-EXPEDITED			US-PFIZER INC-2019182274		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16270009	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019185390			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Apparent Death; Burnout Syndrome; Drug Interaction; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Restlessness; Stress	Ibuprofen	S	Unknown	Unk	Pfizer
	Ciprallex [Escitalopram]	S	Unknown	5 Mg, Unk	Not Reported
	Ciprallex [Escitalopram]	S	Unknown	5 Mg, 1x/Day	Not Reported
	Ciprallex [Escitalopram]	S	Unknown	7.5 Mg, Alternate Day	Not Reported
	Ciprallex [Escitalopram]	S		Unk	Not Reported
	Escitalopram	S		Unk	Not Reported
	Escitalopram	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16271465	EXPEDITED (15-DAY)		OT	GR-ELI_LILLY_AND_COMP ANY-GR201904013112		212 DAY	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Lymphocytic Leukaemia; Foetal Exposure During Pregnancy	Ladose 20mg			S	Transplacental	20 Mg, Daily		Not Reported
	Ladose 20mg			S	Transplacental	20 Mg, Daily		Not Reported
	Entact			S	Transplacental	5 Mg, Daily		Not Reported
	Entact			S	Transplacental	5 Mg, Daily		Not Reported
	Fugentin [Amoxicillin Trihydrate;Clavulanate			C	Unknown	Unk, Unknown		Not Reported
	Fugentin [Amoxicillin Trihydrate;Clavulanate			C	Unknown	Unk, Unknown		Not Reported
	Utrogestan			C	Unknown	Unk, Unknown		Not Reported
	Utrogestan			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16271878	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1042179		25 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asthenia; Disorientation; Drug Ineffective; Hypersensitivity; Movement Disorder; Product Substitution Issue;	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Form, Qd		Mylan

FDA Adverse Event Reporting System

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Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16271952	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1042422		40 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flight Of Ideas; Sensory Disturbance	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported	
	Lamictal			C	Oral	200 Milligram		Mylan	
	Rivotril			C	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2019	16274369	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-036243		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Indapamide			S	Oral	1.5 Mg Prolonged-Release Film-Coated Tablet		Not Reported	
	Valaciclovir			S	Oral			Not Reported	
	Oxybutynin			S	Oral	5 Mg, Scored Tablet		Not Reported	
	Perindopril/Perindopril Erbumine			S	Oral			Not Reported	
	Escitalopram			S	Oral	5 Mg Film-Coated Tablets		Not Reported	
	Amlodipine			S	Oral			Zydus Pharm	
	Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride			C	Oral	Powder For Oral Solution In Sachet		Not Reported	
	Paracetamol			C	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	15072563	EXPEDITED (15-DAY)		HO	LU-ALLERGAN-1832491US			Female	LUX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram Oxalate - Bp	S	Oral	Unk	Allergan
	Gilenya	S	Oral	1 Df, Qd	Not Reported
	Lyrica	C	Oral	100 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16199453	EXPEDITED (15-DAY)		OT	DE-ARALEZ PHARMACEUTICALS R&D INC.-2019-ARA-001126		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Succinate			S	Oral	Unk, Hexal		Aralez Pharmaceuticals
	Metoprolol Succinate			S	Oral	Unk		Aralez Pharmaceuticals
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S		Unk, Mylan		Not Reported
	Escitalopram			S		Unk, Stada		Not Reported
	Escitalopram			S		Unk, Hexal		Not Reported
	Metoprolol Tartrate			S		Unk, Stada		Not Reported
	Metoprolol Tartrate			S		Unk, Mylan		Not Reported
	Ibuprofen			S		Unk, Stada		Not Reported
	Ibuprofen			S		Unk, Hormosan		Not Reported
	Ibuprofen			S		Unk		Not Reported
	Ibuprofen			S		Unk, Hexal		Not Reported
	Prednisolon /00016201/			S		Unk, Stada		Not Reported
	Prednisolon /00016201/			S		25 Mg, Unk		Not Reported
	Prednisolon /00016201/			S		Unk, Jenapharm		Not Reported
	Prednisolon /00016201/			S		Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Pantozol /01263204/			S		Unk		Not Reported
	Implanon			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Salbutamol	S	Unk, Stada	Not Reported
Salbutamol	S	Unk	Not Reported
Salbutamol	S	Unk	Not Reported
Amitriptyline	S	Unk	Not Reported
Methotrexate	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16240189	EXPEDITED (15-DAY)		DE, OT	FR-ALLERGAN-1845971US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Creatinine Increased; Death; Diarrhoea; Gamma-Glutamyltransferase Increased; Urinary Retention	Escitalopram Oxalate Unk			S	Unknown	15 Ot, Unk		Allergan
	Votrient			S	Oral	800 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16271749	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-206741		19 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Paracetamol		Y	S	Oral	12 Grams, Unk		Ohm Lab
	Tramadol			S	Oral	()		Sun
	Seroplex 20 Mg, Comprime			S	Oral	560 Mg, Unk		Not Reported
	Pellicule Secable							
	Diazepam			S	Oral	100mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16271759	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL		53 YR	Female	FRA

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Freedom of Information Act (FOIA)

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INDUSTRIES LTD-
2019RR-206742

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral	()		Not Reported
	Mirtazapine			S	Oral	()		Sun
	Lamotrigine			S	Oral	()		Not Reported
	Racecadotril Bgr			S	Oral	()		Not Reported
	Levothyrox			S	Oral	()		Not Reported
	Coveram			S	Oral	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16275765	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2019GSK080041		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Wellbutrin XI			S	Oral	150 Mg, Bid		Glaxosmithkline
	Domperidone			S	Oral	10 Mg, Bid		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline
	Ferrous Sulfate			S	Oral	300 Mg, Tid		Glaxosmithkline
	Gabapentin			S	Oral	600 Mg, Bid		Glaxosmithkline
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, 1d		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16277606	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2019M1042396		56 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Toxicity To	Escitalopram			S	Oral	Unk		Not Reported

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Various Agents	Metoprolol	S	Oral	Unk	Mylan
	Xarelto	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16279004	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1904434US			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	Unk		Not Reported
	Clozaril			S	Oral	50 Mg, Qam		Not Reported
	Clozaril			S	Oral	125 Mg, Qpm		Not Reported
	Olanzapine			S	Oral	20 Mg, Qd		Not Reported
	Omeprazole			C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16279105	EXPEDITED (15-DAY)		HO	AU-TAKEDA-2019TUS027869			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Irritability; Suicidal Ideation	Brintellix			S	Unknown	10 Milligram		Takeda
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	14373900	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2017008205			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk, Unspecified		Macleods
	Escitalopram Tablet			S	Oral	Unk, Unspecified		Macleods

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Abasaglar	S	Subcutaneous	Unk, Unspecified	Not Reported
Fondaparinux Sodium	S	Subcutaneous	Unk, (Solution For Injection), Unspecified	Not Reported
Lipanthyl	S	Oral	Unk, Unspecified	Not Reported
Movicol	S	Oral	Unk, Unspecified	Not Reported
Novorapid	S	Subcutaneous	Unk, Unspecified	Not Reported
Primperan	S	Oral	Unk, Unspecified	Not Reported
Xeloda	S	Oral	Unk, Unspecified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	14376008	EXPEDITED (15-DAY)	HO		FR-MYLANLABS-2018M1002399		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Axonal Neuropathy; Cyanosis; Livedo Reticularis; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Quetiapine			S	Oral	400 Mg, Qd		Not Reported	
	Quetiapine			S		Unk		Not Reported	
	Quetiapine			S		Unk		Not Reported	
	Methylphenidate			S	Oral	110 Mg, Qd		Not Reported	
	Methylphenidate			S		Unk		Not Reported	
	Methylphenidate			S	Oral	100 Mg, Unk		Not Reported	
	Laroxyl			S	Unknown	Unk		Mylan	
	Laroxyl			S		Unk		Mylan	
	Laroxyl			S		Unk		Mylan	
	Lexapro			S	Oral	10 Mg, Qd		Mylan	
	Lexapro			S		Unk		Mylan	
	Lexapro			S		Unk		Mylan	
	Xeroquel			S		Unk		Mylan	
	Xeroquel			S		Unk		Mylan	
	Xeroquel			S	Oral	400 Mg, Qd		Mylan	
	Seroplex			S	Oral	10 Mg, Qd		Mylan	
	Seroplex			S		Unk		Mylan	

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Seroplex	S		Unk	Mylan
Ritaline	S	Oral	100 Mg, Unk	Mylan
Ritaline	S		Unk	Mylan
Ritaline	S	Oral	110 Mg, Qd	Mylan
Ritaline	S		Unk	Mylan
Lepticur	S	Unknown	15 Mg, Unk	Mylan
Lepticur	S		Unk	Mylan
Lepticur	S		Unk	Mylan
Abilify	S		Unk	Mylan
Abilify	S	Oral	15 Mg, Qd	Mylan
Abilify	S		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	15897568	EXPEDITED (15-DAY)		OT	GB- ELI_LILLY_AND_COMP ANY-GB201901013817		46 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Olanzapine			S	Oral	20 Mg, Daily		Eli Lilly And Co	
	Clozaril			S	Oral	175 Mg, Each Morning		Not Reported	
	Clozaril			S	Oral	125 Mg, Each Evening		Not Reported	
	Clozaril			S	Oral	50 Mg, Each Morning		Not Reported	
	Clozaril			S	Oral	Unk, Unknown		Not Reported	
	Clozaril			S	Oral	Unk Unk, Unknown		Not Reported	
	Clozaril			S	Oral	Unk, Unknown		Not Reported	
	Escitalopram			S	Oral	20 Mg, Daily		Not Reported	
	Omeprazole			C	Oral	20 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16279637	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US02879			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram		S	Unknown	Unk			Invagen	
	Escitalopram		S					Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16279673	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US02881			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen	
	Escitalopram			S				Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16279699	EXPEDITED (15-DAY)		OT	IN-CIPLA LTD.- 2019IN02904			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Escitalopram			S	Unknown	30 Milligram, Per Day, For Past 5 Years		Invagen	
	Risperidone			S	Unknown	Unk, Augmentation Therapy, For Past 5 Years		Not Reported	
	Fluvoxamine			S	Unknown	Upto 350 Mg/Day, For Past 5 Years		Not Reported	
	Sertraline			S	Unknown	Up To 100mg/Day, For Past 5 Years		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16279774	EXPEDITED (15-DAY)		LT	FR-ROCHE-2312038		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Diazepam			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Tramadol			S	Oral			Not Reported	
	Paracetamol			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16279795	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-207133			Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Blood	Escitalopram			S	Unknown	10 Milligram, Daily		Not Reported	
Prolactin Increased;	Escitalopram			S	Unknown	20 Milligram, Daily		Not Reported	
Breast Pain;	Fluoxetine			S	Unknown	20 Milligram, Daily		Sun	
Galactorrhoea; Intentional Product Misuse									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16280043	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US02953			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall;	Escitalopram			S	Oral	10 Milligram, Unk		Invagen	
Gait Disturbance; Loss Of	Escitalopram			S				Invagen	
Consciousness; Seizure	Ibgard			C	Unknown	Unk, Tid (3 Times A Day Before Meals)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16280633	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2019-024337			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health	Perindopril			S	Oral	8 Milligram, Once A Day		Aurobindo	
Deterioration;	Amlodipine			S	Oral	10 Milligram, Once A Day		Aurobindo	
Hypokalaemia;	Ditropan			S	Oral	2 Dosage Form, Once A Day		Not Reported	
Hyponatraemia	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported	
	Fludex (Indapamide)			S	Oral	Inconnue		Not Reported	
	Zelitrex			S	Oral	6 Dosage Form, Once A		Not Reported	

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Cortancyl	C	Oral	Day	Not Reported
Paracetamol	C	Oral	2 Milligram, Once A Day	Not Reported
Movicol	C	Oral	3 Dosage Form, Once A Day	Not Reported
			2 Dosage Form, Once A Day	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16283975	EXPEDITED (15-DAY)		HO, OT	PT-ALLERGAN-1919091US			Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram Oxalate - Bp			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Allergan
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Not Reported
	Bupropion			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Diazepam			C				Not Reported
	Venlafaxine			C				Not Reported
	Olanzapine			C				Not Reported
	Topiramate			C				Not Reported
	Hydroxycarbamide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16283976	EXPEDITED (15-DAY)		DS	DE-ALLERGAN-1919068US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Product Use In Unapproved Indication; Tremor	Escitalopram Oxalate - Bp			S	Unknown	Unk, Unknown		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Gtt, Unknown		Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	14781731	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018012697			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Communication Disorder; Lethargy; Loss Of Personal Independence In Daily Activities; Memory Impairment; Sluggishness	Escitalopram 10mg Tablet			S	Oral	10 Mg, Qd, (1 Tablet Per Day 10mg)		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	15795074	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC- 2019007588		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Doxepin Hcl			S	Oral	Unk		Pfizer	
	Acetaminophen			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16284905	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US02878			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown	Unk		Invagen	
	Escitalopram			S				Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16285202	EXPEDITED (15-DAY)		HO, LT, OT	GB-ACCORD-126336		84 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Escitalopram			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypotension	Furosemide	S	Oral		Accord
	Irbesartan	S	Oral		Accord
	Braltus	C			Not Reported
	Seretide	C		125	Not Reported
	Simvastatin	C			Not Reported
	Zapain	C		1-2 Four Times Daily	Not Reported
	Salbutamol	C			Not Reported
	Sando-K	C		Various Acute Scripts	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16286356	EXPEDITED (15-DAY)		OT	FR-ROCHE-2310609			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hyperkalaemia; Hypokalaemia; Nephropathy Toxic; Ototoxicity; Sedation	Mycophenolate Mofetil			S	Unknown			Not Reported
	Fluconazole			S	Unknown			Not Reported
	Nicardipine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Roxithromycine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Ursodesoxycholic Acid			S	Unknown			Not Reported
	Voriconazole			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Posaconazole			S	Unknown			Not Reported
	Piperacilline [Piperacillin]			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Vincristine			S	Unknown			Not Reported
	Trimetoprim			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16286559	NON-EXPEDITED			US-PFIZER INC-2019191839		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Phytomenadione			S		Unk		Unknown
	Bromine			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]			S		Unk		Not Reported
	Lopressor			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Tenormin			S		Unk		Not Reported
	Carvedilol			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Losartan Potassium			S		Unk		Not Reported
	Metrogel			S		Unk		Not Reported
	Propoxyphene			S		Unk		Not Reported
	Thimerosal			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16288101	EXPEDITED (15-DAY)		DS	PHHY2019ES103835		32 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Derealisation; Disturbance In Attention; Feeling	Alprazolam			S	Unknown	0,25 Por La Mañana, Y A Veces Por La Tarde		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Palpitations; Somnolence					Noche	
	Escitalopram	S	Unknown	5 Mg, Unk (Diarios)		Not Reported
	Rhodiola Rosea	C	Unknown	Unk		Not Reported
	Pantoprazol	C	Unknown	Unk (1 Al Día)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16289847	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro 20mg			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	13997082	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2017403746		18 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Overdose; Suicide Attempt	Pf-06886992			S	Intramuscular	0.5 MI, Single		Pfizer
	Pf-06886992			S		0.5 MI, Single		Pfizer
	Geodon			S	Oral	20 Mg, Qhs		Pfizer
	Lexapro			S	Oral	10 Mg, Daily		Not Reported
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S	Oral	10 Mg, 2x/Day		Not Reported
	Celexa /00582602/			C	Oral	20 Mg, Daily		Not Reported
	Celexa /00582602/			C	Oral	20 Mg, 2x/Day		Not Reported
	Trileptal			C	Oral	150 Mg, 2x/Day		Not Reported
	Gianvi			C	Oral	1 Tab, Daily		Not Reported
	Buspirone			C	Oral	10 Mg, 2x/Day		Not Reported
	Ambien			C	Oral	10 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16261340	EXPEDITED (15-DAY)		HO, LT	FR-ALLERGAN- 1918464US			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan
	Fludex (Indapamide)			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	6 Df, Qd		Not Reported
	Zelitrex			S				Not Reported
	Ditropan			S	Oral	2 Df, Qd		Not Reported
	Perindopril			S	Oral	8 Mg, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Movicol			C	Oral	2 Df, Qd		Not Reported
	Paracetamol			C	Oral	3 Df, Qd		Not Reported
	Cortancyl			C	Oral	2 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16288562	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-02855		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Disorder; Headache; Hyperhidrosis; Hypothalamic Pituitary Adrenal Axis Suppression; Nausea; Oedema	Levothyroxine			S	Unknown	Unk		Lupin
	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Escitalopram			S	Unknown	5 Milligram, Qd (Decrease)		Lupin
	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Premarin			C	Unknown	625 Microgram, Bid (12 Hour)		Not Reported
	Biotin			C	Unknown	10000 Microgram, Qd		Not Reported
	Fish Oil			C	Unknown	1200 Milligram, Qd		Not Reported
	Vitamin B12 Aaa			C	Unknown	5000 Microgram, Qd		Not Reported
	Selenium			C	Unknown	200 Microgram, Qd		Not Reported
	Dexilant			C	Unknown	30 Milligram, Qd		Not Reported
	Magnesium			C	Unknown	250 Milligram, Qd		Not Reported
	Vitamin D3			C	Unknown	5000 International Unit, Qd		Not Reported

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Glucosamine Chondroitin & Msm	C	Unknown	1500 Milligram, Qd	Not Reported
Armour Thyroid	C	Unknown	7.5 Milligram, Qd (On Mondays And Thursdays)	Not Reported
Tirosint	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16290607	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087695			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Aleve			S	Unknown	1000 Mg, Qd		Bayer
	Aleve			S	Unknown	Unk		Bayer
	Cimzia			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	50 Mg		Not Reported
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Tylenol [Paracetamol]			S	Topical			Not Reported
	Diclofenac			S	Topical	Unk Unk, Qd		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16290610	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087696			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Aleve			S	Unknown	Unk		Bayer
	Aleve			S	Unknown	1000 Mg, Qd		Bayer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	50 Mg	Not Reported
Escitalopram	S	Oral	20 Mg, Qd	Not Reported
Nortriptyline	S		25 Mg, Qd	Not Reported
Tylenol [Paracetamol]	S	Topical	Unk	Not Reported
Voltaren [Diclofenac]	S	Topical	Unk Unk, Qd	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Infliximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	C	Intravenous (not otherwise specified)	600 Mg	Not Reported
Infliximab	C	Intravenous (not otherwise specified)	700 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16290834	EXPEDITED (15-DAY)		OT	PHHY2019US102561		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation;	Pramipexole			S	Unknown			Not Reported
Delirium; Delusion;	Quetiapine			S	Unknown			Novartis
Depression; Hallucination;	Selegiline			S	Unknown			Not Reported
Paranoia; Therapeutic	Levodopa/Carbidopa			S	Unknown			Not Reported
Response Decreased	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16291689	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2019AMR079671			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Product	Wellbutrin Sr Prolonged-Release			S		20 Mg, Bid		Glaxosmithkline
Use In Unapproved	Tablet							
Indication; Therapy	Lexapro			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Change

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16296687	DIRECT					58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Substitution Issue	Escitalopram Oxalate 10 Mg			S	Oral	Quantity:1 Tablet(S);		Accord	
	Telmisartan			C				Not Reported	
	One A Day Multi Vitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	15920586	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2019M1009721		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Fear-Related Avoidance Of Activities; Learning Disorder; Mental Impairment; Overdose; Therapeutic Product Effect Incomplete	Escitalopram			S	Unknown	Unk (Overdose: 37.5 Mg Per Day)		Not Reported	
	Escitalopram			S		10 Milligram, Qd		Not Reported	
	Tianeptine			C	Unknown	10 Milligram, Qd (10 Mg Daily)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16248927	EXPEDITED (15-DAY)		HO	DE-ACCORD-124522		44 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Escitalopram			S	Oral	Also Taken 5 Mg From 11-Jan-2019 To 19-Jan-2019(9 Days)Dose Increased		Not Reported	
	Olanzapine			C	Oral	Taking Since> 2016, Daily Dose: 15 Mg Milligram(S) Every Days		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16296285	NON-EXPEDITED			US-PFIZER INC-2019197183		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Effexor Xr			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16297416	EXPEDITED (15-DAY)		DS	ES-AUROBINDO-AUR-APL-2019-024772			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	0,25 Por La Mañana, Y A Veces Por La Tarde Noche		Aurobindo	
	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Unknown	5mg Diarios		Aurobindo	
	Rhodiola			C	Unknown	Unk		Not Reported	
	Pantoprazol			C	Unknown	1 Al Día		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16298729	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2019SE68070			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Zeneca	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Trigoa			S	Unknown	Unk		Not Reported	
	Bisoprolol			S	Unknown	1.25mg Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16299196	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1046587		91 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Fludex (Indapamide)			S	Oral	Unknown		Not Reported
	Zelitrex 500 Mg, Comprime			S	Oral			Not Reported
	Enrobe							
	Ditropan 5 Mg, Comprime			S	Oral			Not Reported
	Secable							
	Perindopril			S	Oral			Not Reported
	Seroplex 5 Mg, Comprime			S	Oral			Not Reported
	Pellicule							
	Amlodipine			S	Oral			Teva
	Movicol, Poudre Pour Solution			C	Oral			Not Reported
	Buvable En Sachet							
	Paracetamol			C	Oral			Not Reported
	Cortancyl			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16299547	EXPEDITED (15-DAY)		HO	IT-ACCORD-126790		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Lorazepam			C				Not Reported
	Depakin Chrono			C		500 Mg Prolonged-Release Tablets		Not Reported
	Clonazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16300125	EXPEDITED (15-DAY)		HO	FI-TEVA-2019-FI-1047433		71 YR	Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Lip Oedema; Oral Discomfort; Skin Burning Sensation	Escitalopram			S	Oral	10,Mg,Daily		Ivax
	Vagifem			C	Vaginal	10,Mg,Daily		Not Reported

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Betaserc	C	Oral	8,Mg,Daily	Not Reported
Brilique	C	Oral	180,Mg,Daily	Not Reported
Kalcipos-D	C	Oral		Not Reported
Cardace	C	Oral		Not Reported
Primaspan	C	Oral	100,Mg,Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16301213	EXPEDITED (15-DAY)		HO, OT	US-EMD SERONO-7058874			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Rebif			S	Subcutaneous			Not Reported
Anxiety; Bacterial Colitis;	Lexapro			S				Not Reported
Catheter Site Infection;	Prednisone			S				Not Reported
Coeliac Disease;	Asacol			C				Not Reported
Cognitive Disorder; Colitis	Coumadin /00014802/			C				Not Reported
Ulcerative; Crohn'S								
Disease; Depression; Hip								
Arthroplasty;								
Hypoaesthesia;								
Incoherent; Injection Site								
Reaction; Malignant								
Melanoma; Oesophageal								
Stenosis; Paranoia; Renal								
Disorder; Staphylococcal								
Infection; Wrong Device								
Used								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16301314	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1919876US			Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dissociation;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Pneumothorax; Psychotic								
Disorder; Suicide Attempt								

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12-May-2019	16301927	EXPEDITED (15-DAY)		HO	PHHY2019FR106762		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Loss Of Consciousness; Malaise	Fentanyl			S	Transdermal	1 Df, Q72h		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd		Novartis	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported	
	Lyrica			S	Oral	1 Df, Qd		Not Reported	
	Lasix			S	Oral	1 Df, Qd		Not Reported	
	Oxynormoro			S	Oral	3 Df, Qd		Not Reported	
	Ebixa			S	Oral	1 Df, Qd		Not Reported	
	Eliquis			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Diffu K			C	Unknown			Not Reported	
	Transipeg			C	Unknown			Not Reported	
	Gaviscon			C	Unknown			Not Reported	
	Okimus			C	Unknown	Unk		Not Reported	
	Melaxose			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	15204006	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-933317		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	
	Escitalopram			S				Ivax	
	Acetaminophen			C				Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Aczone			C				Not Reported	
	Azithromycin			C		Form Of Admin: Not		Not Reported	

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			Specified	
Benzaclin Topical	C			Not Reported
Calcium	C		Form Of Admin: Not Specified	Not Reported
Canesten-Hc 1% Cream-Powder Mixture	C			Not Reported
Cetaphil Acne Principles	C			Not Reported
Cetaphil Moisturizing Lotion	C			Not Reported
Cetaphil Oily Skin Cleanser	C			Not Reported
Cipralex	C			Not Reported
Diclofenac	C			Not Reported
Domperidone	C			Not Reported
Epival Ect 250mg	C			Not Reported
Flovent Diskus	C			Not Reported
Flovent Hfa	C			Not Reported
Genteal	C			Not Reported
Nasacort Aq	C		Form Of Admin: Spray, Metered Dose	Not Reported
Omega 3-6-9	C		Form Of Admin: Not Specified	Not Reported
Otrivin Saline Hypertonic Nasal Spray	C	Nasal		Not Reported
Seroquel	C			Not Reported
Seroquel	C			Not Reported
Synthroid	C		Form Of Admin: Not Specified	Not Reported
Tears Plus 1.4%	C			Not Reported
Tecta	C			Not Reported
Toviaz	C			Not Reported
Tylenol	C			Not Reported
Tylenol Extra-Strength Tab 500mg	C			Not Reported
Vitamin D2 1000 International Units Tablet	C			Not Reported
Zinc Gluconate	C		Form Of Admin: Not Specified	Not Reported
Zyloprim	C			Not Reported
Benzoyl Peroxide/Clindamycin Phosphate	C			Not Reported
Clotrimazole/Hydrocortisone	C			Not Reported

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Polyvinyl Alcohol/Povidone		C		Not Reported					
Valproate Semisodium		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	15856239	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1002492		89 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram			S	Unknown			Ivax	
	Heparin Sodium			S	Subcutaneous	Form Of Admin : Solution Intravenous Dose:5000.0 Units		Not Reported	
	Heparin Sodium			S	Oral	15 Milligram Daily;		Not Reported	
	Rivaroxaban (Bay59-7939)			S				Not Reported	
	Asa			S				Not Reported	
	Rivaroxaban (Bay59-7939)			S	Unknown	Form Of Admin :Solution Block/Infiltration		Not Reported	
	Bupivacaine			C				Not Reported	
	Epinephrine			C				Not Reported	
	Hydromorphone			C				Not Reported	
	Lidocaine			C				Not Reported	
Asa			S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	15947429	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-006751			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Heart Rate Increased; Myocarditis	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Olanzapine			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Clozaril			S	Oral	125 Milligram, Once A Day,125 Milligram, Pm		Not Reported	
	Clozaril			S	Oral	50 Milligram, Once A		Not Reported	

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Clozaril	S	Unknown	Day,50 Milligram, Am	Not Reported
Clozaril	S	Oral	Unk	Not Reported
Omeprazole	C	Oral	20 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16303656	NON-EXPEDITED		HO	US-JNJFOC-20190500102			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Noncompliance	Haloperidol			S	Oral			Not Reported
	Abilify Maintena			S	Other			Not Reported
	Aripiprazole			S	Unknown			Not Reported
	Wellbutrin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16304233	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1919878US		49 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Abuse; Cerebellar Syndrome; Drug Abuse; Hepatomegaly; Incorrect Route Of Product Administration	Escitalopram Oxalate - Bp			S	Nasal	1 Df (Tablet), Qam		Allergan
	Cannabis			S	Respiratory (inhalation)	1 Day Per Month		Not Reported
	Alcohol			S	Oral	20 Units, Qd		Not Reported
	Nicotiana Tabacum			S	Respiratory (inhalation)	10 Cigarettes, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16305221	EXPEDITED (15-DAY)		HO, OT	AT-MYLANLABS-2019M1044133			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Aggression; Agitation;	Escitalopram	S		10 Mg	Not Reported
Alcoholism; Apraxia;	Escitalopram	S		3 Mg, Qd	Not Reported
Behaviour Disorder;	Pregabalin	S	Oral	25 Mg, Bid	Not Reported
Cognitive Disorder;	Pregabalin	S	Oral	50 Mg	Not Reported
Dementia; Dementia With	Oxazepam	S		Unk	Not Reported
Lewy Bodies; Depression;	Lorazepam	S		Unk	Mylan
Drug Ineffective;	Piracetam	S		1200 Mg	Mylan
Dysphoria; Hallucination;	Cerebrolysin	S		Unk	Mylan
Hallucination, Visual;	Mirtazapine	S		15 Mg	Mylan
Insomnia; Korsakoff'S	Rivastigmine	S	Transdermal	4.6 Mg, Qd	Mylan
Syndrome; Mania; Muscle	Rivastigmine	S	Transdermal	Unk (Dose Increased).	Mylan
Rigidity; Parkinsonism;	Risperdal	S		Unk	Mylan
Restlessness; Sleep	Risperidone	S		3 Mg, Qd	Mylan
Disorder; Tremor; Urinary	Risperidone	S		1 Mg	Mylan
Incontinence	Risperidone	S		Unk	Mylan
	Quetiapine	S	Oral	100 Mg	Mylan
	Quetiapine	S		25 Mg In The Eveningunk	Mylan
	Quetiapine	S		Slowly Increased Unk	Mylan
	Valproic Acid	S		1000 Mg, Qd	Mylan
	Naltrexone	S		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16305434	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1047609		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dry Mouth;	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
Tension Headache	Apixaban			C				Not Reported	
	Rosuvastatin Tablet			C				Not Reported	
	Zopiclone			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16305435	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1047610		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Affective Disorder; Condition Aggravated; Insomnia	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Atorvastatin Calcium			C				Not Reported	
	Candesartan			C				Not Reported	
	Januvia			C				Not Reported	
	Pantoloc /01263204/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16305439	EXPEDITED (15-DAY)		LT	CA-TEVA-2019-CA-1047600		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sinus Bradycardia; Syncope; Torsade De Pointes	Escitalopram			S	Oral	20 Milligram Daily;		Ivax	
	Pramipexole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16306117	EXPEDITED (15-DAY)		HO	US-GLAXOSMITHKLINE-US2019AMR082943			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Noncompliance	Wellbutrin			S		Unk		Glaxosmithkline	
	Escitalopram			S		Unk		Glaxosmithkline	
	Aripiprazole			S		Unk		Not Reported	
	Haloperidol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16306876	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1919875US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Exposure During Pregnancy; Hypoglycaemia Neonatal	Escitalopram Oxalate - Bp	S	Transplacental	20 Mg, Qd	Allergan
	Saroten Retard	S	Transplacental	25 Mg, Qd	Not Reported
	Atarax	S	Transplacental	12.5 Mg, Qd	Not Reported
	Dafalgan	S	Transplacental	Unk, Prn	Not Reported
	Pantoprazol	S	Transplacental	Usual Treatment	Not Reported
	Levetiracetam	S	Transplacental	500 Mg, Qod	Not Reported
	Pregabalin	S	Unknown	150 Mg, Qod	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16307403	EXPEDITED (15-DAY)		HO, OT	CH-UCBSA-2019018502		< 1 DAY	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy	Levetiracetam			S	Transplacental	500 Milligram, 2x/Day (Bid)		Not Reported
	Atarax			S	Transplacental	12.5 Milligram, Once Daily (Qd)		Not Reported
	Dafalgan			S	Transplacental	As Necessary		Not Reported
	Saroten Retard			S	Transplacental	25 Milligram, Once Daily (Qd)		Not Reported
	Pantoprazol			S	Transplacental	40 Milligram, Once Daily (Qd)		Not Reported
	Pregabalin			S	Transplacental	150 Milligram, 2x/Day (Bid)		Not Reported
	Ciprallex			S	Transplacental	20 Milligram, Once Daily (Qd)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16307598	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2019AP013765		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Tonic-Clonic Seizure; Partial Seizures	Olanzapine			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tramadol	S	Unknown	Unk	Apotex
Escitalopram	S	Unknown	Unk	Apotex
Clopidogrel	S	Unknown	Unk	Apotex
Ciprofloxacin	S	Unknown	Unk	Apotex
Prednisone	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16307713	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-207706		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Perindopril			S	Oral	8 Milligram, Daily		Not Reported
	Amlodipine			S	Oral	10 Milligram, Daily		Sun
	Fludex 1,5 Mg, Comprime			S	Oral	Unk		Not Reported
	Pellicule A Liberation Prolongee							
	Zelitrex 500 Mg, Comprime			S	Oral	6 Dosage Form, Daily		Not Reported
	Enrobe							
	Ditropan 5 Mg, Comprime			S	Oral	2 Dosage Form, Daily		Not Reported
	Secable							
	Seroplex 5 Mg, Comprime			S	Oral	1 Dosage Form, Daily		Not Reported
	Pellicule							
	Movicol, Poudre Pour Solution			C	Oral	2 Dosage Form, Daily		Not Reported
	Buvable En Sachet							
	Paracetamol			C	Oral	3 Dosage Form, Daily		Not Reported
	Cortancyl			C	Oral	2 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16307961	EXPEDITED (15-DAY)		HO	US-APOTEX- 2019AP013773		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation; Condition Aggravated; Delusion; Hallucination;	Escitalopram			S	Unknown	Unk		Apotex
	Quetiapine			S	Unknown	Unk		Apotex

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Paranoia; Therapeutic Product Effect Incomplete	Carbidopa Levodopa	C	Unknown	Unk	Not Reported				
	Pramipexole	C	Unknown	Unk	Not Reported				
	Selegiline	C	Unknown	Unk	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16309055	NON-EXPEDITED			US-PFIZER INC-2019200923			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Levofloxacin			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16309120	EXPEDITED (15-DAY)		OT	US-BAYER-2019-093902		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoptysis; Labelled Drug-Drug Interaction Medication Error; Pulmonary Alveolar Haemorrhage	Acetylsalicylic Acid (Cardio)		Y	S				Bayer	
	Warfarin			S				Not Reported	
	Metoprolol			S				Not Reported	
	Atorvastatin			S				Not Reported	
	Escitalopram			S				Not Reported	
	Glipizide			S				Not Reported	
	Loratadine			S				Not Reported	
	Losartan			C				Not Reported	
	Omeprazole			C				Not Reported	
	Pirfenidone			C		801 Mg, Tid		Not Reported	
	Acetaminophen			C				Not Reported	
	Multivitamins [Vitamins Nos]			C				Not Reported	
	Paracetamol			C				Bayer	
	Gabapentin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16310999	NON-EXPEDITED			US-VALIDUS PHARMACEUTICALS LLC-US-			Unknown	USA

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2019VAL000163

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Demerol			S	Unknown	Unk		Validus
	Ambien			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Carbidopa/Levodopa			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Hydrocortisone			S	Unknown	Unk		Not Reported
	Oxaprozin			S	Unknown			Not Reported
	Donepezil Hydrochloride			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Cefalexin			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Paroxetine Hydrochloride			S	Unknown			Not Reported
	Promethazine			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Zonisamide			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Talwin /00052102/			S	Unknown			Not Reported
	Nabumetone			S	Unknown			Not Reported
	Indocin /00003805/			S	Unknown			Not Reported
	Hycotuss			S	Unknown			Not Reported
	Provigil /01265601/			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Duloxetine	S	Unknown		Not Reported
Tiagabine	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Pramipexole	S	Unknown		Not Reported
Ropinirole	S	Unknown	Unk	Not Reported
Trazodone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16311002	NON-EXPEDITED			US-VALIDUS PHARMACEUTICALS LLC-US- 2019VAL000168			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Confusional State; Dizziness; Fatigue; Headache; Insomnia; Nausea; Pruritus; Rash; Urticaria	Demerol			S	Unknown			Validus
	Talwin Nx			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Carbidopa/Levodopa			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Cortizone 10			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Daypro			S	Unknown	Unk		Not Reported
	Donepezil Hydrochloride			S		Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Gabitril			S	Unknown			Not Reported
	Hycotuss			S	Unknown	Unk		Not Reported
	Indocin /00003801/			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Keflex /00145501/	S	Unknown		Not Reported
Levetiracetam	S	Unknown	Unk	Not Reported
Lamotrigine	S	Unknown	Unk	Not Reported
Lexapro	S	Unknown	Unk	Not Reported
Pramipexole Hydrochloride	S	Unknown	Unk	Not Reported
Nabumetone	S	Unknown	Unk	Not Reported
Paroxetine Hydrochloride	S	Unknown		Not Reported
Promethazine	S		Unk	Not Reported
Provigil /01265601/	S	Unknown		Not Reported
Requip	S	Unknown		Not Reported
Trazodone Hydrochloride	S			Not Reported
Venlafaxine Hydrochloride	S	Unknown	Unk	Not Reported
Zonisamide	S	Unknown	Unk	Not Reported
Hydrocodone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16311842	EXPEDITED (15-DAY)		DS	ES-TEVA-2019-ES-1048255		32 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam O,25			S	Unknown	0.25 In The Morning, And Sometimes In The Evening		Actavis
	Escitalopram Flas Cinfa 10 Mg Tablets Bucodispersables Efg, 28 Tablets			S	Oral	5 Mg Daily		Not Reported
	Rhodiola			C	Unknown			Not Reported
	Pantoprazol 20,Mg			C	Unknown	1 A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	15001540	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1038482		54 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Breast Cyst	Escitalopram	S	Oral	10 Mg, Unk (Currently)	Not Reported
	Escitalopram	S	Oral	15 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	15545805	EXPEDITED (15-DAY)	HO, OT		CA-PFIZER INC-2018433138		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Pantoprazole			S	Unknown	Unk		Pfizer
Anger; Anxiety; Arthropod	Amlodipine Besilate			S	Unknown	10 Mg, 1x/Day		Pfizer
Bite; Blood Pressure	Calcium Carbonate			S	Unknown	Unk		Pfizer
Increased; Blood Pressure	Hydromorphone Hydrochloride			S	Unknown	Unk		Unknown
Systolic Increased;	Ergocalciferol			S	Unknown	Unk		Not Reported
Bronchitis;	Sandostatin			S	Intramuscular	20 Mg, Monthly		Not Reported
Cerebrovascular Accident;	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
Contusion; Cough; Crying;	Sandostatin			S	Intramuscular	20 Mg, Monthly		Not Reported
Depressed Mood;	Sandostatin			S	Intramuscular	30 Mg, Unk		Not Reported
Depression; Diarrhoea;	Sandostatin			S	Intramuscular	20 Mg, Monthly		Not Reported
Drug Hypersensitivity;	Sandostatin			S	Subcutaneous	Unk, Bid		Not Reported
Emotional Distress;	Sandostatin			S	Subcutaneous	20 Mg, Unk		Not Reported
Erythema; Fall; Fatigue;	Escitalopram			S	Unknown	Unk		Not Reported
Feeling Abnormal; Feeling	Acetaminophen			C	Unknown	Unk		Not Reported
Jittery; Gait Disturbance;	Gabapentin			C	Unknown	Unk		Not Reported
Head Banging; Headache;	Olanzapine			C	Unknown	Unk		Not Reported
Hypertension; Hypoacusis;	Prucalopride Succinate			C	Unknown	Unk		Not Reported
Inappropriate Schedule Of	Perindopril			C	Unknown	4 Mg, 1x/Day		Not Reported
Product Administration;	Prednisone			C		35 Mg, Unk		Not Reported
Joint Swelling; Malaise;	Hydromorphone Hcl			C		Unk		Not Reported
Malignant Neoplasm								
Progression; Mental								
Disorder; Muscular								
Weakness;								
Nasopharyngitis; Nausea;								
Nervousness; Pain In								
Extremity; Peripheral								
Swelling; Pneumonia;								
Pollakiuria; Productive								
Cough; Psychiatric								
Symptom; Rash; Rib								
Fracture; Screaming;								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16310375	EXPEDITED (15-DAY)		OT	FR-ACCORD-127174			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Prescription Form Tampering	Escitalopram			S	Unknown	Unspecified		Not Reported	
	Quetiapine			S	Unknown	Unspecified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16312715	EXPEDITED (15-DAY)		HO, OT	PT-MACLEODS PHARMACEUTICALS US LTD- MAC2019021249			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Mg Of 20 Mg + 27 Mg Of 10 Mg, Autointoxication		Macleods	
	Lorazepam			S	Oral	Unk, 72 Mg Of 2.5 Mg		Not Reported	
	Bupropiom			C	Unknown	Unk		Not Reported	
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported	
	Diazepam			C	Unknown	Unk		Not Reported	
	Venlafaxine			C	Unknown	Unk		Not Reported	
	Olanzapine			C	Unknown	Unk		Not Reported	
	Topiramate			C	Unknown	Unk		Not Reported	
	Hydroxycarbamide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16312717	EXPEDITED (15-DAY)		DS	DE-MACLEODS PHARMACEUTICALS US LTD-			Unknown	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

MAC2019021255

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram			S	Unknown	5 (Drp)		Macleods	
	Escitalopram			S	Unknown	20 Mg/ML, 6-7 Tropfen		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16314139	EXPEDITED (15-DAY)		OT	US-APOTEX- 2019AP013768		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Sexually Inappropriate Behaviour	Escitalopram			S	Unknown			Apotex	
	Donepezil			C	Unknown	10 Mg, Qd		Not Reported	
	Memantine			C	Unknown	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16317170	NON-EXPEDITED			US-SA-2019SA129843			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dyspnoea; Feeling Abnormal	Multaq			S		Unk Unk, Unk		Sanofi	
	Escitalopram Oxalate			S		Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16320331	DIRECT		OT			25 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Not Reported	

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Allegra			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16109405	EXPEDITED (15-DAY)		HO	PHHY2019FR063146		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazol			S	Unknown	40 Mg, Qd		Novartis	
	Escitalopram			S	Oral	1 Df, Qd		Not Reported	
	Lasilix Special			S	Oral	2 Df, Qd		Not Reported	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Coumadine			C	Oral	2 Df, Qd		Not Reported	
	Spironolactone			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16115195	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1912513US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate - Bp			S	Oral	1 Df, Daily		Allergan	
	Pantoprazole			S	Unknown	40 Mg, Daily		Not Reported	
	Lasilix Special			S	Oral	2 Df, Daily		Not Reported	
	Bisoprolol			C				Not Reported	
	Coumadine			C	Oral	2 Df, Qd		Not Reported	
	Spironolactone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16179374	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019151433		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown	40 Milligram, Qd		Pfizer	
	Lasilix Special [Furosemide]			S	Oral	1000 Milligram, Qd (Two Dosage Form)		Not Reported	

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	Escitalopram	S	Oral	1 Df, 1x/Day	Not Reported
	Bisoprolol Fumarate	C		Unk	Not Reported
	Coumadine	C	Oral	4 Milligram, Qd	Not Reported
	Spironolactone	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16318276	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-027137			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Aurobindo
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Aurobindo
	Bupropion			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Venlafaxine			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported
	Topiramate			C	Unknown	Unk		Not Reported
	Hydroxycarbamide			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16319648	EXPEDITED (15-DAY)		OT	US-AKORN PHARMACEUTICALS- 2019AKN01020		16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Self-Injury; Off Label Use; Underdose	Myorisan			S	Oral	20 Mg, 1x/Day		Akorn
	Lexapro			S		5 Mg, 1x/Day		Not Reported
	Lexapro			S		"Dose Increased"		Not Reported
	Buspirone			S		5 Mg, 3x/Day		Not Reported
	Buspirone			S		"Dose Increased"		Not Reported

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Lo Loestrin Fe	C	10 Mg, 1x/Day	Not Reported
Methylfolate	C	400 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16320812	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1046824		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Loss Of Consciousness; Malaise	Bisoprolol			S	Oral	10 Milligram, Qd		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported
	Fentanyl			S	Transdermal	1 Dosage Form, Q3d		Not Reported
	Lyrica			S	Oral	1 Dosage Form, Qd		Mylan
	Ebixa			S	Oral	1 Dosage Form, Qd		Mylan
	Oxynormoro			S	Oral	3 Dosage Form, Qd		Mylan
	Lasilix /00032601/			S	Oral	1 Dosage Form, Qd		Mylan
	Esomeprazole			C				Mylan
	Diffu K			C				Mylan
	Transipeg /00754501/			C				Mylan
	Gaviscon /00237601/			C				Mylan
	Okimus			C				Mylan
	Eliquis			C				Mylan
Melaxose			C				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16320878	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2019204342		57 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Hypotension; Intentional Overdose; Poisoning; Somnolence	Lorazepam			S	Oral	Seventy Two (72) 2.5 Mg Tablets		Pfizer
	Escitalopram			S	Oral	Fourteen (14) 20 Mg Tablets + Twenty Seven (27) 10 Mg Tablets		Not Reported

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	Bupropion	C	150	Not Reported
	Acetylsalicylic Acid	C	100	Not Reported
	Diazepam	C	5	Not Reported
	Venlafaxine	C	225	Not Reported
	Olanzapine	C	5	Not Reported
	Topiramate	C	25	Not Reported
	Hydroxycarbamide	C	500	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321489	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1006457		27 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Drug Abuser; Sopor; Suicide Attempt	Escitalopram			S	Oral	15 Milliliter, Total		Not Reported	
	Delorazepam			S	Oral	10 Milliliter, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321515	NON-EXPEDITED			US-TEVA-2019-US-1049312		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fall; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vision Blurred	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321774	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1920570US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Tonic-Clonic Seizure; Overdose; Postictal State; Tongue Biting	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Qd		Allergan	
	Dipiperon			S	Unknown	40 Mg, Qd		Not Reported	

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	Tavor		C	Unknown	1 Mg, Prn			Not Reported	
	Zopiclon		C	Unknown	7.5 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321974	EXPEDITED (15-DAY)		HO, OT	PT-TEVA-2019-PT-1050137		57 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp Of 20 Mg + 27 Cp Of 10 Mg		Ivax	
	Lorazepam			S	Oral	72 Cp Of 2.5 Mg		Not Reported	
	Bupropion			C				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Diazepam			C				Not Reported	
	Venlafaxine			C				Not Reported	
	Olanzapine			C				Not Reported	
	Topiramate			C				Not Reported	
	Hydroxycarbamide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16322080	EXPEDITED (15-DAY)		DS	ES-PFIZER INC-2019201771		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S		0.25 Unk, Unk (0.25 In The Morning And Sometimes At Night)		Pfizer	
	Escitalopram Cinfa			S		5 Mg, Daily		Not Reported	
	Rhodiola Rosea			C		Unk		Not Reported	
	Pantoprazol [Pantoprazole]			C		1 Df, Daily (1 A Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	13115532	EXPEDITED (15-DAY)		OT	IE-JNJFOC-20170100967			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Intentional Overdose; Intentional Self-Injury	Paracetamol	Y	S	Unknown	Not Reported
	Paracetamol		S	Unknown	Not Reported
	Diazepam		S	Unknown	Not Reported
	Zopiclone		S	Unknown	Not Reported
	Alprazolam		S	Unknown	Not Reported
	Escitalopram		S	Unknown	Not Reported
	Zolpidem		S	Unknown	Not Reported
	Pregabalin		S	Unknown	Not Reported
	Venlafaxine		S	Unknown	Not Reported
	Flurazepam		S	Unknown	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Ibuprofen		S	Unknown	Not Reported
	Alcohol		S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16195824	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2019ZA01906			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gout	Lexamil			S	Oral	10 Milligram, Qd		Invagen	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16287999	EXPEDITED (15-DAY)		HO	JP-ALLERGAN- 1919446US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Metabolic Acidosis; Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 28 Tablets		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
	Zolpidem Tartrate			C	Oral	Overdose: 22 Tablets		Not Reported	
	Zolpidem Tartrate			C	Oral	Unk		Not Reported	
	Marvelon			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16323226	EXPEDITED (15-DAY)		DS	ES-APOTEX-2019AP014078		32 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	Unk (0.25 In The Morning, And Sometimes In The Evening)		Apotex
	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
	Rhodiola /02220301/			C	Unknown	Unk		Not Reported
	Pantoprazol /01263201/			C	Unknown	1 Al Día		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16323739	EXPEDITED (15-DAY)		HO	ZA-LUPIN PHARMACEUTICALS INC.-2019-02952			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block	Zartan Tablets			S	Oral	100 Milligram		Lupin
	Bilocor Tablets			S	Oral	5 Milligram		Not Reported
	Lexamil			S	Oral	10 Milligram		Not Reported
	Humalog Mix			S	Intramuscular	Unk		Not Reported
	Puresis			S	Oral	40 Milligram		Not Reported
	Aspavor			S	Oral	20 Milligram		Not Reported
	Ecotrin			S	Oral	81 Milligram		Not Reported
	B-Cal-D			S	Oral	Unk (Swallow)		Not Reported
	Puricos			S	Oral	100 Milligram		Not Reported
	Coxflam			S	Oral	15 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16324095	EXPEDITED (15-DAY)		LT	FR-ACCORD-127776		15 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16324185	EXPEDITED (15-DAY)		DS	DE-TEVA-2019-DE-1049129		57 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram 20 Mg/ML			S		5gtt		Ivax	
	Escitalopram 20 Mg/ML			S		6-7 Tropfen		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16324249	EXPEDITED (15-DAY)		DS	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-207875		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S	Unknown	0,25 Por La Manana, Y A Veces Por La Tarde Noche ()		Sun	
	Escitalopram Flas Cinfa 10 Mg Comprimidos Bucodispersables Efg , 28...			S	Unknown	5mg Diarios ()		Not Reported	
	Rhodiola			C	Unknown	()		Not Reported	
	Pantoprazol 20,Mg			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325132	EXPEDITED (15-DAY)		HO, OT	PT-APOTEX- 2019AP014010		57 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Hypotension; Intentional	Escitalopram			S	Oral	Unk		Apotex	
	Lorazepam			S	Oral	Unk		Not Reported	

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Overdose; Somnolence	Bupropion	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
	Diazepam	C	Unknown	Unk	Not Reported
	Venlafaxine	C	Unknown	Unk	Not Reported
	Olanzapine	C	Unknown	Unk	Not Reported
	Topiramate	C	Unknown	Unk	Not Reported
	Hydroxycarbamide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325196	EXPEDITED (15-DAY)		OT	PT-APOTEX-2018AP025261		27 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dystonia; Gait Disturbance; Posture Abnormal; Stiff Person Syndrome	Escitalopram			S	Unknown	20 Mg, Unknown		Apotex
	Escitalopram			S				Apotex
	Insulin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325528	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2019206937		91 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral	10 Mg, 1x/Day		Pfizer
	Zelitrex			S	Oral	3000 Mg, 1x/Day		Not Reported
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Fludex [Indapamide]			S	Oral	Unk		Not Reported
	Perindopril			S	Oral	8 Mg, 1x/Day		Not Reported
	Ditropan			S	Oral	10 Mg, 1x/Day		Not Reported
	Paracetamol			C	Oral	3 Df, 1x/Day		Not Reported
	Movicol			C	Oral	2 Df, 1x/Day		Not Reported
	Cortancyl			C	Oral	2 Mg, 1x/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16326497	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1920582US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Intentional Overdose	Escitalopram Oxalate - Bp			S	Oral	120 Mg In Total		Allergan	
	Seresta			S	Oral	48 Df In Total		Not Reported	
	Bromazepam			S	Oral	180 Mg In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16326621	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA-2019SE73316		59 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Drug Interaction; Electrocardiogram Qt Prolonged; Psychomotor Skills Impaired	Escitalopram			S	Oral			Not Reported	
	Nexium Mups			S	Oral			Astrazeneca	
	Novorapid			C				Not Reported	
	Lantus			C				Not Reported	
	Aspirin Cardio			C				Not Reported	
	Wellvone			C				Not Reported	
	Atacand			C				Not Reported	
	Beloc Zok			C				Not Reported	
	Tivicay			C				Not Reported	
	Descovy			C				Not Reported	
	Laxoberon			C				Not Reported	
	Pregabalin			C				Not Reported	
	Colecalciferol			C				Not Reported	
	Transtec			C				Not Reported	
	Temgesic			C				Not Reported	
						As Necessary			
	Bulboid			C				Not Reported	
						As Necessary			
	Riopan			C				Not Reported	
						As Necessary			
	Dafalgan			C				Not Reported	
						As Necessary			
	Capecitabine			C				Not Reported	
	Capecitabine			C				Not Reported	
	Temozolomide			C		Cyclical		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16327324	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1046576		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum Disorder	Escitalopram			S	Oral	5 Gtt Drops, Qd		Not Reported	
	Risperidone			S	Oropharyngeal	1 Milligram, Qd		Not Reported	
	Depakin			C	Oral	100 Milligram, Qd		Mylan	
	Rivotril			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16327673	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1920837US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anhedonia; Apathy; Depression; Fatigue; Flatulence; Frequent Bowel Movements; Gastrointestinal Sounds Abnormal; Malaise; Negative Thoughts; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Allopurinol			C	Unknown	1 Df		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16327838	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-027795			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported	
	Clonazepam			S				Not Reported	

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Clonazepam
Zopiclone

S
S

Oral

7.5 Milligram, Two Times
A Day

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16327966	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-027906			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angle Closure Glaucoma; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Underdose	Escitalopram Tablets			S	Oral	5 Milligram, Unk		Aurobindo
	Saphris			S	Oral	1.25 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16327974	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027628			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Duloxetine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16327975	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-026644			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Duloxetine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16327976	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR- APL-2019-027622			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Motor Dysfunction; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression; Spinal Cord Oedema	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Heparin Sodium			S	Subcutaneous	Two Times A Day		Not Reported	
	Heparin Sodium			S				Not Reported	
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported	
	Rivaroxaban			S				Not Reported	
	Rivaroxaban			S				Not Reported	
	Bupivacaine			C	Unknown	Unk		Not Reported	
	Epinephrine			C	Unknown	Unk		Not Reported	
	Hydromorphone			C	Unknown	Unk		Not Reported	
	Lidocaine			C	Unknown	3 Milliliter		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16328029	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027428			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Tablets			S	Unknown	15 Milligram		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Quetiapine Film-Coated Tablet			S	Unknown	150 Milligram		Aurobindo	
	Levothyroxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16328084	EXPEDITED (15-DAY)		HO	FR-ZYDUS-036741		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Loss Of Consciousness; Malaise	Zolpidem			S	Oral			Not Reported	
	Pregabalin			S	Oral			Not Reported	
	Memantine			S	Oral			Not Reported	
	Oxynormoro			S	Oral	5 Mg, Orodispersible Tablet		Not Reported	

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Furosemide	S	Oral	40 Mg, Scored Tablet	Not Reported
Escitalopram	S	Oral		Cadila
Bisoprolol Hemifumarate	S	Oral		Not Reported
Esomeprazole	C	Unknown		Not Reported
Potassium	C	Unknown		Not Reported
Macrogol	C	Unknown		Not Reported
Alginic Acid/Aluminium Hydroxide Gel/Dried/Magnesium Trisilicate/Sodium Bicarbonate	C	Unknown		Not Reported
Okimus	C	Unknown		Not Reported
Fentanyl	S	Transdermal		Not Reported
Apixaban	C	Unknown		Not Reported
Lactulose	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16328454	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-026662			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Incorrect Dose Administered; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	112.5 Milligram		Aurobindo
	Ciprallex			S	Unknown	15 Milligram, Daily		Not Reported
	Ciprallex			S	Unknown	20 Milligram		Not Reported
	Effexor			S	Unknown	75 Milligram		Not Reported
	Effexor			S	Unknown	37.5 Milligram		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Seroquel			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16331733	DIRECT		DS, HO, LT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Akathisia; Anxiety; Fear; Malaise	Lorazepam	S	Oral	Pfizer
	Escitalopram	S		Not Reported
	Olanzapine	S		Not Reported
	Risperidone	S		Not Reported
	Abilify	S		Not Reported
	Aripiprazole	S		Not Reported
	Alprazolam	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2019	16328736	EXPEDITED (15-DAY)		OT	TN-PRINSTON PHARMACEUTICAL INC.-2019PRN00493		38 YR	Female	TUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	Unk		Prinston Pharmaceutical
	Carbamazepine			S	Unknown	Unk		Not Reported
	Levomepromazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16307366	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US03035			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Intolerance; Off Label Use; Product Use In Unapproved Indication; Sexually Inappropriate Behaviour	Escitalopram			S	Unknown	Unk		Invagen
	Gabapentin			S	Unknown	300 Milligram, Tid		Invagen
	Donepezil			C	Unknown	10 Milligram		Not Reported
	Memantine			C	Unknown	10 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16329841	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2019-027926			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Escitalopram 10 Mg Film-Coated Tablets Efg			S	Oral	10 Milligram, Once A Day		Aurobindo

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Torase mide	S	Oral	5 Milligram, Once A Day	Aurobindo
Torase mide	S	Oral	10 Milligram (10 Mg Dia)	Aurobindo
Aldactone	S	Oral	25 Milligram, Once A Day (1-0-0)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16330184	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK088551		17 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; General Physical Health Deterioration; Overdose; Seizure; Toxicity To Various Agents	Bupropion Hydrochloride XI			S		Unk		Glaxosmithkline
	Escitalopram			S		Unk		Glaxosmithkline
	Quetiapine			S		Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16334217	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019208397		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Loss Of Consciousness; Malaise	Fentanyl			S	Transdermal	1 Df, Unk		Unknown
	Lyrica			S	Oral	75 Mg, 1x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	10 Mg, 1x/Day		Not Reported
	Oxynormoro			S	Oral	15 Mg, 1x/Day		Not Reported
	Lasilix [Furosemide]			S	Oral	40 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Zolpidem			S	Oral	10 Mg, 1x/Day		Not Reported
	Ebixa			S	Oral	20 Mg, 1x/Day		Not Reported
	Esomeprazole			C				Not Reported
	Diffu K			C				Not Reported
	Transipeg [Macrogol]			C				Not Reported
	Gaviscon [Alginic Acid;Aluminium Hydroxide;Sodium			C				Not Reported

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Alginate;Sodium Bica			
Okimus	C		Not Reported
Eliquis	C		Not Reported
Melaxose	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16334623	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1920862US			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage;	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
Subarachnoid Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown	40 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	14561323	NON-EXPEDITED			US-PFIZER INC-2018074666		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Gabapentin			S		300 Mg, Unk		Pfizer
	Prazosin Hcl			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Zoloft			S		50 Mg, Unk		Pfizer
	Ziprasidone Hcl			S		Unk		Pfizer
	Bupropion			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Duloxetine			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Olanzapine			S		Unk		Not Reported
	Prilosec			S		Unk		Not Reported
	Paroxetine			S		Unk		Not Reported
	Prochlorperazine			S		Unk		Not Reported
	Tizanidine			S		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	15594986	EXPEDITED (15-DAY)		HO, OT	JP-AMGEN- JPNCT2018155553		83 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Appendicitis Perforated; Dehydration; Hepatic Function Abnormal; Renal Impairment	Cinacalcet Hcl			S	Oral	25 Milligram, Bid		Amgen	
	Cinacalcet Hcl			S	Oral	25 Milligram, Tid		Amgen	
	Lexapro			S	Oral	5 Milligram		Not Reported	
	Bonalon			C	Oral	35 Milligram		Not Reported	
	Tramcet			C	Oral	4 Dosage Form		Not Reported	
	Hachimijiogan			C	Oral	5 Gram		Not Reported	
	Ninjinto [Atractylodes Lancea Rhizome;Glycyrrhiza Spp. Root;Panax Gins			C	Oral	5 Gram		Not Reported	
	Tokishigyakukagoshuyushokyo o			C	Oral	5 Gram		Not Reported	
	Hochuekkito [Angelica Acutiloba Root;Astragalus Spp. Root;Atractylodes			C	Oral	5 Gram		Not Reported	
	Yokukansankachimpihange [Angelica Acutiloba Root;Atractylodes Lancea R Seishinrenshiin			C	Oral	5 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16038129	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1908236US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Mouth; Intentional Overdose; Slow Speech	Escitalopram Oxalate Unk			S	Oral	In Total: Overdose 300 Mg		Allergan	
	Lorazepam			S	Oral	20 Mg (In Total)		Not Reported	
	En			S	Oral	40 Mg (In Total)		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16200479	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-019422			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual; Suicide Attempt; Toxicity To Various Agents	Paracetamol			S	Oral	2 G, 1 Total		Aurobindo	
	Seroplex			S	Oral	40 Mg, 1 Total		Not Reported	
	Seresta			S	Oral	10 Mg, 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16335135	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-208256		38 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Milligram, Daily		Not Reported	
	Omeprazole			S	Unknown	20 Milligram, Daily		Sun	
	Ramipril			S	Unknown	2.5 Milligram, Daily		Ranbaxy	
	Amisulpride			S	Unknown	300 Milligram, Daily		Not Reported	
	Atorvastatin			S	Unknown	10 Milligram, Daily		Sun	
	Spironolactone			S	Unknown	25 Milligram, Daily		Sun	
	Bisoprolol			S	Unknown	2.5 Milligram, Daily		Sun	
	Furosemide			S	Unknown	20 Milligram, Daily		Not Reported	
	Melatonin			S	Unknown	2 Milligram, Daily		Not Reported	
	Testosterone Depot			S	Unknown	1 Gram Every 10-14 W		Not Reported	
	Ferrograd			S	Unknown	325 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16335170	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-027718			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Confusional State; Loss Of Consciousness; Malaise	Fentanyl	S	Transdermal	1 Dosage Form, Every 72 Hours	Not Reported
	Escitalopram	S	Oral	10 Milligram, Once A Day	Aurobindo
	Bisoprolol	S	Oral	10 Milligram, Once A Day	Aurobindo
	Zolpidem	S	Oral	10 Milligram, Once A Day	Aurobindo
	Lyrica	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ebixa	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Oxynormoro	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Lasilix	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Diffu K	C	Unknown	Unk	Not Reported
	Transipeg	C	Unknown	Unk	Not Reported
	Gaviscon	C	Unknown	Unk	Not Reported
	Okimus	C	Unknown	Unk	Not Reported
	Eliquis	C	Unknown	Unk	Not Reported
	Melaxose	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16336396	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-192866		24 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Drug Ineffective; Drug Intolerance; Electrocardiogram Qt Prolonged; Schizophrenia	Clozapine			S	Unknown	350 Milligram, Daily		Sun
	Clozapine			S	Unknown	600 Milligram, Daily		Sun
	Clozapine			S	Unknown	5 Milligram, Daily		Sun
	Clozapine			S	Unknown	30 Milligram, Daily		Sun
	Aripiprazole			S	Unknown	Unk Unk, Daily		Not Reported

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Escitalopram	S	Unknown	Unk	Not Reported
Mirtazapine	S	Unknown	15 Milligram, Daily	Sun
Mirtazapine	S	Unknown	30 Milligram, Daily	Sun
Olanzapine	S	Unknown	5 Milligram, Daily	Sun
Olanzapine	S	Unknown	30 Milligram, Daily	Sun
Risperidone	S	Unknown	Unk	Ranbaxy
Prazepam	S	Unknown	20 Milligram, Daily	Not Reported
Paliperidone Palmitate	C	Unknown	150 Milligram, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16336457	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2019-028512			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Malaise; Oedema Peripheral; Orthostatic Hypotension; Syncope	Potassium Chloride			S	Unknown	Unk		Aurobindo
	Zyloprim			S	Unknown	Unk		Not Reported
	Eliquis			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	Unk		Not Reported
	Thalitone			S	Unknown	Unk		Not Reported
	Colace			S	Unknown	Unk		Not Reported
	Inspira			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported
	Neurontin			S	Unknown	Unk		Not Reported
	Humulin R			S	Unknown	Unk		Not Reported
	Imdur			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Mobic			S	Unknown	Unk		Not Reported
	Zaroxolyn			S	Unknown	Unk		Not Reported
	Lopressor			S	Unknown	Unk		Not Reported

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Proamatine	S	Unknown	Unk	Not Reported
Protonix	S	Unknown	Unk	Not Reported
Demadex	S	Unknown	Unk	Not Reported
Anoro Ellipta	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16337965	EXPEDITED (15-DAY)		OT	TN-JUBILANT CADISTA PHARMACEUTICALS- 2019JUB00189		38 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram			S	Unknown	Unk		Jubilant	
	Carbamazepine			S	Unknown	Unk		Jubilant	
	Levomepromazine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16339968	EXPEDITED (15-DAY)		HO	ES-TEVA-2019-ES- 1051192		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram 10 Mg Comprimido			S	Oral	10 Milligram Daily;		Ivax	
	Torsemida (2351a)			S	Oral	5 Milligram Daily;		Teva	
	Torsemida (2351a)			S	Oral	10 Mg A Day .		Teva	
	Aldactone 25 Mg			S	Oral	25 Milligram Daily; 1-0-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16123763	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1030442		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Pantoprazole			S	Unknown	40 Milligram Daily;		Teva	
	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax	
	Lasilix Special 500 Mg, Comprime Secable			S	Oral	2 Dosage Forms Daily; Lasilix Special 500 Mg,		Not Reported	

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Bisoprolol (Fumarate Acide De)	C		Comprime Secable	Not Reported
Coumadine 2 Mg, Comprime	C	Oral	2 Dosage Forms Daily;	Not Reported
Secable				
Spironolactone	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16126890	EXPEDITED (15-DAY)		HO	FR-ZYDUS-034889		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown			Not Reported
	Furosemide			S	Oral			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Spironolactone			C	Oral			Not Reported
	Warfarin			C	Oral			Not Reported
	Bisoprolol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16138982	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-203402		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S	Unknown	40 Milligram, Daily		Sun
	Escitalopram			S	Oral	1 Dosage Form, Daily		Not Reported
	Lasilix Special 500 Mg, Comprime Secable			S	Oral	2 Dosage Form, Daily		Not Reported
	Bisoprolol (Fumarate Acide De)			C	Unknown	Unk		Not Reported
	Coumadine 2 Mg, Comprime Secable			C	Oral	2 Dosage Form, Daily		Not Reported
	Spironolactone			C	Oral	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16189055	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED- 2019SP003105			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Off Label Use; Wrong Technique In Product Usage Process	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Buspirone Hydrochloride			S	Unknown	Unk		Strides	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	15 Mg, Unknown		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Not Reported	
	Escitalopram			S	Unknown	Reduce To 12.5 Mg Over Eight Weeks		Not Reported	
	Escitalopram			S	Unknown	15 Mg, Unknown		Not Reported	
	Escitalopram			S	Unknown	15 Mg, Unknown		Not Reported	

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Escitalopram			S		Unknown		15 Mg, Unknown		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16340268	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-208519		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Loss Of Consciousness; Malaise	Bisoprolol			S	Oral	10 Milligram, Daily		Sun	
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported	
	Fentanyl			S	Transdermal	1 Dosage Form, Once In 72 Hours		Not Reported	
	Zolpidem			S	Oral	10 Milligram, Daily		Sun	
	Lyrica 75 Mg, Gelule			S	Oral	1 Dosage Form, Daily		Not Reported	
	Ebixa 20 Mg, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported	
	Oxynormoro 5 Mg, Comprime Orodispersible			S	Oral	3 Dosage Form, Daily		Not Reported	
	Lasilix 40 Mg, Comprime Secable			S	Oral	1 Dosage Form, Daily		Not Reported	
	Esomeprazole			C	Unknown	()		Not Reported	
	Diffu K			C	Unknown	()		Not Reported	
	Transipeg			C	Unknown	()		Not Reported	
	Gaviscon			C	Unknown	()		Not Reported	
	Melaxose			C	Unknown	()		Not Reported	
	Okimus			C	Unknown	()		Not Reported	
	Eliquis 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16341250	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1051173		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Loss Of	Fentanyl			S	Transdermal	1 Dosage Forms		Actavis	

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Consciousness; Malaise	Zolpidem	S	Oral	10 Milligram Daily;	Teva
	Escitalopram	S	Oral	10 Milligram Daily;	Ivax
	Bisoprolol (Hemifumarate De)	S	Oral	10 Milligram Daily;	Teva
	Lyrica 75 Mg, Gélule	S	Oral	1 Dosage Forms Daily;	Not Reported
	Ebixa 20 Mg, Comprimé Pelliculé	S	Oral	1 Dosage Forms Daily;	Not Reported
	Oxynormoro 5 Mg, Comprimé Orodispersible	S	Oral	3 Dosage Forms Daily;	Not Reported
	Lasilix 40 Mg, Comprimé Sécable	S	Oral	1 Dosage Forms Daily;	Not Reported
	Esomeprazole	C			Not Reported
	Diffu K	C			Not Reported
	Transipeg	C			Not Reported
	Gaviscon	C			Not Reported
	Okimus	C			Not Reported
	Eliquis 5 Mg, Comprimé Pelliculé	C			Not Reported
	Melaxose	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16341550	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-028434			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Lasilix Special			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Spironolactone			C	Oral	Unk		Not Reported
	Coumadine			C	Oral	2 Dosage Form, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16344151	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019209205		83 YR	Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Aldactone			S	Oral	25 Mg, Once Daily In The Morning (1-0-0)		Pfizer	
	Escitalopram			S	Oral	10 Mg, Once Daily		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Torsemide			S	Oral	5 Mg, Once Daily		Not Reported	
	Torsemide			S	Oral	10 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16344476	EXPEDITED (15-DAY)		HO, OT	CN- ELI_LILLY_AND_COMP ANY-CN201905005245			Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Anxiety; Asthenia; Depression; Dizziness; Headache; Off Label Use; Restlessness; Somatic Symptom Disorder; Tinnitus	Zyprexa			S	Oral	3.75 Mg, Daily		Eli Lilly And Co	
	Escitalopram Oxalate			S	Oral	15 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16344699	EXPEDITED (15-DAY)		OT	CA-ALLERGAN- 1921361US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Cimzia			S	Subcutaneous			Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown	1000 Mg, Qd		Not Reported	
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported	
	Tylenol			S	Topical			Not Reported	
	Voltaren			S	Topical			Not Reported	
	Diclofenac Potassium			S	Unknown	50 Mg		Not Reported	

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	Diclofenac	C	Ophthalmic		Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	700 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16344701	EXPEDITED (15-DAY)		LT	CA-ALLERGAN-1921434US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Product Use In Unapproved Indication; Swelling; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Apo-Sulfatrim			S	Unknown	160 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	14876032	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2018M1031837		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Use Issue; Off Label Use; Product Use In Unapproved Indication; Toxic Epidermal Necrolysis	Escitalopram			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	
	Bisoprolol			S	Oral	Unk		Not Reported	
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported	
	Ciprofloxacin			S	Intravenous drip	Unk		Not Reported	
	Methotrexate			S	Intravenous drip	Unk		Not Reported	
	Methotrexate			S	Intravenous drip	Unk		Not Reported	
	Methotrexate			S	Intravenous drip	Unk		Not Reported	
	Valaciclovir			S	Oral	Unk		Not Reported	

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Valaciclovir	S	Oral	Unk	Not Reported
Furosemide	S	Oral	Unk	Not Reported
Furosemide	S	Oral	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Ondansetron	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported
Bromazepam	S	Oral	Unk	Not Reported
Pantoprazole	S	Intravenous drip	Unk	Mylan
Pantoprazole	S	Intravenous drip	Unk	Mylan
Pantoprazole	S	Unknown	Unk	Mylan
Rituximab	S	Intravenous drip	Unk	Mylan
Rituximab	S	Intravenous drip	Unk	Mylan
Rituximab	S	Oral	Unk	Mylan
Calciparine	S	Subcutaneous	Unk	Mylan
Calciparine	S	Subcutaneous	Unk	Mylan
Doxorubicine /00330901/	S	Intravenous drip	Unk	Mylan
Doxorubicine /00330901/	S	Intravenous drip	Unk	Mylan
Lidocaine	S	Buccal	Unk	Mylan
Lidocaine	S	Buccal	Unk	Mylan
Lidocaine	S	Unknown	Unk	Mylan
Fungizone	S	Buccal	Unk	Mylan
Fungizone	S	Buccal	Unk	Mylan
Fungizone	S	Unknown	Unk	Mylan
Voraxaze	S	Intravenous drip	Unk	Mylan
Voraxaze	S	Intravenous drip	Unk	Mylan
Zarzio	S	Subcutaneous	Unk	Mylan
Zarzio	S	Subcutaneous	Unk	Mylan
Cyclophosphamide	S	Intravenous drip	Unk	Mylan
Cyclophosphamide	S	Intravenous drip	Unk	Mylan

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Exacyl	S	Intravenous drip	Unk	Mylan
Exacyl	S	Intravenous drip	Unk	Mylan
Exacyl	S	Unknown	Unk	Mylan
Prednisone	S	Intravenous drip	Unk	Mylan
Prednisone	S	Intravenous drip	Unk	Mylan
Eprex	S	Subcutaneous	Unk	Mylan
Eprex	S	Subcutaneous	Unk	Mylan
Vincristine	S	Intravenous drip	Unk	Mylan
Vincristine	S	Intravenous drip	Unk	Mylan
Bactrim	S	Oral	Unk	Mylan
Bactrim	S	Oral	Unk	Mylan
Hextril	S	Buccal	Unk	Mylan
Hextril	S	Buccal	Unk	Mylan
Hextril	S	Unknown	Unk	Mylan
Meropenem Anhydrous	S	Intravenous drip	Unk	Mylan
Meropenem Anhydrous	S	Intravenous drip	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	15241302	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-038910			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Malaise; Tremor; Vertigo	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo
	Deniban			S	Oral	25 Milligram, Once A Day		Not Reported
	Valium			S	Oral	16 Gtt, Once A Day		Not Reported
	Leponex			S	Oral	150 Milligram, Once A Day		Not Reported
	Arlevertan			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Resilient			S	Oral	1 Dosage Form, Once A Day		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16343221	EXPEDITED (15-DAY)		DE, OT	DE-JNJFOC-20190526600		70 YR	Male	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Death	Haldol			S	Unknown			Not Reported	
	Valproate Sodium			S	Unknown			Not Reported	
	Diazepam			S	Unknown			Not Reported	
	Remergil			S	Unknown			Not Reported	
	Seroquel			S	Unknown			Not Reported	
	Ciprallex			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346186	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-026927			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Loss Anaemia;	Clopidogrel			S	Oral	75 Milligram, Daily		Aurobindo	
Haematoma Muscle	Escitalopram			S	Oral	5 Milligram, Daily (1-0-0)		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346419	EXPEDITED (15-DAY)		OT	SE-ACCORD-128893		57 YR	Female	SWE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Colitis Microscopic	Escitalopram			S		5 Mg Is Escalated To 20 Mg		Not Reported	
	Duloxetine/Duloxetine Hydrochloride			S		30 Mg Escalated To 60 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16348649	EXPEDITED (15-DAY)		OT	FR-UCBSA-2019021161		60 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Cholestasis; Hepatocellular Injury	Vimpat	S	Oral		Ucb
	Pantoprazole	S	Oral	Unk	Not Reported
	Tinzaparine Sodique	S	Subcutaneous	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Spironolactone	S	Oral		Not Reported
	Trileptal	S	Oral	Unk	Not Reported
	Diltiazem	S	Oral	Unk	Not Reported
	Bactrim	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16349942	EXPEDITED (15-DAY)		DS, OT	AT-ALLERGAN-1921445US			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty; Erectile Dysfunction; Fatigue; Feeling Abnormal; Hyperhidrosis; Hypoaesthesia; Hypoaesthesia; Illusion; Loss Of Libido; Malaise; Memory Impairment; Orgasm Abnormal; Orgasmic Sensation Decreased; Personality Change; Poisoning; Tremor; Tunnel Vision	Escitalopram Oxalate - Bp			S	Unknown	20 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16349947	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1921460US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Pemphigoid	Escitalopram Oxalate - Bp	S	Oral	Unk, Unknown	Allergan
	Furosemide	S	Oral	60 Mg, Qd	Not Reported
	Esomeprazole	C	Unknown	Unk, Unknown	Not Reported
	Toujeo	C	Unknown	Unk, Unknown	Not Reported
	Dafalgan	C	Unknown	Unk, Unknown	Not Reported
	Dermoval	C	Unknown	Unk, Unknown	Not Reported
	Vitabact	C	Unknown	Unk, Unknown	Not Reported
	Innohep	C	Unknown	Unk, Unknown	Not Reported
	Desloratadine	C	Unknown	Unk, Unknown	Not Reported
	Novorapid	C	Unknown	Unk, Unknown	Not Reported
	Diffu K	C	Unknown	Unk, Unknown	Not Reported
	Theralene	C	Unknown	Unk, Unknown	Not Reported
	Ventoline	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	10447316	EXPEDITED (15-DAY)		CA, HO, OT	CA-FRI-1000070527			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Premature Baby; Trismus	Escitalopram Oxalate Unk			S	Transplacental	20 Mg, Qd		Allergan
	Quetiapine			S	Transplacental	300 Mg, Bid (300 Mg Sustained Release And 300 Mg Immediate Release)		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported
	Benzotropine			S	Transplacental	1.5 Mg, Qd		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Methadone			S	Transplacental	70 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	15571782	EXPEDITED (15-DAY)		HO, OT	CA-MALLINCKRODT-T201804686		1 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Methadose			S	Transplacental	70mg, Qd		Mallinckrodt	
	Benzotropine Mesylate			S	Transplacental	1.5 Mg, Qd		Not Reported	
	Escitalopram			S	Transplacental	20 Mg, Qd		Not Reported	
	Gabapentin			S	Transplacental	1800 Mg, Qd		Not Reported	
	Nortriptyline			S	Transplacental	20 Mg, Qd		Not Reported	
	Quetiapine			S	Transplacental	300 Mg, Q12h		Not Reported	
	Rabeprazole			S	Transplacental	Unknown		Not Reported	
	Zopiclone			S	Transplacental	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16351333	EXPEDITED (15-DAY)		OT	PHHY2019AU117895		38 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported	
	Furosemide			S	Unknown	20 Mg, Unk		Novartis	
	Omeprazole			S	Unknown	20 Mg, Unk		Not Reported	
	Ramipril			S	Unknown	2.5 Mg, Unk		Not Reported	
	Amisulpride			S	Unknown	300 Mg, Unk		Not Reported	
	Atorvastatin			S	Unknown	10 Mg, Unk		Not Reported	
	Bisoprolol			S	Unknown	2.5 Mg, Unk		Not Reported	
	Melatonin			S	Unknown	2 Mg, Unk		Not Reported	
	Testosterone			S	Unknown	1 G, Unk (Every 10-14 W)		Not Reported	
	Spironolactone			S	Unknown	25 Mg, Unk		Not Reported	
	Ferrograd			S	Unknown	325 Mg, Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16351562	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US03904			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sedation Complication	Escitalopram			S	Unknown	10 Milligram		Invagen
	Escitalopram			S				Invagen
	Lorazepam			S	Unknown	0.5 Milligram, Per Day		Not Reported
	Lorazepam			S				Not Reported
	Clonazepam			S	Unknown	0.5 Milligram, Per Day		Not Reported
	Clonazepam			S				Not Reported
	Clonidine			C	Unknown	0.2 Milligram, At Night		Not Reported
	Clobazam			C	Unknown	15 Mg In Am, 15 Mg Noon, 40 Mg At Night		Not Reported
	Clobazam Ranitidine			C C	Unknown	150 Milligram, Qd (Daily At Bed Time)		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16352035	NON-EXPEDITED			US-NOVEN PHARMACEUTICALS, INC.-US2019000137			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Application Site Pruritus; Fatigue; Somnolence	Daytrana			S	Transdermal	Unk, Unknown		Noven
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Tylenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16353918	EXPEDITED (15-DAY)		HO	CH-OTSUKA- 2019_020637		21 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Use In Unapproved Indication; Suicidal	Abilify Maintena			S	Unknown	400 Mg, Unk		Otsuka
	Ciprallex			S	Unknown	15 Mg, Unk		Not Reported

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Ideation; Thinking
Abnormal; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16354119	EXPEDITED (15-DAY)		DE, OT	DE-ASTRAZENECA- 2019SE75650		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Seroquel			S	Unknown	Slowly Increased Dosage Since 13-Dec-2008		Astrazeneca	
	Diazepam			S	Unknown			Not Reported	
	Cipralex			S	Unknown			Not Reported	
	Haldol			S	Unknown			Not Reported	
	Remergil			S	Unknown			Not Reported	
	Ergenyl			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16355092	EXPEDITED (15-DAY)		OT	TR-ALLERGAN- 1920015US			Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Pallor; Shock; Somnolence; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Unknown		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16355097	EXPEDITED (15-DAY)		HO	CH-ALLERGAN- 1921726US			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication; Suicidal Ideation; Thinking Abnormal; Weight	Escitalopram Oxalate - Bp			S	Unknown	15 Mg		Allergan	
	Abilify			S	Unknown	400 Mg		Not Reported	
	Reagila			C	Unknown	3 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2019	15993805	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-094209		24 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Cardiac Disorder; Drug Ineffective; Drug Intolerance; Electrocardiogram Qt Prolonged	Escitalopram			S				Not Reported
	Aripiprazole			S		10 To 30 Mg Daily		Not Reported
	Clozapine			C				Not Reported
	Mirtazapine			C		15 Mg, 30 Mg Daily		Not Reported
	Loxapine/Loxapine Hydrochloride/Loxapine Succinate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16161938	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-117753		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Overdose; Psychomotor Skills Impaired	Escitalopram			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported
	Lorazepam			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Accord
	Quetiapine			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported
	Trittico			S	Oral	Date And Time Of Last Administration: 20-Jan-2019		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16356507	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1054438		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram Oxalate	S	Oral	Ivax
	Vortioxetine Hydrobromide	C		Not Reported
	Sertraline	C		Not Reported
	Asenapine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16356554	EXPEDITED (15-DAY)		DE, OT	DE-009507513-1905DEU010170		70 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remergil Soltab			S		30 Mg, Qd		Merck
	Ergenyl Chrono			S		1000 Mg, Qd		Not Reported
	Haldol			S		10 Mg, Qd		Not Reported
	Diazepam			S		5 Mg, Qd		Not Reported
	Seroquel			S		Slowly Titrated From 13-Dec-2008		Not Reported
	Cipralex			S		10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16356975	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP014646		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Generalised	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Pms Escitalopram			S	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16357572	EXPEDITED (15-DAY)		OT	FR-ACCORD-129265		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral			Unknown
	Spironolactone			S	Oral			Accord
	Lacosamide			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pantoprazole	S	Oral	Not Reported
Tinzaparin	S	Subcutaneous	Not Reported
Trileptal	S	Oral	Not Reported
Diltiazem	S	Oral	Not Reported
Sulfamethoxazole/Trimethoprim	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16357594	EXPEDITED (15-DAY)	DE		SE-ACCORD-129266		28 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram Accord			S	Oral	Strength: 10 Mg		Not Reported
	Elvanse			S	Oral			Not Reported
	Lamictal			S	Oral	Strength: 100 Mg		Not Reported
	Voxra			S	Oral	Strength: 150 Mg		Not Reported
	Melatonin Agb			C		Strength: 4 G, Max 2 Pcs Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16357675	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAUSCH-BL-2019-015164		17 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion XI			S	Oral	Unknown Amount		Not Reported
	Escitalopram			S	Oral	Unknown Amount		Not Reported
	Quetiapine			C	Oral	Unknown Amount		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16358741	EXPEDITED (15-DAY)		HO	PHHY2019FR117006		84 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Valsartan			S	Oral	160 Mg, Qd		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Esomeprazole	S	Oral	20 Mg, Qd	Not Reported
Lasilix	S	Oral	40 Mg, Qd	Not Reported
Seroplex	S	Oral	1 Df, Qd	Not Reported
Discotrine	C	Transdermal	1 Df, Qd	Not Reported
Simvastatine	C	Oral	20 Mg, Qd	Not Reported
Manidipine Hydrochloride	C	Oral	10 Mg, Qd	Not Reported
Seresta	C	Oral	1 Df, Qd	Not Reported
Bisoce	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	15206555	NON-EXPEDITED			US-PFIZER INC- 2018299471		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Neurontin			S		300 Mg, As Needed		Pfizer
	Neurontin			S		600 Mg, As Needed		Pfizer
	Geodon			S		20 Mg, Unk		Pfizer
	Xanax			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Ziprasidone Hcl			S		Unk		Pfizer
	Prazosin Hcl			S		Unk		Pfizer
	Metoprolol Tartrate			S		75 Mg, Unk		Unknown
	Prozac			S		Unk		Not Reported
	Adderall			S		Unk		Not Reported
	Buspar			S		90 Mg, Unk		Not Reported
	Latuda			S		Unk		Not Reported
	Ritalin			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Viibryd			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zyprexa	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported
L-Methylfolate	S	Unk	Not Reported
Concerta	S	Unk	Not Reported
L-Tyrosine	S	Unk	Not Reported
Klonopin	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Guanfacine	S	Unk	Not Reported
Lamictal	S	75 Mg, Unk	Not Reported
5 Htp [Ascorbic Acid;Biotin;Folic Acid;Nicotinamide;Oxipriptan;Pyridoxine Hydrochloride;Zinc Citrate]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	15367652	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016488459		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Thinking Abnormal; Withdrawal Syndrome	Lyrica			S	Oral	225 Mg, 2x/Day		Pfizer
	Lyrica			S		225 Mg, 2x/Day		Pfizer
	Lyrica			S				Pfizer
	Amlodipine Besilate			S		5 Mg, 1x/Day		Pfizer
	Escitalopram			S		20 Mg, 1x/Day		Not Reported
	Meloxicam			S		15 Mg, 1x/Day		Not Reported
	Clonazepam			S		1 Mg, Unk (Up To 3 Times Daily)		Not Reported
	Carisoprodol			C		350 Mg, Unk (2x 350 Mg)		Not Reported
	Amphetamine Salts			C		30 Mg, Unk (2x 30 Mg)		Not Reported
	Tramadol			C		50 Mg, Unk (Up To 6x		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Triamterene Hctz			C		Daily) Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16209748	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1916535US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Muscle Spasms; Peripheral Venous Disease	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Daily		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Daily		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Daily		Allergan	
	Magnesium			S	Unknown	Unk, Q Month		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16280460	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-004244		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition Aggravated; Dizziness; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Middle Insomnia; Panic Attack; Supraventricular Tachycardia	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustment		Jazz	
	Xyrem			S	Oral	4.25 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Lexapro			S	Oral	10 Mg, Unk		Not Reported	
	Lexapro			S		5 Mg, Unk		Not Reported	
	Wellbutrin			S	Oral	150 Mg XI		Not Reported	
	Wellbutrin			S		100 Mg XI		Not Reported	
	Propranolol			S	Unknown			Not Reported	
	Adderall			S				Not Reported	
	Armodafinil			C				Not Reported	
	Diurex Water Pills			C				Not Reported	
	Ibuprofen			C				Not Reported	
	Magnesium Oxide			C				Not Reported	
	Methylphenidate			C				Not Reported	
	Nuvigil			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Senna Lax	C	Not Reported
Vitamin B Complex	C	Not Reported
Vitamin D3	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16359428	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-029510			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lormetazepam Arrow 2 Mg, Tablet			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Trileptal			C	Unknown	Unk		Not Reported
	Urorec			C	Unknown	Unk		Not Reported
	Coveram			C	Unknown	Unk		Not Reported
	Simvastatine			C	Unknown	Unk		Not Reported
	Gabapentine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16359452	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-029507			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Valsartan			S	Oral	160 Milligram, Once A Day		Aurobindo
	Esomeprazole			S	Oral	20 Milligram, Once A Day		Aurobindo
	Seroplex			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Lasilix			S	Oral	40 Milligram, Once A Day		Not Reported
	Discotrine			C	Transdermal	1 Dosage Form, Once A Day		Not Reported
	Simvastatine			C	Oral	20 Milligram, Once A Day		Not Reported
	Manidipine Hydrochloride			C	Oral	10 Milligram, Once A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seresta	C	Oral	1 Dosage Form, Once A Day	Not Reported
Bisoce	C	Oral	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16359459	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-029370			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Bromazepam			S	Oral	180 Milligram, Daily		Not Reported	
	Escitalopram			S	Oral	120 Milligram, 1 Total		Aurobindo	
	Seresta			S	Oral	48 Dosage Form, 1 Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16359494	EXPEDITED (15-DAY)		DE	DE-ROCHE-2323381		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Interaction	Diazepam			S	Unknown			Not Reported	
	Ergenyl Chrono			S	Unknown			Not Reported	
	Haldol [Haloperidol]			S	Unknown			Not Reported	
	Remergil			S	Unknown			Not Reported	
	Seroquel			S	Unknown	Langsam Aufdosiert Ab 13.12.2008		Not Reported	
	Ciprallex [Escitalopram]			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16360002	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2018-044728			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Loss Of Personal Independence In Daily Activities; Palpitations;	Escitalopram			S	Unknown			Aurobindo	

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Product Substitution Issue

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16360464	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2018-044853			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Feeling Hot; Hypersensitivity	Escitalopram			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16360621	EXPEDITED (15-DAY)		HO, LT, OT	CA-ACCORD-129655		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect	Bupropion/Bupropion Hydrochloride			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine/Quetiapine Fumarate			C	Oral	Unknown Amount		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16361802	NON-EXPEDITED			US-PFIZER INC- 2019225352		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Product Use Issue	Neurontin			S		Unk Unk, As Needed As Needed [300-600 Mg (As Needed)]		Pfizer	
	Latuda			S		Unk		Not Reported	
	Viibryd			S		Unk		Not Reported	
	Seroquel			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Zyprexa			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Trazodone			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16362150	NON-EXPEDITED			US-SUNOVION-2019SUN002066			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Migraine	Latuda			S	Oral			Sunovion	
	Rexulti			S		1/4 Of A Tablet Or 1/2 A Tablet		Not Reported	
	Abilify			S	Unknown			Not Reported	
	Lexapro			S	Unknown	60 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16363245	EXPEDITED (15-DAY)		DE, OT	DE-ALLERGAN-1922180US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Ergenyl Chrono			S	Unknown	1000 Mg, Qd		Not Reported	
	Haldol			S	Unknown	10 Mg, Qd		Not Reported	
	Diazepam			S	Unknown	5 Mg, Qd		Not Reported	
	Remergil			S	Unknown	30 Mg, Qd		Not Reported	
	Seroquel			S	Unknown	200 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16363246	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1922156US			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental	Escitalopram Oxalate - Bp			S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Unk		Allergan	

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Disorder; Wrong Technique In Product Usage Process	Escitalopram Oxalate - Bp	S	Unknown	15 Mg, Unk	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	Reduced To 12.5 Mg Over 8 Weeks	Allergan
	Lorazepam	S	Unknown	Unk	Not Reported
	Lorazepam	S			Not Reported
	Lorazepam	S			Not Reported
	Lorazepam	S			Not Reported
	Mirtazapine	S	Unknown	15 Mg, Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Mirtazapine	S		Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported
	Buspirone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16363255	EXPEDITED (15-DAY)		OT	AU-ALLERGAN- 1922192US			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anaemia; Breast Tenderness; Condition Aggravated; Condition Aggravated; Confusional State; Depression; Diarrhoea; Disturbance In Attention; Dizziness; Drug Interaction; Fatigue; Headache; Infection; Irritability; Mental Impairment; Muscle	Citalopram Hydrobromide - Bp			S	Unknown			Allergan
	Lexapro			S	Unknown			Not Reported
	Provera			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

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Spasms; Nervousness;
Pain In Extremity;
Premenstrual Syndrome;
Somnolence; Suicidal
Ideation; Syncope;
Varicose Vein; Vision
Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16363294	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1048185			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Headache	Mirtazapine			S	Unknown	30 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Qhs		Not Reported
	Levocarb 1 A Pharma			S	Unknown	0.5 Df, Unk		Mylan
	Acetylsalicylic Acid			C	Unknown	100 Mg, Qd		Mylan
	Atorvastatin			C	Unknown	300 Mg, Qhs		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	15359280	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-043532			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Anxiety; Contraindicated Product Administered; Dehydration; Depression; Drug Interaction; Drug Level Increased; Intentional Overdose; Intentional Product Misuse; Neuroleptic Malignant Syndrome; Product Administration Error; Psychomotor Hyperactivity; Suicide Attempt; Vasoplegia	Lercanidipine Film-Coated			S	Unknown	300 Milligram, Total,(Overdose: 300 Mg)		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram, Monthly		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram, 1 Month		Not Reported
	Zuclopenthixol Decanoate			S	Unknown	300 Milligram		Not Reported
	Zuclopenthixol Decanoate			S				Not Reported
	Zuclopenthixol Acetate			S	Intramuscular	100 Milligram		Not Reported
	Zuclopenthixol Hydrochloride			S	Unknown	Titrated From 5 To 40mg Daily Over 2 Weeks		Not Reported
	Cyamemazine			S	Unknown	50 Milligram, Once A Day		Not Reported

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Syndrome; Wrong Dosage Formulation	Cyamemazine	S	Unknown	50 Mg To 100 Mg Daily	Not Reported
	Cyamemazine	S	Unknown	In Total (Overdose 750 Mg)	Not Reported
	Cyamemazine	S	Unknown	25 Mg To 75 Mg Daily (Overdose) ()	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Metformine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16365122	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP015264		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Seizure; Sympathomimetic Effect	Escitalopram			S	Oral	Unk		Apotex	
	Bupropion			S	Oral	Unk		Not Reported	
	Quetiapine			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16366408	EXPEDITED (15-DAY)		OT	CH-TEVA-2019-CH-1056289		59 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Benign Prostatic Hyperplasia; Urinary Retention; Urinary Retention	Escitalopram-Mepha Lactab 10mg			S	Unknown	10 Milligram Daily;		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16366448	EXPEDITED (15-DAY)		DS, OT	AT-TEVA-2019-AT-1055324		25 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of	Escitalopram			S				Ivax	
	Escitalopram			S				Ivax	

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Consciousness;
Disturbance In Attention;
Emotional Poverty;
Erectile Dysfunction;
Fatigue; Feeling
Abnormal; Hyperhidrosis;
Hypoaesthesia;
Hypoaesthesia; Illusion;
Loss Of Libido; Malaise;
Memory Impairment;
Orgasm Abnormal;
Orgasmic Sensation
Decreased; Personality
Change; Poisoning;
Tremor; Tunnel Vision

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16368029	EXPEDITED (15-DAY)		OT	TN-AMNEAL PHARMACEUTICALS- 2019AMN00616		38 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Escitalopram Oxalate			S	Unknown	Unk		Amneal	
	Escitalopram Oxalate			S		Unk		Amneal	
	Carbamazepine			S	Unknown	Unk		Not Reported	
	Amoxicilline			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	
	Levomepromazine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16368154	EXPEDITED (15-DAY)		DS	IT-MYLANLABS- 2019M1050045		19 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depressed Mood; Insomnia	Risperidone			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Rivotril			S	Oral	30 Gtt Drops, Qd		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16369080	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1922342US			Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transient Ischaemic Attack	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	14184336	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-16X-056-1260803-00		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clonus; Confusional State; Drug Abuse;	Escitalopram			S	Oral	840 Milligram		Not Reported	
Electrocardiogram Qt Prolonged; Eye Movement Disorder; Hypoglycaemia; Intentional Overdose; Intentional Product Misuse; Medication Error; Nystagmus; Overdose; Psychomotor Retardation; Psychomotor Skills Impaired; Suicidal Ideation; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	840 Milligram, Total		Not Reported	
	Venlafaxine			S	Oral	7875 Mg, Unk		Not Reported	
	Venlafaxine			S	Oral	7875 Milligram, Total		Not Reported	
	Bromazepam			S	Oral	180 Mg, Unk		Not Reported	
	Bromazepam			S	Oral	180 Milligram, Total		Not Reported	
	Lormetazepam			S	Oral	14 Mg, Unk		Mylan	
	Lormetazepam			S	Oral	14 Milligram, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16209518	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2019M1033344		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Dehydration; Drug Interaction; Drug Level Increased; Intentional Overdose; Neuroleptic	Lercanidipine			S		Unk		Not Reported	
	Lercanidipine			S		300 Milligram, Total		Not Reported	
	Escitalopram			S		10 Milligram, Qd		Not Reported	
	Zuclopenthixol Dihydrochloride			S		Titrated From 5 To 40mg		Mylan	

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Malignant Syndrome; Product Administration Error; Suicidal Ideation; Vasoplegia Syndrome	Zuclopenthixol Decanoate	S	Intramuscular	Daily Over 2 Weeks	Mylan
	Zuclopenthixol Acetate	S		300 Milligram, Monthly	
	Cyamemazine	S		100 Milligram	
	Cyamemazine	S		750 Milligram, Total	
	Cyamemazine	S		50 Mg To 100 Mg Daily	
	Cyamemazine	S		25 Mg To 75 Mg Daily	
	Cyamemazine	S		50 Milligram, Qd	
	Atorvastatin	C		Unk	
	Metformin	C		Unk	
	Bisoprolol	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16357728	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019223542		89 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rectal Haemorrhage	Amiodar			S	Oral	200 Mg, Daily		Not Reported	
	Duoplavin			S	Oral	175 Mg, Qd		Not Reported	
	Ciprallex [Escitalopram Oxalate]			S	Oral	10 Mg, Qd		Not Reported	
	Ranexa			C	Unknown	Unk		Not Reported	
	Ebixa			C	Unknown	Unk		Not Reported	
	Tareg			C	Unknown	Unk		Not Reported	
	Minitran [Glyceryl Trinitrate]			C	Unknown	Unk		Not Reported	
	Crestor			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16369558	EXPEDITED (15-DAY)		HO, LT, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03338		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Intentional	Quetiapine			S	Oral	Unk		Lupin	

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Overdose; Seizure;	Escitalopram	S	Oral	Unk	Lupin
Sympathomimetic Effect;	Bupropion	S	Oral	Unk (Overdose)	Lupin
Toxicity To Various Agents					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16370807	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-029828			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hyponatraemia	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Spironolactone			S	Oral	75 Milligram, Daily		Aurobindo
	Keppra			S	Oral	2000 Milligram, Daily		Not Reported
	Zebinix			S	Oral	800 Milligram (800mg X 1.5)		Not Reported
	Chronadalate			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			C	Unknown	Unk		Not Reported
	Januvia			C	Unknown	Unk		Not Reported
	Urbanyl			C	Unknown	Unk		Not Reported
	Fortzaar			C	Unknown	Unk		Not Reported
	Glimepiride			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16372056	EXPEDITED (15-DAY)		OT	CA-ALEMBIC PHARMACUETICALS LIMITED- 2019SCAL000324			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion Hydrochloride			S		Unk		Alembic
	Quetiapine Fumarate			S		Unk		Alembic
	Escitalopram			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16372718	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS-2019M1050760		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			C	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16372879	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1922346US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Lormetazepam Arrow			S	Oral	1 Df, Qd		Not Reported	
	Trileptal			C	Unknown	Unk		Not Reported	
	Urorec			C	Unknown	Unk		Not Reported	
	Coveram			C	Unknown	Unk		Not Reported	
	Simvastatine			C	Unknown	Unk		Not Reported	
	Gabapentine			C	Unknown	Unk		Not Reported	
	Kardegic			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16372886	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1922339US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Premature Ejaculation; Spontaneous Ejaculation	Escitalopram Oxalate - Bp			S	Oral	1 Df		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16372908	EXPEDITED (15-DAY)		OT	PL-ALLERGAN-1922349US			Female	POL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
	Atenolol			S	Oral	25 Mg, Unknown		Not Reported	
	Oxynorm			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported	
	Hydroxyzine			S	Oral	Unk, Unknown		Not Reported	
	Hydroxyzine			S	Unknown	Unk, Unknown		Not Reported	
	Ketonal (Ketoprofen)			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported	
	Pyralgin [Metamizole\Nimesulide]			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported	
	Fenactil			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported	
	Oxycontin			S	Oral	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16374776	EXPEDITED (15-DAY)		OT	CA-PRINSTON PHARMACEUTICAL INC.-2019PRN00533		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Overdose; Seizure	Bupropion Hydrochloride			S	Oral			Prinston Pharmaceutical	
	Escitalopram			S	Oral			Prinston Pharmaceutical	
	Quetiapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16376807	DIRECT					16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Prolactin Increased; Depression; Galactorrhoea; Suicide Attempt	Escitalopram			S	Oral			Not Reported	
	Duloxetine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	10349162	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014205300		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hallucination; Muscle Spasms; Muscle Tightness; Muscle Twitching; Nausea; Restlessness; Serotonin Syndrome; Skin Burning Sensation; Tachycardia; Tremor; Vomiting	Effexor Xr			S	Oral	37.5 Mg (1 Capsule), 1x/Day		Pfizer	
	Cipralext			S	Oral	5 Mg, 1x/Day (At Night)		Not Reported	
	Cipralext			S	Oral	5 Mg (1 Df), 1x/Day (In The Morning)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	14413400	EXPEDITED (15-DAY)		DE	NO-TAKEDA-2018TUS001617		60 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Ineffective; Prescribed Overdose	Brintellix			S	Oral	10 Milligram		Takeda	
	Brintellix			S	Oral	5 Milligram		Takeda	
	Cipralext /01588501/			S	Oral	10 Milligram, Qd		Not Reported	
	Cipralext /01588501/			S	Oral	20 Milligram, Qd		Not Reported	
	Cipralext /01588501/			S	Unknown	30 Milligram		Not Reported	
	Cipralext /01588501/			S	Oral	Unk		Not Reported	
	Seretide Discus			C	Unknown	250/50 Microgram, Unk		Not Reported	
	Amlodipin Sandoz /00972402/			C	Oral	5 Milligram, Qd		Not Reported	
	Ventoline /00139501/			C	Other	Unk		Not Reported	
	Crestor			C	Oral	40 Milligram, Qd		Not Reported	
	Valsartan Actavis			C	Oral	160 Milligram, Qd		Not Reported	
	Imovane			C	Oral	Unk		Not Reported	
	Loratadin Orifarm			C	Oral	Unk Unk, Qd		Not Reported	
	Emconcor			C	Oral	5 Milligram, Qd		Not Reported	

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Ezetrol	C	Oral	10 Milligram, Qd	Not Reported
Lansoprazol Krka	C	Oral	Unk	Not Reported
Albaryl-E	C	Oral	75 Milligram, Qd	Not Reported
Nitrolingual	C	Unknown	0.4 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	14463774	NON-EXPEDITED			US-HETERO CORPORATE- HET2018US00073		9 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Pruritus; Rash	Escitalopram			S	Oral	Unk Unk, Qd (2.5 MI Every Morning)		Hetero
	Intuniv			C	Unknown			Not Reported
	Clonidine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16227151	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-021301			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome;	Mirtazapine			S	Unknown	15 Milligram		Aurobindo
Electrocardiogram Qt	Mirtazapine			S				Aurobindo
Prolonged; General	Mirtazapine			S				Aurobindo
Physical Health	Mirtazapine			S				Aurobindo
Deterioration; Mental	Mirtazapine			S				Aurobindo
Disorder; Wrong	Buspirone			S	Unknown	Unk		Not Reported
Technique In Product	Buspirone			S				Not Reported
Usage Process	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported
	Lorazepam			S				Not Reported

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	Escitalopram		S	Unknown	15 Milligram		Not Reported		
	Escitalopram		S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks		Not Reported		
	Escitalopram		S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported		
	Escitalopram		S				Not Reported		
	Escitalopram		S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16280638	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-024430			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Decreased Appetite; Restlessness; Tremor	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16375195	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US04055			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective; Feeling Abnormal; Headache; Malaise; Withdrawal Syndrome	Escitalopram			S	Unknown	Unk, 15 Years		Invagen	
	Escitalopram			S	Oral	20 Milligram, Qd (In Morning)		Invagen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16375407	EXPEDITED (15-DAY)		DE	FR-ZYDUS-037112		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral			Cadila	
	Rivaroxaban			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16375994	EXPEDITED (15-DAY)		LT	FR-ACCORD-130171		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
	Racecadotril Bgr			S	Oral			Not Reported	
	Coveram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	
	Levothyrox			S	Oral			Not Reported	
	Mirtazapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16376299	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1055944		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral	Unspecified		Ivax	
	Xarelto			S	Oral	Unspecified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16376482	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2019-030153			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral	Unk (Unspecified)		Aurobindo	
	Xarelto			S	Oral	Unk (Unspecified)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16376596	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2019-DE-1056169		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Interaction	Diazepam			S				Barr	

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	Ergenyl Chrono	S							Not Reported
	Haldol	S							Not Reported
	Remergil	S							Not Reported
	Seroquel	S							Not Reported
						Slowly Added Up From 13.12.2008			
	Ciprallex	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16376861	EXPEDITED (15-DAY)		OT	HR-ASTRAZENECA- 2019SE77623			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral	4.0g Unknown		Zeneca	
	Elicea			S	Oral	360.0mg Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16377296	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019229721		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor	Effexor Xr			S	Oral	150 Mg, 1x/Day		Pfizer	
	Ciprallex [Escitalopram Oxalate]			S	Oral	20 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16378995	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1050366		56 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Thrombosis	Prednisone			S	Oral	4 Milligram, Qd		Not Reported	
	Valaciclovir			S	Oral	1000 Milligram, Qd		Not Reported	
	Methotrexate			S	Subcutaneous	20 Milligram, Qw		Not Reported	

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	Desloratadine	S	Oral	5 Milligram, Qd	Not Reported
	Paracetamol	S	Oral	2 Dosage Form, Qd	Not Reported
	Lisinopril	S	Oral	10 Milligram, Qd	Not Reported
	Escitalopram	S	Oral	20 Milligram, Qd	Not Reported
	Risedronate	S	Oral	35 Milligram, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
	Speciafoldine	S	Oral	10 Milligram, Qw	Mylan
	Codeine	S	Oral	2 Dosage Form, Qd	Mylan
	Uvedose	S	Oral	1 Dosage Form	Mylan
	Cacit /07357001/	S	Oral	1 Dosage Form, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16379004	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1050285		81 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hydrocephalus; Intraventricular Haemorrhage	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Kardegic			S	Oral	75 Milligram, Qd		Mylan
	Xarelto			S	Oral	20 Mg/J		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16379023	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1051030		49 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	14 Dosage Form, Total		Not Reported
	Lorazepam			S	Oral	40 Milligram, Total		Not Reported
	Aripiprazole			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16383614	DIRECT		DS			28 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Impaired Quality Of Life; Palpitations; Paraesthesia; Pollakiuria; Sexual Dysfunction; Skin Burning Sensation; Withdrawal Syndrome	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16570246	DIRECT	Y	LT			36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2019	16380579	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2019-031821			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral	10 Milligram		Aurobindo	
	Atenolol			S	Oral	25 Milligram		Not Reported	
	Oxynorm			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxyzinum			S	Oral	Unk		Not Reported	
	Hydroxyzinum			S				Not Reported	
	Ketonal			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Pyralgin [Metamizole Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Fenactil			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Oxycontin			S	Oral	Unk		Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16381306	EXPEDITED (15-DAY)		OT	CA-TWI PHARMACEUTICAL, INC-2019SCTW000012			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Intentional Overdose; Seizure	Bupropion Hydrochloride			S	Oral	Unk		Two Pharmaceuticals	
	Escitalopram			S	Oral	Unk		Not Reported	
	Quetiapine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16381880	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1057100		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Valsartan			S	Oral	160 Milligram Daily;		Teva	
	Esomeprazole			S	Oral	20 Milligram Daily;		Teva	
	Lasix 40 Mg, Comprimé Sécable			S	Oral	40 Milligram Daily;		Not Reported	
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Discotrine			C	Transdermal	1 Dosage Forms Daily;		Not Reported	
	Simvastatine			C	Oral	20 Milligram Daily;		Not Reported	
	Manidipine (Chlorhydrate De)			C	Oral	10 Milligram Daily;		Not Reported	
	Seresta 10 Mg, Comprimé			C	Oral	1 Dosage Forms Daily;		Not Reported	
	Bisoce 2,5 Mg, Comprimé Pelliculé Sécable			C	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16382120	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-209524		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State;	Spironolactone			S	Oral	75 Milligram, Daily		Sun	

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Hyponatraemia	Escitalopram	S	Oral	5 Milligram	Not Reported
	Keppra 1000 Mg, Comprime Pellicule	S	Oral	2000 Milligram, Daily	Not Reported
	Zebinix 800 Mg, Comprime	S	Oral	800mg X 1.5	Not Reported
	Chronadalate	C	Unknown	Unk	Not Reported
	Fenofibrate	C	Unknown	Unk	Not Reported
	Chlorhydrate De Sotalol	C	Unknown	Unk	Not Reported
	Januvia	C	Unknown	Unk	Not Reported
	Urbanyl 10 Mg, Comprime Secable	C	Unknown	Unk	Not Reported
	Fortzaar 100 Mg/25 Mg, Comprime Pellicule	C	Unknown	Unk	Not Reported
	Glimepiride	C	Unknown	Unk	Not Reported
	Kardegic	C	Unknown	Unk	Not Reported
	Metformine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16382440	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1057087		79 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy	Escitalopram			S	Oral	5 Milligram Daily;		Ivax
	Lormetazepam Arrow 2 Mg, Scored Tablet			S	Oral	1 Dosage Forms Daily;		Not Reported
	Trileptal 300 Mg Film-Coated Tablets			C				Not Reported
	Urorec			C				Not Reported
	Coveram			C				Not Reported
	Simvastatine			C				Not Reported
	Gabapentine			C				Not Reported
	Kardegic			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16382854	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019227203		85 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depression; Gait Disturbance; Somnolence	Lorazepam	S	Oral	1 Mg, 1x/Day (Every 24 Hours, 0-0-1)	Pfizer
	Escitalopram Cinfa	S	Oral	15 Mg, 1x/Day(1 Every 24 Hours)	Not Reported
	Lexatin [Bromazepam]	S	Oral	1.5 Mg, 3x/Day (Every 8 Hours, 1-1-1)	Not Reported
	Deprax [Sertraline Hydrochloride]	S	Oral	50 Mg, 1x/Day(Every 24 Hours, 0-0-1/2)	Not Reported
	Zyloric	C	Oral	Unk	Not Reported
	Omeprazole	C	Oral	Unk	Not Reported
	Uniket	C	Oral	Unk	Not Reported
	Monoprost	C	Ophthalmic	Unk	Not Reported
	Crestor	C	Oral	Unk	Not Reported
	Secalip	C	Oral	Unk	Not Reported
	Tesavel	C	Oral	Unk	Not Reported
	Emconcor Cor	C	Oral	Unk	Not Reported
	Acfol	C	Oral	Unk	Not Reported
	Seguril	C	Oral	Unk	Not Reported
	Sintrom	C	Oral	Unk	Not Reported
	Zaldiar	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16382917	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037291		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral			Cadila
	Rhinomaxil			S	Nasal			Not Reported
	Galantamine/Galantamine Hydrobromide			S	Oral			Zydus Pharm
	Fenofibrate			S	Oral			Not Reported
	Spironolactone			S	Oral			Zydus Pharm

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Cholecalciferol			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16383099	EXPEDITED (15-DAY)		OT	CA-JUBILANT CADISTA PHARMACEUTICALS- 2019JUB00202		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Overdose; Seizure	Bupropion			S	Oral			Jubilant	
	Escitalopram			S	Oral			Jubilant	
	Quetiapine			S	Oral			Jubilant	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16384052	EXPEDITED (15-DAY)		HO	GB-MYLANLABS- 2019M1051090		82 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dyspnoea; Upper Gastrointestinal Haemorrhage	Alendronate			S	Oral	70 Milligram, Qw		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Qd		Mylan	
	Acetylsalicylic Acid			S	Oral	75 Milligram, Qd		Mylan	
	Felodipine			C		Unk		Mylan	
	Levothyroxine			C		Unk		Mylan	
	Adcal D3			C		Unk		Mylan	
	Doxazosin			C		Unk		Mylan	
	Simvastatin			C		Unk		Mylan	
	Salbutamol			C		Unk		Mylan	
	Seretide			C		Unk		Mylan	
	Dymista			C		Unk		Mylan	
	Montelukast			C		Unk		Mylan	
	Gabapentin			C		Unk		Mylan	
	Ferrous Fumarate			C		Unk		Mylan	
	Zopiclone			C		Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16384377	EXPEDITED (15-DAY)		OT	CA-HERITAGE PHARMACEUTICALS- 2019HTG00240		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Overdose; Seizure	Bupropion Hydrochloride			S	Oral			Heritage	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16385780	NON-EXPEDITED			PHEH2019US022446		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Gilenya			S	Unknown	0.5 Mg, Unk		Novartis	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16158159	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX- 2019AP010534		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Ibuprofen			S	Oral	400 Mg, Prn		Apotex	
	Diclofenac Sodium			S	Oral	50 Mg, Bid		Apotex	
	Diclofenac Sodium			S	Oral	2 Df, Qd		Apotex	
	Cipraxel /01588501/			S	Oral	10 Mg, Qd		Not Reported	
	Eliquis			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16230461	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2019166272			Unknown	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome;	Lorazepam			S	Unknown	Unk		Pfizer
Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Lorazepam			S				Pfizer
	Escitalopram			S		12.5 Mg, Unk		Not Reported
	Escitalopram			S		15 Mg, Unk		Not Reported
	Escitalopram			S		5 Mg To Reach Approx. 12.5 Mg In 6 Weeks'		Not Reported
	Escitalopram			S				Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			S		15 Mg, Unk		Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Mirtazapine			S				Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported
	Buspirone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16386562	NON-EXPEDITED		HO, OT	IN-LUPIN LIMITED-2019-02343		45 YR	Female	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Escitalopram			S	Unknown	20 Milligram		Lupin
	Escitalopram			S	Unknown	5 Milligram		Lupin
	Olanzapine			S	Unknown	10 Milligram		Not Reported
	Fluoxetine			S	Unknown	20 Milligram		Lupin
	Divalproex Sodium			C	Unknown	500 Milligram		Not Reported

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04-Jun-2019	16387190	EXPEDITED (15-DAY)		OT	CA-HETERO CORPORATE- HET2019CA00784		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Seizure; Sympathomimetic Effect	Quetiapine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Hetero	
	Bupropion XI			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16387681	EXPEDITED (15-DAY)		OT	FR-ACCORD-130930		89 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral			Not Reported	
	Furosemide			S	Oral			Accord	
	Pantoprazole			S	Oral			Not Reported	
	Candesartan			S	Oral			Not Reported	
	Alprazolam			C				Not Reported	
	Spagulax Pure Mucilage			C				Not Reported	
	Gaviscon			C				Not Reported	
	Voltarene Emulgel			C		1%		Not Reported	
	Levothyrox			C				Not Reported	
	Rilmenidine/Rilmenidine Phosphate			C				Not Reported	
	Eupressyl			C				Not Reported	
	Loxen L P			C		50 Mg		Not Reported	
	Uvedose			C		100 000 Ui, Oral Solution In Ampoule		Not Reported	
	Doliprane			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16387696	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-032690			Unknown	ESP

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Bundle Branch Block Left;	Escitalopram			S	Unknown	Unk		Aurobindo
Electrocardiogram Qt	Omeprazole			S	Unknown	Unk		Aurobindo
Prolonged;	Enalapril;Hydrochlorothiazide			S	Unknown	Unk		Not Reported
Hypocalcaemia;	Trazodone			S	Unknown	Unk		Not Reported
Hypomagnesaemia;	Metformin			C	Unknown	Unk		Not Reported
Ventricular Extrasystoles								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16387699	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-032118			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Escitalopram			S	Oral			Aurobindo
	Lormetazepam			S	Oral	2 Milligram, Once A Day		Not Reported
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo
	Phenergan			S	Oral	25 Milligram, Once A Day		Not Reported
	Agomelatine			S	Oral	25 Milligram, Once A Day		Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Tilcotil			C	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388550	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-030996			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo
	Fenofibrate			S	Oral	67 Milligram, Daily		Aurobindo

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Galantamine	S	Oral	16 Milligram, Daily	Aurobindo
Spironolactone	S	Oral	50 Milligram, Daily	Aurobindo
Rhinomaxil	S	Nasal	Unk	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388563	EXPEDITED (15-DAY)		OT	FR- ELI_LILLY_AND_COMP ANY-FR201905015563		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mitral Valve Incompetence	Cymbalta			S	Oral	1 Dosage Form, Daily		Eli Lilly And Co
	Baclofene			S	Oral	Unk, Unknown		Not Reported
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported
	Seroplex			S	Oral	Unk, Unknown		Not Reported
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported
	Noctamide			S	Oral	Unk, Unknown		Not Reported
	Gabapentine			S	Oral	1 Dosage Form, Daily		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Weekly (1/W)		Not Reported
	Effexor			S	Oral	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388641	EXPEDITED (15-DAY)		OT	PL-TEVA-2019-PL- 1057369		77 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral			Ivax
	Atenolol			S	Oral			Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxyzinum			S	Oral			Not Reported
	Hydroxyzinum			S				Not Reported

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Ketonal (Ketoprofen)	S	Intravenous (not otherwise specified)	Not Reported
Pyralgin [Metamizole Sodium]	S	Intravenous (not otherwise specified)	Not Reported
Fenactil	S	Intravenous (not otherwise specified)	Not Reported
Oxycontin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16389649	NON-EXPEDITED			US-TEVA-2019-US-1049613		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Escitalopram			S	Unknown	5 Milligram Daily;		Ivax	
	Escitalopram			S				Ivax	
	Loratadine			C	Unknown			Not Reported	
	Albuterol			C	Respiratory (inhalation)			Not Reported	
	Budesonide /Formoterol			C	Respiratory (inhalation)			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16389980	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1923427US			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activation Syndrome	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Meilax			C	Oral			Not Reported	
	Olanzapine			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16585606	DIRECT	Y					Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error	Escitalopram 20mg Tablets			S				Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16391581	EXPEDITED (15-DAY)		HO, LT, OT	CA-MACLEODS PHARMACEUTICALS US LTD- MAC2019021528			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Oxalate			S	Oral	Unk,Unknown Amount		Macleods	
	Bupropion			S	Oral	Unk, Unknown Amount		Not Reported	
	Quetiapine			C	Oral	Unk, Unknown Amount		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16392568	EXPEDITED (15-DAY)		OT	PL-ALVOGEN-2019- ALVOGEN-099931		77 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Atenolol			S	Oral	25.0mg Unknown		Not Reported	
	Hydroxyzine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Oxycodone Hydrochloride			S	Oral			Not Reported	
	Oxycodone Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Ketoprofen			S	Intravenous (not otherwise specified)			Not Reported	
	Metamizole Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Chlorpromazine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxyzine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16393971	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1923327US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd: 0. - 11.3. Gestational Week		Allergan	
	Femi Baby			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16394148	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019233325		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Spironolactone			S	Oral	50 Mg, 1x/Day		Pfizer	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Rhinomaxil			S	Nasal	Unk		Not Reported	
	Galantamine Base			S	Oral	16 Mg, 1x/Day		Not Reported	
	Fenofibrate			S	Oral	67 Mg, 1x/Day		Not Reported	
	Cholecalciferol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16395507	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1051448		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthermia; Intentional Overdose; Miosis; Orthostatic Hypotension; Somnolence	Escitalopram			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported	
	Bromazepam			S	Oral	Prise Estimée À 20 Cp De Bromazépam 6 Mg		Not Reported	
	Aripiprazole			S	Oral	Dose Exacte Lors De L'Imv Inconnue		Not Reported	

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Zolpidem	S	Oral	Dose Exacte Lors De L'Imv Inconnue	Not Reported
Olanzapine	S	Oral	Dose Exacte Lors De L'Imv Inconnue	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	15270581	EXPEDITED (15-DAY)		DS	IT-ALLERGAN-1839414US			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaesthesia; Anorgasmia; Disturbance In Attention; Erectile Dysfunction	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16225578	EXPEDITED (15-DAY)		OT	GB-009507513-1904GBR005968			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome;	Mirtazapine			S	Unknown	15 Milligram		Merck	
Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Wrong Technique In Product Usage Process	Mirtazapine			S				Merck	
	Mirtazapine			S				Merck	
	Mirtazapine			S				Merck	
	Mirtazapine			S				Merck	
	Buspirone			S		Unk		Not Reported	
	Buspirone			S				Not Reported	
	Buspirone			S				Not Reported	
	Buspirone			S				Not Reported	
	Lorazepam			S		Unk		Not Reported	
	Lorazepam			S				Not Reported	
	Lorazepam			S				Not Reported	
	Lorazepam			S				Not Reported	
	Escitalopram 5 Mg Film-Coated Tablets			S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported	
	Escitalopram 5 Mg Film-Coated Tablets			S	Unknown	15 Mg		Not Reported	

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Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	Cutting Bits To 5 Mg To Reach Approx. 12.5 Mg In 6 Weeks	Not Reported
Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	15 Milligram	Not Reported
Escitalopram 5 Mg Film-Coated Tablets	S	Unknown	15 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16246871	EXPEDITED (15-DAY)		DS, OT	ES-ACCORD-124378		45 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Female Sexual Dysfunction; Loss Of Libido	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Sertraline			S	Oral	Also Received 100 Mg For 90 Days		Accord
	Enalapril			C	Oral	20 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16376648	EXPEDITED (15-DAY)		HO	ES-ASTRAZENECA-2019SE78869		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Hypomagnesaemia; Ventricular Extrasystoles	Omeprazole			S	Unknown			Not Reported
	Enalapril, Hydrochlorothiazide			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Metformin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16397065	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD-MAC2019021479			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate	S	Unknown	Unk	Macleods
	Tiaprizal	S	Oral	100 Milligram, Tid, Per 8 Hour	Not Reported
	Tiaprizal	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16397326	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-031493			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram			S	Oral	Unknown Amount		Aurobindo
	Bupropione			S	Oral	Unknown Amount		Not Reported
	Quetiapine			C	Oral	Unknown Amount		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399515	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT- 00014174		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Unknown
	Escitalopram			S	Transplacental	10 [Mg/D]		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399999	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1923647US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Escitalopram Oxalate - Bp			S	Oral	1 Df		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400009	EXPEDITED (15-DAY)		OT	CH-ALLERGAN- 1923585US			Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Epistaxis; Fatigue; Oromandibular Dystonia	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S	Oral	5 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S	Oral	Increased Up To 20 Mg, Qd	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400013	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1923423US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Agomelatine			S	Oral			Not Reported
	Phenergan			S	Oral			Not Reported
	Clotiazepam			S	Oral	15 Mg		Not Reported
	Risperidone			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tilcotil			C	Unknown			Not Reported
	Atorvastatine			C	Unknown			Not Reported
	Kardegic			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400015	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1923642US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mitral Valve Incompetence	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan
	Baclofen			S	Oral	Unk		Not Reported
	Laroxyl			S	Oral	1 Df, Qd		Not Reported
	Seresta			S	Oral	1 Df, Qd		Not Reported
	Noctamide			S	Oral	Unk		Not Reported

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Gabapentine	S	Oral	1 Df, Qd	Not Reported
Cymbalta	S	Oral	1 Df, Qd	Not Reported
Methotrexate	S	Subcutaneous	1 Df, Q Week	Not Reported
Effexor	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400017	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1923361US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Loss Of Consciousness; Malaise; Orthostatic Hypotension; Vomiting	Escitalopram Oxalate - Bp			S	Oral	7.5 Mg, Qd		Allergan	
	Contramal L.P.			S	Oral	200 Mg, Qd		Not Reported	
	Xatral Lp			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16401059	EXPEDITED (15-DAY)		OT	CN-ALLERGAN-1923672US			Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16401230	EXPEDITED (15-DAY)		DS, OT	ES-ALLERGAN-1923583US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dizziness; Feeling Abnormal; Walking Disability	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16401429	EXPEDITED (15-DAY)		CA, HO	FR-ALLERGAN-1923983US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd		Allergan
	Imovane	S	Oral			Not Reported
	Donormyl (Doxylamine Succinate)	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16404221	DIRECT						Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Escitalopram			S					Not Reported
	Mirtazapine			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	15948882	EXPEDITED (15-DAY)		HO	LU-ACCORD-106585		47 YR	Female	LUX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Actin Antibody Positive; Gamma-Glutamyltransferase Increased; Hepatocellular Injury	Escitalopram			S	Oral				Not Reported
	Gilenya			S	Oral				Not Reported
	Lyrica			C	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16214465	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1916563US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Restlessness; Stress; Underdose	Escitalopram Oxalate - Bp			S	Unknown	5 Mg			Allergan
	Escitalopram Oxalate - Bp			S	Unknown	7.5 Mg, Qd			Allergan
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd			Allergan
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg			Allergan
	Escitalopram			S	Unknown	Unk			Not Reported
	Escitalopram			S					Not Reported
	Ibuprofen			S	Unknown	Unk			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16251255	EXPEDITED (15-DAY)		DS	IT-MYLANLABS-2019M1039123		61 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dysgraphia; Dyskinesia; Off Label Use; Therapeutic Product Effect Decreased; Tremor	Escitalopram			S		Unk		Not Reported	
	Sertraline			S	Unknown	50 Milligram, Qd		Not Reported	
	Sertraline			S		200 Milligram, Qd		Not Reported	
	Sertraline			S				Not Reported	
	Venlafaxine			S		Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Not Reported	
	Mirtazapine			S				Not Reported	
	Quetiapine			S	Oral	Unk		Not Reported	
	Valproic Acid			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16279023	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1918879US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oedema Peripheral; Pruritus	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Irbesartan			C	Oral	300 Mg, Qd		Not Reported	
	Kardegic			C	Oral	1 Df, Qd		Not Reported	
	Lercanidipine			C	Oral	10 Mg, Qd		Not Reported	
	Physiotens			C	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16301322	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1919880US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	15 Mg, Qd		Allergan	

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Prolonged; Syncope; Torsade De Pointes	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S	Unknown	5 Mg, Qd	Allergan
	Captohexal	S	Unknown	25 Mg, Qd	Not Reported
	Captohexal	S	Unknown	50 Mg, Qd	Not Reported
	Dipiperon	S	Unknown	80 Mg, Qd	Not Reported
	Esidrix	S	Unknown	25 Mg, Qd	Not Reported
	Esidrix	S	Unknown	12.5 Mg, Qd	Not Reported
	Galantamine Hydrobromide	S	Unknown	2.5 Mg, Qd	Not Reported
	Galantamine Hydrobromide	S	Unknown	8 Mg, Qd	Not Reported
	Galantamine Hydrobromide	S	Unknown	5 Mg, Qd	Not Reported
	Amlodipin	C	Unknown	2.5 Mg, Qd	Not Reported
	Amlodipin	C	Unknown	5 Mg, Qd	Not Reported
	Marcumar	C	Unknown	Nach Inr	Not Reported
	Calcium Carbonate	C	Unknown	2 Df, Qd	Not Reported
	Trazodone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16402878	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-209863		84 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Valsartan			S	Oral	160 Milligram, Daily		Ranbaxy
	Esomeprazole			S	Oral	20 Milligram, Daily		Sun
	Lasilix 40 Mg, Comprime			S	Oral	40 Milligram, Daily		Not Reported
	Secable							
	Seroplex 10 Mg, Comprime			S	Oral	1 Dosage Form, Daily		Not Reported
	Pellicule Secable							
	Discotrine			C	Transdermal	1 Dosage Form, Daily		Not Reported
	Simvastatine			C	Oral	20 Milligram, Daily		Not Reported
	Manidipine (Chlorhydrate De)			C	Oral	10 Milligram, Daily		Not Reported
	Seresta 10 Mg, Comprime			C	Oral	1 Dosage Form, Daily		Not Reported

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Bisoce 2,5 Mg, Comprime
Pellicule Secable

C

Oral

1 Dosage Form, Daily

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403214	EXPEDITED (15-DAY)		CA, OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM- 2019-05155			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Aortic Anomaly; Foetal Exposure During Pregnancy; Premature Baby; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect	Aripiprazole			S	Transplacental	Unk		Alkem
	Escitalopram			S	Transplacental	Unk		Not Reported
	Dihydroergotamine			S	Transplacental	Unk		Not Reported
	Oxazepam			S	Transplacental	Unk		Not Reported
	Pipamperone			S	Transplacental	Unk		Not Reported
	Loprazolam			S	Transplacental	Unk		Not Reported
	Dipotassium Clorazepate			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403224	EXPEDITED (15-DAY)		OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM- 2019-05179			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Aripiprazole			S	Transplacental	Unk		Alkem
	Escitalopram			S	Transplacental	Unk		Not Reported
	Methadone Hydrochloride			S	Transplacental	Unk		Alkem
	Zopiclone			S	Transplacental	Unk		Not Reported
	Alprazolam			S	Transplacental	Unk		Not Reported
	Mirtazapine			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403455	EXPEDITED (15-DAY)		HO, LT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-		17 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Seizure; Toxicity To Various Agents	Bupropion			S	Oral	Unk		Sun
	Escitalopram			S	Oral	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403505	EXPEDITED (15-DAY)		CA	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019021585			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Milligram, Qd, 0. - 11.3. Gestational Week		Macleods
	Minerals Nos/Vitamins Nos			C	Transplacental	Unk, 0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403752	EXPEDITED (15-DAY)		CA	DE-HETERO CORPORATE- HET2019DE00792		1 DAY	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Hetero
	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16404211	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20190601728		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Fall; Spinal Fracture	Risperidone	S	Oral	Not Reported
	Agomelatine	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Phenergan	S	Oral	Not Reported
	Clotiazepam	S	Oral	Not Reported
	Lormetazepam	S	Oral	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Kardegic	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Tilcotil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16405824	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1058115			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral			Teva	
	Elicea			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16410338	DIRECT					84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Oral	Quantity:1 Tablet(S);	90 DAY	Teva	
	Flomax			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16410660	DIRECT		OT			75 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergic Reaction To Excipient; Product Substitution Issue; Rash; Urticaria	Benazepril, 20 Mg	Y		S	Oral	Quantity:1 Tablet(S);	1 DAY	Princeton Pharmaceutical
	Estradiol	Y		S	Oral	Quantity:1 Tablet(S);		Barr
	Metoprolol Succinate			S				Not Reported
	Sertraline			S				Not Reported
	Hydralazine			S				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2019	16407695	EXPEDITED (15-DAY)		HO	PHHY2019FR127994		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Risperidone			S	Oral	1 Mg, Qd		Novartis
	Lormetazepam			S	Oral	2 Mg, Qd		Not Reported
	Agomelatine			S	Oral	25 Mg, Qd		Not Reported
	Phenergan			S	Oral	25 Mg, Qd		Not Reported
	Clotiazepam			S	Oral	15 Mg, Qd		Not Reported
	Tilcotil			C	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16363375	EXPEDITED (15-DAY)			JP-JNJFOC- 20190533993		48 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Pain	Invega			S	Oral			Not Reported
	Lonasen			S	Oral			Not Reported

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Loxonin	S	Unknown	Not Reported
Metgluco	S	Oral	Not Reported
Irbetan	S	Oral	Not Reported
Lexapro	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16391237	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1923348US			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Product Use Issue; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Quetiapine			S	Unknown	Unk		Not Reported
	Bupropion XI			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16391245	EXPEDITED (15-DAY)		DE	US-ALLERGAN-1923607US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown			Allergan
	Cyproheptadine			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16408582	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209946		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Spironolactone			S	Oral	50 Milligram, Daily		Sun
	Fenofibrate			S	Oral	67 Milligram, Daily		Not Reported

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	Galantamine Base	S	Oral	16 Milligram, Daily	Not Reported
	Rhinomaxil 100 Microgrammes/Dose, Suspension Pour Pulverisation Nasale	S	Nasal	()	Not Reported
	Cholecalciferol	C	Unknown	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16408589	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1057671		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Galantamine Base			S	Oral	16 Milligram Daily;		Barr
	Fenofibrate			S	Oral	67 Milligram Daily;		Teva
	Spironolactone			S	Oral	50 Milligram Daily;		Actavis
	Rhinomaxil 100 Micrograms/Dose, Nasal Spray Suspension			S	Nasal			Not Reported
	Cholecalciferol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16408641	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-206562		21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Abnormal;	Absorica			S	Unknown	30 Milligram, Bid		Sun
Hypoaesthesia;	Levocetirizine			S	Unknown			Sun
Paraesthesia; Product Dose Omission	Adderall			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

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10-Jun-2019	16409107	NON-EXPEDITED			US-TEVA-2019-US-1052744		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexually Inappropriate Behaviour	Escitalopram			S	Unknown			Ivax	
	Donepezil			C	Unknown			Not Reported	
	Memantine			C	Unknown	10 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16409627	EXPEDITED (15-DAY)		OT	PL-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00220			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown			Jubilant	
	Ginseng			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16410777	EXPEDITED (15-DAY)		OT	PHHY2019FR128033		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mitral Valve Incompetence	Baclofen			S	Oral	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	1 Df, Qw		Novartis	
	Gabapentin			S	Oral	1 Df, Qd		Not Reported	
	Laroxyl			S	Oral	1 Df, Qd		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Seresta			S	Oral	1 Df, Qd		Not Reported	
	Noctamide			S	Oral	Unk		Not Reported	
	Cymbalta			S	Oral	1 Df, Qd		Not Reported	
	Effexor			S	Oral	Unk		Not Reported	

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10-Jun-2019	16411548	EXPEDITED (15-DAY)		OT	HR-INDIVIOR LIMITED-INDV-119938-2019		16 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse; Product Use Issue	Subutex Tablet			S	Oral	1 Dose, Unk		Reckitt Benckiser	
	Pregabalin			S	Oral	1 Dose, Unk		Not Reported	
	Misar /00595201/			S	Oral	1 Dose, Unk		Not Reported	
	Serpentil /01588502/			S	Oral	1 Dose, Unk		Not Reported	
	Sanval			S	Oral	1 Dose, Unk		Not Reported	
	Kventiax			S	Oral	1 Dose, Unk		Not Reported	
	Normabel			S	Oral	1 Dose, Unk		Not Reported	
	Xanax			S	Oral	1 Dose, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16411713	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1053655			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Kidney Duplex	Escitalopram			S	Transplacental	10 Milligram, Qd		Not Reported	
	Escitalopram			S	Transplacental	5 Milligram, Qd		Not Reported	
	Magnetrans /01486820/			C	Transplacental	Unk		Mylan	
	Ibuprofen			C	Transplacental	400 [Mg/D]/ On Demand, Max Once Per Week		Mylan	
	Cetirizine			C	Transplacental			Mylan	
	Paracetamol			C	Transplacental	1500 [Mg/D]/ 1000-1500 Mg/D, In Total 2-3 Times		Mylan	
	Cytotec			C	Transplacental	Unk		Mylan	
	Olynth			C	Transplacental	If Required		Mylan	
	Folio Forte			C	Transplacental	0.8 [Mg/D]/ From Week 14 0.4mg/D		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16412209	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1923640US			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; No Adverse Event; Product Administered To Patient Of Inappropriate Age; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	70 Mg, Overdose		Allergan	
	Aripiprazole			S	Oral	30 Mg, Unknown		Not Reported	
	Xanax			S	Oral	2 Df, Unknown		Not Reported	
	Diazepam			S	Oral	20 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16248696	EXPEDITED (15-DAY)		HO	FR-ACCORD-124498		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Pantoprazole			S				Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Lasix			S	Oral	500 Mg, Scored Tablet		Not Reported	
	Spironolactone			C	Oral			Not Reported	
	Coumadine			C	Oral	2 Mg Scored Tablet		Not Reported	
	Bisoprolol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16254732	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-018012			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Intentional Product Use Issue; Muscle Spasms; Peripheral Venous Disease; Seasonal Affective Disorder; Vein Disorder	Magnesium			S	Unknown	Unk		Aurobindo	
	Seroplex			S	Unknown	5 Milligram, Once A Day		Not Reported	
	Seroplex			S	Unknown	10 Milligram, Once A Day		Not Reported	

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11-Jun-2019	16385005	EXPEDITED (15-DAY)			JP-ALLERGAN-1923132US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema; Proteinuria	Escitalopram Oxalate - Bp			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16412966	EXPEDITED (15-DAY)		CA	DE-AUROBINDO-AUR-APL-2019-032482			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 Milligram, Daily (10 [Mg/D]		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16413224	EXPEDITED (15-DAY)		OT	PL-APOTEX-2019AP015917		77 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dry Mouth; Headache; Nausea; Sedation; Vomiting	Escitalopram			S	Oral	10 Mg, Unk		Apotex	
	Atenolol			S	Oral	25 Mg, Unk		Not Reported	
	Oxynorm			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxizinum			S	Oral	Unk		Not Reported	
	Hydroxizinum Ketonal /00321701/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Pyralgil /03155201/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Fenactil			S	Intravenous (not otherwise specified)	Unk		Not Reported	

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Oxycontin			S		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jun-2019	16413504	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03479			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Confusional State; Delirium; Drug Hypersensitivity; Dyspepsia; Fatigue; Mental Status Changes; Nausea; Pruritus; Vomiting	Escitalopram			S	Unknown	Unk			Lupin	
	Fluoxetine			S	Unknown	Unk			Lupin	
	Cephalexin			S	Unknown	Unk			Lupin	
	Duloxetine			S	Unknown	Unk			Lupin	
	Oxycodone			S	Unknown	Unk			Novel Labs	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk			Novel Labs	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jun-2019	16413595	EXPEDITED (15-DAY)		HO, LT, OT	CA- GLAXOSMITHKLINE- CA2019GSK096346		17 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion Hydrochloride XI			S	Oral	Unk			Glaxosmithkline	
	Escitalopram			S	Oral	Unk			Glaxosmithkline	
	Quetiapine			C	Oral	Unk			Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Jun-2019	16413892	EXPEDITED (15-DAY)		HO, LT	FR-ACCORD-131912		91 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Amlodipine			S	Oral				Accord	
	Zelitrex			S	Oral	Strength:500 Mg			Not Reported	
	Seroplex			S	Oral	Strength: 5 Mg			Not Reported	

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Perindopril	S	Oral		Not Reported
Ditropan	S	Oral	Strength: 5 Mg	Not Reported
Fludex (Indapamide)	S	Oral	Strength: 1.5 Mg	Not Reported
Cortancyl	C	Oral		Not Reported
Paracetamol	C	Oral		Not Reported
Movicol	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16413899	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-131813		57 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp Of 20 Mg + 27 Cp Of 10 Mg		Not Reported
	Lorazepam			S	Oral	72 Cp Of 2.5 Mg		Not Reported
	Bupropion/Bupropion Hydrochloride			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Diazepam			C				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			C				Not Reported
	Olanzapine			C				Not Reported
	Topiramate			C				Not Reported
	Hydroxycarbamide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16414773	NON-EXPEDITED			US-PFIZER INC-2019240987		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Drug Ineffective; Loss Of Personal Independence In Daily Activities	Zoloft			S		100 Mg, Unk [30 Ds/30 Quantity]		Pfizer
	Pristiq			S		Unk		Pfizer
	Prozac			S		10 Mg, Unk [30 Ds/ 30 Quantity]		Not Reported

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Remeron	S	Unk, 1x/Day	Not Reported
Lexapro	S	Unk, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16415310	EXPEDITED (15-DAY)		OT	PHHY2019HR131063		16 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Sanval			S	Oral	1 Ot, Unk		Novartis
	Pregabalin			S	Oral	1 Ot, Unk		Not Reported
	Cocaine			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Misar (Alprazolam)			S	Oral	1 Df, Unk		Not Reported
	Serpentil (Escitalopram Oxalate)			S	Oral	1 Ot, Unk		Not Reported
	Kventiax			S	Oral	1 Ot, Unk		Not Reported
	Subutex			S	Oral	1 Ot, Unk		Not Reported
	Normabel (Diazepam)			S	Oral	1 Ot, Unk		Not Reported
	Xanax			S	Oral	1 Ot, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16417208	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2019-0067165			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertonia Neonatal; Respiratory Depression	Oxynorm			S	Transplacental	30 Mg, Daily		Purdue
	Oxycontin Lp			S	Transplacental	(Strength 5mg)		Purdue
	Seroplex			S	Transplacental	20 Mg, Daily		Not Reported
	Seresta			S	Transplacental	Cf Commentaire		Not Reported
	Laroxyl			S	Transplacental	2 Df, Daily		Not Reported
	Inexium /01479302/			C	Transplacental	40 Mg, Daily		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16417449	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1054505			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Medication Error; Overdose	Escitalopram			S	Oral	30 Milligram, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16421126	DIRECT		HO			41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar II Disorder; Mania; Serotonin Syndrome; Weight Decreased	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Lamotrigine			C				Not Reported	
	Lisinopril			C				Not Reported	
	Clonazepam			C				Not Reported	
	Propranolol Er			C				Not Reported	
	Hydroxyzine Pamoate			C				Not Reported	
	Gabapentin			C				Not Reported	
	Norlyda			C				Not Reported	
	Sumatriptan			C				Not Reported	
	Meloxicam			C				Not Reported	
	Ketorolac			C				Not Reported	
	Carisoprodol			C				Not Reported	
	Lexapro			C				Not Reported	
	Zoloft			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	14099163	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2017-41966			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Intentional Self-Injury; Sopor	Delorazepam Tablet			S	Oral	1mg		Not Reported	
	Losartan Film-Coated Tablets			S	Oral	Dosage Form: Unspecified, Tablets, 50		Aurobindo	

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Escitalopram Accord	S	Oral	Mg	Not Reported
Haldol	S	Oral	20 Milligram	Not Reported
			Dosage Form: Solution	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	15125501	EXPEDITED (15-DAY)		OT	CN-APOTEX-2018AP016929		37 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia;	Seroxat			S	Oral	0.5 Df, Qd, 20 Mg		Apotex
Chorioretinopathy; Cough;	Seroxat			S	Oral	1.5 Df, Qd (Tablet 20 Mg)		Apotex
Depressed Mood;	Seroxat			S	Oral	0.5 Df, Qd (Tablet)		Apotex
Depression; Disease	Seroxat			S	Oral	0.5 Df, Qod (Tablet)		Apotex
Recurrence; Drug	Seroxat			S	Oral	1 Df, Qd		Apotex
Ineffective; Dry Eye; Fear;	Seroxat			S	Oral	1 Df, Qd (Tablet), 25 Mg		Apotex
Product Use In	Seroxat			S	Oral	1 Df, Qd (Tablet), 25 Mg		Apotex
Unapproved Indication;	Seroxat			S	Oral	0.5 Df, Qd		Apotex
Product Use Issue;	Seroxat			S	Oral	1.5 Df, Qd		Apotex
Productive Cough; Soft	Seroxat			S	Oral	0.5 Df, Q.O.D.		Apotex
Tissue Disorder;	Seroxat			S	Oral	Unk		Not Reported
Somnolence; Visual	Seroxat			S	Oral	Unk		Not Reported
Impairment; Weight	Seroxat			S	Oral			
Increased	Seroxat			S	Oral			
	Escitalopram Oxalate			S	Unknown			
	Clonazepam			S	Oral			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16246935	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190433124			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Burnout	Ibuprofen		Y	S	Unknown			Not Reported
Syndrome; Depression;	Ibuprofen			S	Unknown			Not Reported
Drug Interaction; Drug	Escitalopram			S	Unknown			Not Reported
Intolerance; Heart Rate	Escitalopram			S	Unknown			Not Reported
Increased; Hyperhidrosis;	Escitalopram			S	Unknown			Not Reported
Hypertension; Palpitations;	Escitalopram			S	Unknown			Not Reported
Panic Attack;	Escitalopram			S	Unknown			Not Reported

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Restlessness; Stress; Underdose	Escitalopram	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported
	Cipralelex	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16406407	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1052606		83 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Candesartan			S	Oral	16 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported
	Imovane			S	Oral	1 Dosage Form, Qd		Mylan
	Seresta			S	Oral	1 Dosage Form, Qd		Mylan
	Lasilix /00032601/			S	Oral	4 Dosage Form, Qd		Mylan
	Omexel			S	Oral	1 Dosage Form, Qd		Mylan
	Tenordate			S	Oral	1 Dosage Form, Qd		Mylan
	Lovenox			C		Unk		Mylan
	Kardegic			C		Unk		Mylan
	Seebri Breezhaler			C		Unk		Mylan
	Avodart			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16418264	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-031939			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Decreased; Cardiotoxicity; Coma; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Haemodynamic Instability; Hypocalcaemia; Hypokalaemia; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Tachycardia	Fluoxetine			S	Unknown	Unk		Aurobindo	
	Gabapentin			S	Unknown	Unk		Aurobindo	
	Olanzapine			S	Unknown	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Amitriptyline			S				Not Reported	
	Ciprallex			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16420014	NON-EXPEDITED		HO	CA-SCIEGEN PHARMACEUTICALS INC-2019SCILIT00194		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Bupropion Hydrochloride			S				Sciegen	
	Escitalopram			S				Unknown	
	Quetiapine			S				Sciegen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16420232	NON-EXPEDITED			US-PFIZER INC-2019242187			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Simvastatin			S		Unk		Not Reported	
	Sulfacetamide Sodium			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16421905	EXPEDITED (15-DAY)		CA	DE-TEVA-2019-DE-1060176		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	10 [Mg/D]		Ivax	
	Femi Baby			C	Transplacental	0.6 [Mg/D (Bis 0.8 Mg/D)]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16421907	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1054405		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Headache; Sluggishness	Escitalopram			S	Oral	30 Milliliter, Total		Not Reported	
	Alprazolam			S	Oral	20 Milliliter, Total		Not Reported	
	Omeprazole			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16422474	EXPEDITED (15-DAY)		CA, HO	FR-SA-2019SA151986			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Exposure During Pregnancy	Imovane			S	Oral	7.5 Mg, Qd		Not Reported	
	Escitalopram Oxalate			S	Oral	10 Mg Qd		Not Reported	
	Doxylamine Succinate			S	Oral	Unk		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16423601	EXPEDITED (15-DAY)		HO	JP-PRINSTON PHARMACEUTICAL INC.-2019PRN00586		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Escitalopram			S	Unknown	20 Mg, 1x/Day		Prinston	

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Rhabdomyolysis; Serotonin Syndrome	Clomipramine	S	Unknown	50 Mg, 1x/Day	Pharmaceutical
	Alcohol	S	Oral	350 MI	Not Reported
	Flunitrazepam	C	Unknown	2 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16424054	EXPEDITED (15-DAY)		HO	FR-ACCORD-132548		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pemphigoid	Furosemide			S	Oral			Accord
	Seroplex			S	Oral			Not Reported
	Esomeprazole/Esomeprazole			C				Not Reported
	Magnesium/Esomeprazole							
	Sodium							
	Toujeo			C				Not Reported
	Dafalgan			C				Not Reported
	Dermoval			C				Not Reported
	Picloxydine			C				Not Reported
	Innohep			C				Not Reported
	Desloratadine			C				Not Reported
	Novorapid			C				Not Reported
	Diffu K			C				Not Reported
	Theralene			C				Not Reported
	Ventolin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16426530	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2019-CA-1061421		17 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiogenic Shock; Overdose; Seizure; Sympathomimetic Effect	Bupropion XI			S	Oral			Actavis
	Escitalopram			S	Oral			Ivax
	Quetiapine			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16427604	EXPEDITED (15-DAY)		HO	MY-JNJFOC-20190612214		12 YR	Female	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Vitreous Anomaly; Schizophrenia; Sedation	Risperdone			S	Unknown			Not Reported	
	Methylphenidate			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Bromazepam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	15484174	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1848211US			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypotension; Loss Of Consciousness	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qhs		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Zolpidem Tartrate			C	Oral	Unk, Prn		Not Reported	
	Bayaspirin			C	Oral	100 Mg, Qd		Not Reported	
	Carvedilol			C	Oral	1.25 Mg, Qd		Not Reported	
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported	
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported	
	K-Supply			C	Oral	1200 Mg, Q12h		Not Reported	
	Pentasa			C	Oral	500 Mg, Q8hr		Not Reported	
	Wypax			C	Oral	0.5 Mg, Q12h		Not Reported	
	Urief			C	Oral	4 Mg, Q12h		Not Reported	
	Fluconazole			C	Oral	100 Mg, Qd		Not Reported	
	Levofloxacin Hydrate			C	Oral	500 Mg, Qd		Not Reported	
	Magnesium Oxide			C	Oral	660 Mg, Q8hr		Not Reported	
	Sennoside			C	Oral	24 Mg, Prn		Not Reported	
	Filgrastim Bs			C	Subcutaneous	75 Mg, Qd		Not Reported	

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Cyloside

C

30 Mg, Qd

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16429272	EXPEDITED (15-DAY)		OT	FR-ZYDUS-037548		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mitral Valve Incompetence	Baclofene			S	Oral	()		Not Reported
	Amitriptyline			S	Oral			Not Reported
	Escitalopram			S	Oral	()		Not Reported
	Oxazepam			S	Oral			Not Reported
	Lormetazepam			S	Oral	()		Not Reported
	Gabapentin			S	Oral			Zydus Pharm
	Duloxetine			S	Oral			Not Reported
	Methotrexate/Methotrexate Sodium			S	Subcutaneous			Not Reported
	Venlafaxine			S	Oral	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16429274	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037567		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Agomelatine			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila
	Promethazine			S	Oral			Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Risperidone			S	Oral			Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tenoxicam			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Esomeprazole			C				Not Reported

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Ramipril			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16429320	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-033212			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Dosage Form, Daily		Aurobindo	
	Baclofen			S	Oral	Unk		Not Reported	
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported	
	Noctamide			S	Oral	Unk		Not Reported	
	Cymbalta			S	Oral	1 Dosage Form, Daily		Not Reported	
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported	
	Effexor			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16429769	EXPEDITED (15-DAY)		HO	IT-ACCORD-132784		43 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral			Not Reported	
	Vortioxetine			C				Not Reported	
	Sertraline			C				Not Reported	
	Asenapine/Asenapine Maleate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16429832	EXPEDITED (15-DAY)		OT	ES-APOTEX-2019AP016552		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Electrocardiogram Qt	Escitalopram			S	Unknown	Unk		Apotex	

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Prolonged; Hypocalcaemia; Hypomagnesaemia; Ventricular Extrasystoles	Omeprazole Enalapril + Hidroclorotiazida Trazodone Metformin	S S S C	Unknown Unknown Unknown Unknown	Unk Unk Unk Unk	Apotex Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16430036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019248496		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Df, 1x/Day		Pfizer	
	Effexor			S	Oral	Unk		Pfizer	
	Methotrexate			S	Subcutaneous	1 Df, Weekly		Not Reported	
	Baclofene			S	Oral	Unk		Not Reported	
	Laroxyl			S	Oral	1 Df, 1x/Day		Not Reported	
	Seroplex			S	Oral	Unk		Not Reported	
	Seresta			S	Oral	1 Df, 1x/Day		Not Reported	
	Noctamide			S	Oral	Unk		Not Reported	
	Cymbalta			S	Oral	1 Df, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16430579	EXPEDITED (15-DAY)		LT	FR-ACCORD-132676		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Escitalopram			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Bromazepam			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16430585	EXPEDITED (15-DAY)		DS, OT	AT-ACCORD-132855		25 YR	Male	AUT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty; Erectile Dysfunction; Fatigue; Feeling Abnormal; Hyperhidrosis; Hypoaesthesia; Illusion; Loss Of Libido; Malaise; Memory Impairment; Orgasm Abnormal; Orgasmic Sensation Decreased; Personality Change; Poisoning; Tremor; Tunnel Vision	Escitalopram			S		Also Taken 10 Mg From 17-Dec-2018 To 20-Dec- 2018(Dose Increased)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16432026	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1061866		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Agomelatine			S	Oral			Not Reported
	Escitalopram			S	Oral			Ivax
	Risperidone			S	Oral			Actavis
	Phenergan (Promethazine)			S	Oral			Not Reported
	Clotiazepam			S	Oral	Non		Not Reported
	Lormetazepam			S	Oral			Not Reported
	Tilcotil			C				Not Reported
	Atorvastatine			C				Not Reported
	Kardegic			C				Not Reported
	Esomeprazole			C				Not Reported
	Ramipril			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16432770	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1062427		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mitral Valve Incompetence	Gabapentine			S	Oral	1 Dosage Forms		Actavis
	Methotrexate			S	Subcutaneous	1 Dosage Forms		Barr
	Baclofene			S	Oral			Not Reported
	Laroxyl			S	Oral	1 Dosage Forms		Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral	1 Dosage Forms		Not Reported
	Noctamide			S	Oral			Not Reported
	Cymbalta			S	Oral	1 Dosage Forms		Not Reported
	Effexor			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16434334	EXPEDITED (15-DAY)		OT	HR-SA-2019SA156402		16 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral	1 Unk		Not Reported
	Alprazolam			S	Oral	1 Unk		Not Reported
	Escitalopram Oxalate			S	Oral	1 Unk		Not Reported
	Zolpidem Tartrate			S	Oral	1 Unk		Sanofi
	Quetiapine Fumarate			S	Oral	1 Unk		Not Reported
	Buprenorphine Hydrochloride			S	Oral	1 Unk		Not Reported
	Diazepam			S	Oral	1 Unk		Not Reported
	Alprazolam			S	Oral	1 Unk		Not Reported
	Cocaine			S		Unk		Not Reported
	Marijuana			S		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16435147	EXPEDITED (15-DAY)		DE, HO, LT, OT	CH-ASTRAZENECA-2019SE87035		81 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Bradycardia; Dizziness; Dyspnoea; Fall; Ligament Rupture; Multiple Organ Dysfunction Syndrome; Pneumonia	Seroquel			S	Oral			Astrazeneca	
	Diovan			S	Oral			Not Reported	
	Diovan			S	Oral			Not Reported	
	Diovan			S	Oral			Not Reported	
	Jardiance			S	Oral			Not Reported	
	Torem			S	Oral			Not Reported	
	Torem			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Detrusitol			S	Oral			Not Reported	
	Aldactone (Spironolactone)			S	Oral			Not Reported	
	Aldactone (Spironolactone)			S	Oral			Not Reported	
	Januvia			C				Not Reported	
	Xarelto			C				Not Reported	
	Plavix			C				Not Reported	
	Symbicort			C				Not Reported	
	Magnesiocard			C				Not Reported	
	Ramipril			C				Not Reported	
	Nasonex			C				Not Reported	
	Bepanthen			C				Not Reported	
	Spiriva			C				Not Reported	
	Pradif			C				Not Reported	
	Pantozol			C				Not Reported	
	Crestor			C				Not Reported	
	Movicol			C				Not Reported	
	Colecalciferol			C				Not Reported	
	Allopurinol			C				Not Reported	
	Cardioaspirin			C				Not Reported	
	Acidum Folicum			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Ferro Sanol			C				Not Reported	
	Concor			C				Not Reported	

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Magnesium Clcz696d		C S		Not Reported Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16435263	EXPEDITED (15-DAY)		CA, HO	NO-ALLERGAN-1924724US			Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	The Mother Was Treated With Cipralex 20 Mg Daily Throughout The Whole Pregnancy.		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16435277	EXPEDITED (15-DAY)		HO	JP-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00237		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Unknown	20 Mg, 1x/Day		Jubilant	
	Clomipramine			S	Unknown	50 Mg, 1x/Day		Not Reported	
	Alcohol			S	Oral	350 MI		Not Reported	
	Flunitrazepam			C	Unknown	2 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16439644	DIRECT					27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition Aggravated; Obsessive-Compulsive Disorder; Panic Attack	Ach-Escitopram			S	Oral	Quantity:1 Tablet(S);		Accord	
	Cetirizine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2019	16437096	EXPEDITED (15-DAY)		HO	PHHY2019FR133743		70 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral	100 Mg, Qd		Novartis
	Lyrica			S	Unknown	1 Df, Qd		Not Reported
	Lyrica			S	Unknown	1 Df, Qd		Not Reported
	Imovane			S	Oral	1 Df, Qd		Not Reported
	Smofkabiven			S	Intravenous drip	986 Ml, Qd		Not Reported
	Seroplex			S	Oral	1 Df, Qd		Not Reported
	Methotrexate			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Vincristine Sulphate			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Doxorubicine			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported
	Prednisone			C	Oral	Unk (Variable)		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Unk (Variable)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2019	16232180	EXPEDITED (15-DAY)		OT	PHHY2019DE091199			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use Issue; Product Use Issue; Restlessness; Stress; Underdose	Ibuprofen			S	Unknown	Unk		Novartis
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Cipralelex			S	Unknown	10 Mg, Unk		Not Reported
	Cipralelex			S	Unknown	7.5 Mg, Bid		Not Reported
	Cipralelex			S	Unknown	5 Mg, Qd		Not Reported
	Cipralelex			S	Unknown	5 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	15603335	EXPEDITED (15-DAY)		DE, HO, LT	CA-ALLERGAN-1852375US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Diclofenac Potassium			S	Oral	2 Df, Qd		Not Reported	
	Ibuprofen			S	Oral	400 Mg, Unk		Not Reported	
	Eliquis			C	Unknown	5 Mg, Q12h		Not Reported	
	Pantoprazole			C	Unknown	40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	15644068	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1854178US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16438401	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033347			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo	
	Cosentyx			S	Subcutaneous	150 Milligram, Every Week		Not Reported	
	Cosentyx			S	Subcutaneous	150 Milligram, Every Month		Not Reported	
	Cosentyx			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Povidone-Iodine			S	Unknown	Unk		Not Reported	
	Vitamin D3			S	Unknown	Unk		Not Reported	

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	Voltaren		S	Unknown	Unk, Every Week			Not Reported	
	Voltaren		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16438745	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01425			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity; Fatigue; Irritability; Oedema; Palpitations; Tinnitus	Amlodipine Besylate Tablets			S	Unknown	Unk		Lupin	
	Duloxetine Delayed-Release Capsules			S	Unknown	Unk		Lupin	
	Escitalopram Tablets			S	Unknown	Unk		Lupin	
	Gabapentin Tablet			S	Unknown	Unk		Lupin	
	Lorazepam Oral Concentrate			S	Unknown	Unk		Lupin	
	Losartan Potassium Tablet			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16442893	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1924839US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 18 Dosage Forms In Total (In One Day)		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16442895	EXPEDITED (15-DAY)		LT	FR-ALLERGAN- 1924740US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary Oedema; Anaphylactoid Shock; Diarrhoea; Hypotension; Rash Macular; Respiratory	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Selincro			S	Oral	18 Mg, Qd		Not Reported	
	Methadone Ap-Hp			S	Oral	80 Mg, Qd		Not Reported	
	Kardegic			C	Unknown			Not Reported	

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Distress	Lexomil Roche	C	Unknown	Not Reported
	Theralene	C	Unknown	Not Reported
	Loxen	C	Unknown	Not Reported
	Corgard	C	Unknown	Not Reported
	Abilify	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	15603885	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1852505US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Baclofen			C	Unknown			Not Reported	
	Cialis			C	Unknown			Not Reported	
	Pregabalin			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16387677	EXPEDITED (15-DAY)		HO	FI-ACCORD-130509		71 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Lip Oedema; Oral Discomfort; Skin Burning Sensation	Escitalopram			S	Oral	10,Mg,Daily		Not Reported	
	Vagifem			C	Vaginal	10,Mcg,Daily		Not Reported	
	Betaserc			C	Oral	8,Mg,Daily		Not Reported	
	Brilique			C	Oral	180,Mg,Daily		Not Reported	
	Kalcipos-D			C	Oral			Not Reported	
	Cardace			C	Oral			Not Reported	
	Primaspan			C	Oral	100,Mg,Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16443785	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1063298		42 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral	1 Dosage Forms Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16444138	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033477			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Product Substitution Issue	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo	
	Olanzapine			S	Oral	Unk Unk, Once A Day		Aurobindo	
	Lorazepam			S	Oral	Unk Unk, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16444142	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033492			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Product Use In Unapproved Indication; Salivary Hypersecretion; Vomiting	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Escitalopram			S	Oral	20 Milligram, Unk		Aurobindo	
	Escitalopram			S				Aurobindo	
	Abilify			S	Oral	5 Milligram, Unk		Not Reported	
	Abilify			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16444146	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209681		26 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Procalcitonin Increased	Carbamazepine			S	Unknown	Unk		Taro	
	Quetiapine			S	Unknown	Unk		Sun	
	Escitalopram			S	Unknown	Unk		Not Reported	

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Risperidone			S		Unknown		Unk		Ranbaxy	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16444236	EXPEDITED (15-DAY)		OT	DK-ALKEM LABORATORIES LIMITED-DK-ALKEM- 2019-03055		27 YR	Female	DNK	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Condition Aggravated; Drug Ineffective; Exposure During Pregnancy	Aripiprazole			S	Unknown	30 Milligram, Qd		Alkem		
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported		
	Risperidone			S	Unknown	4 Milligram		Not Reported		
	Risperidone			S	Unknown	0.5 Mg		Not Reported		
	Citalopram			S	Unknown	20 Milligram		Not Reported		
	Citalopram			S	Unknown	40 Milligram, Qd		Not Reported		
	Diazepam			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16446860	EXPEDITED (15-DAY)		OT	HR-PFIZER INC- 2019252720		15 YR	Female	HRV	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Xanax			S	Oral	2 Df, Unk		Pfizer		
	Aripiprazol			S	Oral	30 Mg, Unk		Not Reported		
	Escitalopram			S	Oral	70 Mg, Unk		Not Reported		
	Diazepam			S	Oral	20 Mg, Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16447132	EXPEDITED (15-DAY)		HO	NL-ALLERGAN- 1925183US			Female	NLD	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anxiety; Burning Sensation; Condition Aggravated; Depression;	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan		
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan		

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Skin Irritation	Diazepam	C	Unknown	5 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448865	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1064016		18 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Insomnia; Intentional Self-Injury; Psychotic Disorder; Sleep Disorder; Visual Impairment; Withdrawal Syndrome	Escitalopram Abz 10 Mg Filmtabletten			S	Oral	10 Milligram Daily;		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449020	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1063940		16 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral			Not Reported
	Serpentil [Escitalopram Oxalate]			S	Oral			Ivax
	Kventiax			S	Oral			Not Reported
	Marijuana			S				Not Reported
	Cocaine			S				Not Reported
	Misar (Alprazolam)			S	Oral			Not Reported
	Sanval			S	Oral			Not Reported
	Subutex			S	Oral			Not Reported
	Normabel			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449079	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-04849		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Tardive Dyskinesia; Therapy Partial Responder	Aripiprazole	S	Unknown	5 Milligram, Qd	Alkem
	Escitalopram	S	Unknown	10 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449829	EXPEDITED (15-DAY)		OT	JP-MACLEODS PHARMACEUTICALS US LTD- MAC2019021727			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alcohol Interaction; Drug Interaction; Serotonin Syndrome	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods
	Clomipramine			S	Unknown	50 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16451365	NON-EXPEDITED			US-PFIZER INC- 2019256732		75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Fesoterodine			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Pantoprazole			S		Unk		Pfizer
	Pregabalin			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer
	Testosterone Cipionate			S		Unk		Unknown
	Tetracycline Hcl			S		Unk		Pfizer
	Amitriptyline			S				Not Reported
	Bethanechol Chloride			S				Not Reported
	Escitalopram			S				Not Reported
	Hydrocodeine			S				Not Reported
	Hyoscyamine Sulfate			S				Not Reported
	Propantheline			S				Not Reported
	Simvastatin			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16451910	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1056283		64 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported	
	Tramadol			S	Unknown	225 Milligram, Qd		Not Reported	
	Amitriptyline			S	Unknown	25 Milligram, Qd		Mylan	
	Acetaminophen			C	Unknown	3000 Milligram, Qd		Mylan	
	Levofloxacin			C	Unknown	500 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16452417	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019255230		16 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Blood Potassium Increased; Bradycardia; Drug Abuse	Pregabalin			S	Oral	1 (Unit Of Measure Not Reported), Unk		Pfizer	
	Xanax			S	Oral	1 (Unit Of Measure Not Reported), Unk		Pfizer	
	Marijuana			S		Unk		Not Reported	
	Cocaine			S		Unk		Not Reported	
	Misar [Alprazolam]			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported	
	Serpentil [Escitalopram Oxalate]			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported	
	Sanval			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported	
	Kventiax			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported	
	Subutex			S	Oral	1 (Unit Of Measure Not Reported), Unk		Not Reported	
	Normabel			S	Oral	1 (Unit Of Measure Not		Not Reported	

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Reported), Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16454262	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1057377		36 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Persistent Genital Arousal Disorder	Escitalopram			S		En Tablett Dagligen		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16455144	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1925575US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose; Product Use Issue; Suicide Attempt; Vomiting	Escitalopram Oxalate - Bp			S	Oral	Overdose: 44 Tablets At A Time		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	15585502	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1840999US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To	Celexa			S	Oral	Unk Unk, Unknown		Allergan	
	Ciprallex			S	Oral	Unk, Unknown		Not Reported	
	Oxazepam			S	Oral	Unk Unk, Unknown		Not Reported	
	Quetiapine			S	Oral	Unk, Unknown		Not Reported	
	Temazepam			S	Oral	Unk, Unknown		Not Reported	
	Topiramate			S	Oral	Unk, Unknown		Not Reported	
	Naloxone			S	Intramuscular	0.8 Mg, Unknown		Not Reported	
	Clopidogrel			C	Unknown	Unk		Not Reported	
	Ferrous Gluconate			C	Unknown	Unk		Not Reported	
	Fluticasone W/Salmeterol			C	Unknown	Unk		Not Reported	

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Various Agents	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Salbutamol	C	Respiratory (inhalation)	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Advair	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	15969520	EXPEDITED (15-DAY)		HO, OT	CA-PFM-2019-01931			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Propranolol Hydrochloride			S	Oral	40 Mg Twice A Day		Pierre Fabre Medicament
	Azathioprine			S	Unknown	Unknown		Not Reported
	Escitalopram			S	Unknown	10 Mg Daily		Not Reported
	Marijuana			S	Unknown	1 Dosage Form Daily		Not Reported
	Pentasa			S	Unknown	Unknown		Not Reported
	Premarin			S	Unknown	0.625 Mg Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16256103	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-022613			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Burnout Syndrome; Depression; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use	Escitalopram Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Ibuprofen			S	Unknown	Unk		Aurobindo
	Ciprallex			S	Unknown	5 Milligram, Once A Day		Not Reported

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Issue; Restlessness; Stress; Underdose	Cipralex	S	Unknown	10 Milligram	Not Reported
	Cipralex	S	Unknown	7.5 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16288240	EXPEDITED (15-DAY)		LT, OT	PHHY2019DE105598		75 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Syncope; Torsade De Pointes	Esidrix			S	Unknown	12.5 Mg, Qd		Novartis
	Esidrix			S	Unknown	25 Mg, Qd		Novartis
	Captohexal			S	Unknown	50 Mg, Qd		Not Reported
	Captohexal			S	Unknown	25 Mg, Qd		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Reminyl			S	Unknown	8 Mg, Qd		Not Reported
	Reminyl			S	Unknown	5 Mg, Qd		Not Reported
	Reminyl			S	Unknown	2.5 Mg, Unk		Not Reported
	Cipralex			S	Unknown	5 Mg, Qd		Not Reported
	Cipralex			S	Unknown	10 Mg, Qd		Not Reported
	Cipralex			S	Unknown	15 Mg, Qd		Not Reported
	Cipralex			S	Unknown	20 Mg, Qd		Not Reported
	Dipiperon			S	Unknown	80 Mg, Qd		Not Reported
	Amlodipin			C	Unknown	5 Mg, Qd		Not Reported
	Amlodipin			C	Unknown	2.5 Mg, Qd		Not Reported
	Marcumar			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	2 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16374911	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-209103		47 YR	Female	TUR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Paraesthesia Oral	Paxil			S	Unknown	10 Milligram, Daily		Not Reported	
	Paxil			S	Unknown	By The Third Week The Dose Was Increased: 30 Milligram, Daily		Not Reported	
	Paxil			S	Unknown	Decreased To: 20 Mg/Day		Not Reported	
	Xanax			S	Unknown	0.5 Milligram, Bid		Not Reported	
	Xanax			S	Unknown	1.5 Milligram, Daily		Not Reported	
	Cipralext			S	Unknown	20 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16454162	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1063301		15 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; No Adverse Event; Suicide Attempt	Aripiprazol			S	Oral			Teva	
	Xanax			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16454876	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-210887		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mitral Valve Incompetence	Gabapentin			S	Oral	1 Dosage Form, Daily		Ranbaxy	
	Baclofene			S	Oral	()		Not Reported	
	Laroxyl			S	Oral	1 Dosage Form, Daily		Not Reported	
	Seroplex			S	Oral	()		Not Reported	
	Seresta			S	Oral	1 Dosage Form, Daily		Not Reported	
	Noctamide			S	Oral	()		Not Reported	

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	Cymbalta	S	Oral	1 Dosage Form, Daily	Not Reported				
	Methotrexate	S	Subcutaneous	1 Dosage Form, Weekly	Not Reported				
	Effexor	S	Oral	()	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16455933	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-211046		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported	
	Amlodipine			S	Oral	Unk		Sun	
	Lamotrigine			S	Oral	4 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16456847	EXPEDITED (15-DAY)		OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2019021746			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram 10mg Tablet			S	Oral	10 Milligram, Qd, Tablet		Macleods	
	Xanax 0.5 Mg Prolonged Release Tablet			S	Oral	0.5 Milligram, Qd, Orodispersible Tablet, Prolonged Release Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16457269	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1065500		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral			Actavis	
	Seroplex 10 Mg, Comprimé Pelliculé Sécable			S	Oral			Not Reported	

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	Smofkabiven E, Émulsion Pour Perfusion	S	Intravenous drip	Not Reported
	Lyrica 50 Mg, Gélule	S	Oral	Not Reported
	Imovane 3,75 Mg, Comprimé Pelliculé	S	Oral	Not Reported
	Methotrexate	C	Intravenous (not otherwise specified) Variable	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified) Variable	Not Reported
	Vincristine (Sulfate De)	C	Intravenous (not otherwise specified) Variable	Not Reported
	Doxorubicine	C	Intravenous (not otherwise specified) Variable	Not Reported
	Prednisone	C	Oral Variable	Not Reported
	Rituximab ((Mammifere/Hamster/Cellules Cho))	C	Intravenous (not otherwise specified) Variable	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16458250	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1056941		30 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Substance Abuse	Escitalopram			S	Oral	20 Milligram, Total		Not Reported	
	Quetiapine			S	Oral	25 Milligram, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16459208	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1057368		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Depression; Drug Ineffective	Escitalopram			S	Unknown	Unk		Not Reported	
	Diazepam			S	Unknown	Unk		Mylan	
	Dapsone			C	Unknown	100 Milligram, Qd		Mylan	
	Infliximab			C	Unknown	10 Milligram/Kilogram		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16460098	NON-EXPEDITED			US-TEVA-2019-US-1055127			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Rash; Urticaria	Escitalopram			S	Unknown			Ivax	
	Bupropion			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16464517	DIRECT		LT, OT			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depressive Symptom; Product Substitution Issue	Escitalopram	Y		S	Oral	Quantity:1 Tablet(S);	25 DAY	Aurobindo	
	Clonazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16671931	DIRECT	Y	OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Paraesthesia; Tinnitus	Bupropion 150mg			S	Oral			Not Reported	
	Lexapro			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16462459	EXPEDITED (15-DAY)		OT	PL-ACCORD-134099		77 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dry Mouth; Headache;	Escitalopram			S	Oral			Not Reported	
Nausea; Sedation; Vomiting	Atenolol/Atenolol Hydrochloride			S	Oral			Not Reported	
	Oxynorm			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxyzine			S	Oral			Not Reported	

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Ketonal	S	Intravenous (not otherwise specified)	Not Reported
Pyralgin [Metamizole Sodium]	S	Intravenous (not otherwise specified)	Not Reported
Fenactil	S	Intravenous (not otherwise specified)	Not Reported
Oxycontin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16464620	NON-EXPEDITED			US-TEVA-2019-US-1059427			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Headache; Migraine; Vision Blurred	Buspirone			S	Unknown			Teva	
	Rexulti			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16465005	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1925511US			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Dizziness	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 25 Mg		Allergan	
	Propavan			S	Unknown	5 St -25 Mg - 125 Mg		Not Reported	
	Lergigan (Promethazine Hydrochloride)			S	Oral	7 St 25 Mg - 125 Mg		Not Reported	
	Atarax			S	Unknown	25 Mg 7 St- 175 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16465785	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1058002		32 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Stillbirth	Quetiapine			S	Oral	25 [Mg/D] (0. - 35.3. Gestational Week)		Not Reported	

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Escitalopram	S	Oral	20 [Mg/D] (0. - 35.3. Gestational Week)	Not Reported
Presinol	S	Oral	500 [Mg/D (2x250)] (33.4. - 35.3. Gestational Week)	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2019	16466391	EXPEDITED (15-DAY)		OT	HR-ACCORD-134212			Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Foaming At Mouth; Intentional Overdose; Suicide Attempt; Tremor	Quetiapine			S	Oral	Unspecified, Consciousness Disturbed, Foaming At Mouth		Not Reported
	Elicea			S	Oral	Consciousness Disturbed, Foaming At Mou		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2019	16466447	EXPEDITED (15-DAY)		HO	FR-ACCORD-133991		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Accord
	Fenofibrate			S	Oral			Not Reported
	Galantamine/Galantamine Hydrobromide			S	Oral			Not Reported
	Beclometasone			S	Nasal	100 Micrograms / Dose, Nasal Spray Suspension		Not Reported
	Colecalciferol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2019	16466449	EXPEDITED (15-DAY)		DE	FR-ACCORD-134045		79 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma	Escitalopram			S	Oral			Not Reported

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Xarelto			S		Oral		Unspecified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2019	16466506	EXPEDITED (15-DAY)		DE		CA-ALLERGAN-1851643US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Oxalate - Bp				S		0.5 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp				S		1 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp				S				Allergan	
	Clonazepam				S		0.5 Mg, Q8hr		Not Reported	
	Clonazepam				S				Not Reported	
	Clonazepam				S				Not Reported	
	Zopiclone				S	Oral	7.5 Mg, Q12h		Not Reported	
	Zopiclone				S	Oral	Unk, Unknown		Not Reported	
	Zopiclone				S		Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	9564978	EXPEDITED (15-DAY)		OT		PHHY2013CA107716		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cough; Depressed Level Of Consciousness; Depression; Diplopia; Dizziness; Drug Withdrawal Syndrome; Eye Pain; Headache; Malaise; Multiple Sclerosis Relapse; Nasopharyngitis; Neuralgia; Ocular Discomfort; Optic Nerve Disorder; Optic Neuritis; Oropharyngeal Pain; Palpitations; Paraesthesia; Pupillary Disorder; Sleep Disorder; Vision Blurred;	Gilenya				S	Oral	0.5 Mg, Qd		Novartis	
	Gilenya				S	Oral	Unk		Novartis	
	Gilenya				S	Oral	Unk		Novartis	
	Ciprallex /Den/				S	Unknown	Unk		Not Reported	
	Ciprallex /Den/				S	Unknown	Unk		Not Reported	
	Cymbalta				C	Unknown			Not Reported	
	Topamax				C	Unknown	50 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Visual Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	15779138	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-ICU MEDICAL, INC.- ICU2018CA00241		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia;	Dextrose Injection			S	Unknown			Icu Medical	
	Amlodipine Besilate			S	Oral	150 Milligram, Every 1 Day(S)		Not Reported	
	Amlodipine Besilate			S	Unknown	Unk		Not Reported	
	Epinephrine			S	Unknown	30.0 Microgram		Not Reported	
	Escitalopram			S	Unknown	60 Milligram, Every 1 Day(S)		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Norepinephrine Bitartrate			S	Unknown	30 Microgram		Not Reported	
	Risperidone			S	Oral	6.0 Milligram, Every 1 Day(S)		Not Reported	
	Vasopressin			S	Unknown			Not Reported	
	Escitalopram Mylan			S	Oral			Not Reported	
	Potassium Chloride			S	Oral			Not Reported	
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Activated Charcoal			C		50 Gram		Not Reported	
	Insulin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Insulin			C		70 International Unit		Not Reported	
	Amlodipine			C				Not Reported	
	Calcium Gluconate			C				Not Reported	
	Dextrose			C				Not Reported	
	Glucagon			C		Unk		Not Reported	
	Glucagon			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Reversible Cerebral
Vasoconstriction
Syndrome; Shock;
Tachycardia; Toxicity To
Various Agents; Visual
Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16322504	EXPEDITED (15-DAY)		HO, OT	US-VERTEX PHARMACEUTICALS- 2019-004390		18 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicide Attempt	Symdeko			S	Oral	100mg Tezacaftor/150mg Ivacaftor Am; 150mg Ivacaftor Pm		Vertex
	Lexapro			S	Unknown	Unk		Not Reported
	Buspar			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16444859	EXPEDITED (15-DAY)		CA	DE-MYLANLABS- 2019M1055610		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Congenital Laryngeal Stridor; Congenital Tracheomalacia; Foetal Exposure During Pregnancy; Pectus Excavatum	Escitalopram			S	Transplacental	10 Milligram, Qd		Not Reported
	L-Thyroxin /00068001/			C	Transplacental	75 Microgram, Qd,75 [Mg/D]		Mylan
	Xanaflu			C	Transplacental	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16467541	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2019-034963			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram Film-Coated Tablets Xanax	S	Oral	10 Milligram, Daily	Aurobindo
		S	Oral	0.5 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16467714	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2019AP016753		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram			S	Oral	20 Mg, Unk		Apotex
Abdominal Distension;	Escitalopram			S	Oral	10 Mg, Unk		Apotex
Abdominal Pain;	Escitalopram			S	Oral	10 Mg, Unk		Apotex
Arthralgia; Basedow'S	Escitalopram			S	Oral	5 Mg, Unk		Apotex
Disease; Blood Thyroid	Escitalopram			S	Oral	12 Mg, Qd		Not Reported
Stimulating Hormone	Alemtuzumab			S	Intravenous drip	650 Mg, Unk		Not Reported
Decreased; Blood Urine	Acetaminophen			C	Oral	200 Mg, Unk		Not Reported
Present; Burning	Aciclovir			C	Oral	25 Mg, Unk		Not Reported
Sensation; Chest	Benadryl /00000402/			C	Intravenous (not otherwise specified)	Unk		Not Reported
Discomfort; Decreased	Benadryl /00000402/			C	Oral	50 Mg, Unk		Not Reported
Appetite; Depression;	Dimenhydrinate			C	Oral	50 Mg, Unk		Not Reported
Diarrhoea; Disturbance In	Diphenhydramine			C	Oral	Unk		Not Reported
Attention; Dizziness; Drug	Gabapentin			C	Oral	100 Mg, Qd		Not Reported
Hypersensitivity;	Losartan Potassium			C	Oral	100 Mg, Qd		Not Reported
Dysgeusia; Dysphagia;	Losartan Potassium			C	Oral	100 Mg, Unk		Not Reported
Dyspnoea; Dysuria;	Losartan Potassium			C	Oral	4 Df, Qd		Not Reported
Fatigue; Headache;	Methimazole			C	Oral	2 Df, Qd		Not Reported
Hyperhidrosis; Influenza;	Methimazole			C	Oral	5 Mg, Q.O.D.		Not Reported
Insomnia; Migraine; Mood	Methylprednisolone			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
Altered; Muscle Spasms;	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
Nasopharyngitis; Nausea;	Propranolol			C	Oral	Unk		Not Reported
Pain In Extremity; Pruritus;								
Rash; Rash								
Erythematous; Rash								
Macular; Somnolence;								
Stress; Swelling Face;								
Temperature Intolerance;								
Throat Irritation; Thyroid								
Hormones Increased;								
Thyroiditis; Urinary Tract								
Infection; Urticaria;								
Vomiting; Weight								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Wheezing;	Sertraline	C	Oral	100 Mg, Q.12h	Not Reported
White Blood Cell Count	Sertraline	C	Oral	50 Mg, Unk	Not Reported
Decreased	Zantac	C	Oral	150 Mg, Qd	Not Reported
	Zantac	C	Oral	150 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16467769	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016703		35 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16467867	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016711		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Escitalopram			S	Oral	10 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468132	EXPEDITED (15-DAY)		HO, OT	PHHY2019CO130630		39 YR	Female	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Gait Disturbance; Nephrolithiasis; Urinary Retention; Urinary Tract Infection	Gilenya			S	Oral	0.5 Mg, Qd		Novartis	
	Escitalopram			S	Unknown	10 Mg, One After The Breakfast		Not Reported	
	Oxybutynin			C	Unknown	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468239	NON-EXPEDITED			US-APOTEX-2017AP006153			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggression; Depressed Mood; Diarrhoea; Drug Ineffective; Insomnia; Partner Stress; Psychomotor Hyperactivity	Paxil Capsules	S	Unknown	50 Mg, Qd	Apotex
	Wellbutrin Tablet	S	Unknown	10 Mg, Qd	Not Reported
	Lexapro	S	Unknown	10 Mg, Qd	Not Reported
	Zoloft	S	Unknown	20 Mg, Unk	Not Reported
	Omeprazole	C	Unknown	40 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468305	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016730		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Decreased; Breath Sounds Abnormal; Cystic Fibrosis; Dizziness; Dyspnoea; Generalised Erythema; Lung Infection; Moaning; Nasal Congestion; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pulmonary Contusion; Pyrexia; Rash Erythematous; Sinus Congestion; Sinus Headache; Sinusitis; Skin Sensitisation; Skin Warm; Smoke Sensitivity; Upper Respiratory Tract Congestion	Escitalopram			S	Oral	1 Df, Qd		Apotex
	Escitalopram			S				Apotex
	Omalizumab			S	Subcutaneous	300 Mg, Q.O.Wk.		Not Reported
	Omalizumab			S	Subcutaneous	Unk		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg, Unk		Not Reported
	Pulmicort			C	Unknown	1 Df, Qd		Not Reported
	Zenhale			C	Respiratory (inhalation)	1 Df, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468341	EXPEDITED (15-DAY)		HO	FR-ZYDUS-037840		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Smofkabiven E	S	Intravenous drip	Not Reported
Pregabalin	S	Oral	Not Reported
Zopiclone	S	Oral	Not Reported
Allopurinol	S	Oral	Zydus Pharm
Methotrexate	C	Intravenous (not otherwise specified)	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)	Not Reported
Vincristine Sulfate	C	Intravenous (not otherwise specified)	Not Reported
Doxorubicin	C	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Oral	Not Reported
Rituximab ((Mammifere/Hamster/Cellules Cho))	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468421	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP016734		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Allopurinol			C	Unknown			Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Diltiazem			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Tylenol W/Codeine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468524	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016737		56 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	10.0 Mg, Qd		Apotex	
	Baclofen			C	Unknown	Unk		Not Reported	
	Cialis			C	Unknown	Unk		Not Reported	
	Pregabalin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468661	NON-EXPEDITED			US-TEVA-2019-US-1060405			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Fatigue; Heart Rate Increased; Hunger; Muscle Twitching; Pruritus; Somnolence	Escitalopram Tablets Teva			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468729	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016958			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Anxiety Disorder; Breast Cancer; Breast Disorder; Decreased Appetite; Diarrhoea; Ear Discomfort; Frequent Bowel Movements; Hot Flush; Nasopharyngitis; Nausea; Nervousness; Pain; Weight Decreased	Escitalopram			S	Unknown	Unk, Qd		Apotex	
	Tamoxifen			S	Unknown	Unk		Apotex	
	Atezolizumab			S	Intravenous (not otherwise specified)	1200 Mg, Q.3w		Not Reported	
	Ativan			C	Unknown	0.5 Mg, As Required		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468828	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016959			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Angioedema; Chronic Spontaneous Urticaria; Urticaria	Escitalopram	S	Unknown	10 Mg, Unk	Apotex
	Tegretol	S	Oral	1 Df, Qd	Not Reported
	Benadryl /00000402/	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Reactine /00884302/	C	Unknown	1 Df, Bid	Not Reported
	Claritin /00917501/	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469200	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1067262		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram			S	Oral			Ivax	
	Xanax 0,5 Mg Compresse A			S	Oral			Not Reported	
	Rilascio Prolungato								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469394	EXPEDITED (15-DAY)		DS	CA-APOTEX-2019AP016740		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Allopurinol			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Baclofen			C	Unknown	Unk		Not Reported	
	Diltiazem			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
	Tylenol With Codeine No.3			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469395	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016739		75 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Musculoskeletal Pain; Neck Pain; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469398	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016743		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469566	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016757		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Escitalopram			S	Unknown	Unk		Apotex	
Anger; Anxiety; Arthropod Bite; Blood Pressure	Amlodipine			S	Unknown	10 Mg, Qd		Apotex	
Increased; Bronchitis;	Calcium Carbonate			S	Unknown	Unk		Not Reported	
Cerebrovascular Accident;	Hydromorphone			S	Unknown	Unk		Not Reported	
Contusion; Cough; Crying;	Pantoprazole			S	Unknown	Unk		Apotex	
Depressed Mood;	Ergocalciferol			S	Unknown	Unk		Not Reported	
Depression; Diarrhoea;	Sandostatin			S	Intramuscular	20 Mg, Q.M.T.		Not Reported	
Emotional Distress;	Sandostatin			S	Subcutaneous	Unk Unk, Bid		Not Reported	
Erythema; Fall; Fatigue;	Sandostatin			S	Intramuscular	30 Mg, Q.M.T.		Not Reported	
Feeling Abnormal; Feeling Jittery; Gait Disturbance;	Acetaminophen			C	Unknown	Unk		Not Reported	
Head Banging; Headache;	Gabapentin			C	Unknown	Unk		Not Reported	
Hypertension; Hypoacusis;	Olanzapine			C	Unknown	Unk		Not Reported	
Inappropriate Schedule Of Product Administration;	Perindopril			C	Unknown	4 Mg, Qd		Not Reported	
Joint Swelling; Malaise;	Prednisone			C	Unknown	35 Mg, Unk		Not Reported	
Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness;	Prucalopride Succinate			C	Unknown	Unk		Not Reported	

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Nasopharyngitis; Nausea;
Nervousness; Pain In
Extremity; Peripheral
Swelling; Pneumonia;
Pollakiuria; Productive
Cough; Psychiatric
Symptom; Rash; Rib
Fracture; Screaming;
Suicidal Ideation; Suicide
Attempt; Tremor;
Unresponsive To Stimuli;
Vasculitis; Wound; Wrist
Fracture

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470074	EXPEDITED (15-DAY)		DS	CA-APOTEX- 2019AP016715		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dry Mouth; Tension Headache	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Apixaban			C	Unknown	Unk		Not Reported	
	Rosuvastatin			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470144	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019259609		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Lyrica			S	Oral	1 Df, 1x/Day		Pfizer	
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported	
	Imovane			S	Oral	1 Df, 1x/Day		Not Reported	
	Smofkabiven E			S	Intravenous drip	986 MI, 1x/Day		Not Reported	
	Allopurinol			S	Oral	100 Mg, 1x/Day		Not Reported	
	Methotrexate			C	Intravenous (not otherwise specified)	Unk, Variable		Not Reported	

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Cyclophosphamide	C	Intravenous (not otherwise specified)	Variable	Not Reported
Vincristine	C	Intravenous (not otherwise specified)	Unk, Variable	Not Reported
Doxorubicine [Doxorubicin]	C	Intravenous (not otherwise specified)	Variable	Not Reported
Prednisone	C	Oral	Unk, Variable	Not Reported
Rituximab	C	Intravenous (not otherwise specified)	Unk, Variable	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470204	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016718		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Affective Disorder; Condition Aggravated; Insomnia; Nasal Dryness	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Januvia			C	Unknown	Unk		Not Reported
	Pantoloc /01263201/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470264	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016725		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anger; Depressed Mood; Diarrhoea; Mental Disorder; Multiple Sclerosis	Escitalopram			S	Oral	Unk		Apotex
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported
	Cbd Oil			C	Unknown	Unk		Not Reported
	Colloidal Silver			C	Oral	Unk		Not Reported
	Magnesium			C	Oral	Unk		Not Reported
	Vitamin D 3			C	Oral	3000 Iu, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470361	NON-EXPEDITED			US-TEVA-2019-US-1060430			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Fatigue; Heart Rate Increased; Hunger; Muscle Twitching; Pruritus; Pruritus; Somnolence	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470382	NON-EXPEDITED			US-TEVA-2019-US-1060424			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Dry Mouth; Lethargy; Libido Decreased; Malaise	Teva Escitalopram Accord Escitalopram			S S				Ivax Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16470779	EXPEDITED (15-DAY)		HO, OT	PHHY2019TR143463		21 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Borderline Personality Disorder; Depression; Impulsive Behaviour; Intentional Self-Injury; Product Use In Unapproved Indication; Suicidal Ideation; Suicide Attempt; Therapy Non- Responder	Carbamazepine Valproic Acid Quetiapine Escitalopram Sertraline Sertraline Fluoxetine Fluoxetine Risperidone Risperidone			S S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Novartis Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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Olanzapine	S	Unknown	Not Reported
Olanzapine	S		Not Reported
Trifluoperazine	S	Unknown	Not Reported
Trifluoperazine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16474221	DIRECT		DS			38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Adhesions; Confusional State; Disorientation; Drug Ineffective; Hallucination; Irritability; Nervous System Disorder	Escitalopram (Lexapro)	Y		S		Quantity:1 Tablet(S);		Torrent

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16687952	DIRECT	N	CA, OT				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital	Lexapro			S				Not Reported
Hydronephrosis; Maternal	Keppra			C				Not Reported
Drugs Affecting Foetus;	Desyryl			C				Not Reported
Renal Dysplasia								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16688038	DIRECT	N	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous	Latuda			S				Not Reported
	Lithium			S				Not Reported
	Buspar			S				Not Reported
	Lexapro			S				Not Reported
	Letrozole			C				Not Reported
	L-Thyroxine			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	15434547	EXPEDITED (15-DAY)		HO	DE-TORRENT-00009895		28 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyskinesia; Myoclonus	Amisulpride			S	Unknown	Unknown		Unknown	
	Aripiprazole			S	Unknown	Unknown		Unknown	
	Biperiden			S	Unknown	Unknown		Unknown	
	Bupropion			S	Unknown	Unknown		Unknown	
	Clozapine			S	Unknown	75 Mg		Unknown	
	Duloxetine			S	Unknown	Unknown		Unknown	
	Escitalopram			S	Unknown	20 Mg		Unknown	
	Fluoxetine			S	Unknown	Unknown		Unknown	
	Mirtazapine			S	Unknown	Unknown		Unknown	
	Olanzapine			S	Unknown	Unknown		Unknown	
	Promethazine			S	Unknown	Unknown		Unknown	
	Quetiapine			S	Oral	Unknown		Unknown	
	Risperidone			S	Unknown	Unknown		Unknown	
	Venlafaxine			S	Oral	Unknown		Unknown	
	Zopiclone			S	Unknown	Unknown		Unknown	
	Brivaracetam			C	Unknown	200-250mg; Received Over One Year		Unknown	
	Carbamazepine			C	Unknown	Up To 900 Mg		Unknown	
	Clobazam			C	Unknown	Up To 20mg		Unknown	
	Oxazepam			S	Unknown	At Different Doses		Unknown	
	Oxcarbazepine			C	Unknown	Up To 2400mg; Received Over One Year		Unknown	
	Zonisamide			C	Unknown	Up To 100mg		Unknown	
	Benzodiazepine			C		Unknown		Unknown	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	15758328	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2018-060437			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Decreased Appetite; Drug Ineffective; Dyschezia; Inadequate Analgesia; Medication Error; Off Label Use; Pain; Pneumonia; Weight Decreased	Escitalopram			S	Unknown	Unk		Aurobindo	
	Omeprazole 20mg			S	Unknown	20 Milligram, Qd (In The Morning, Fasting), 1 Dosage 20 Mg Daily		Aurobindo	
	Alprazolam			S	Unknown	Unk		Aurobindo	
	Tramadol			S	Unknown	100 Milligram, Bid (200 Milligram Daily; Controlled-Release)		Not Reported	
	Tramadol			S				Not Reported	
	Metoclopramide			S	Unknown	30 Milligram Daily; For About 3 Weeks, 3 Dosages 10 Mg Daily		Not Reported	
	Metamizole			S	Oral	1000 Milligram, Once A Day, 2 Dosages 500 Mg Daily		Not Reported	
	Buprenorphine			S	Unknown	Unk		Not Reported	
	Buprenorphine			S	Unknown	35 Ug/Hour Every 4 Days		Not Reported	
	Buprenorphine			S	Unknown	1 Dosage Form, Qd (35 Ug/H Every 4 Days)		Not Reported	
	Ketoprofen			S	Unknown	Unk		Not Reported	
	Ketoprofen			S	Oral	3 Dosages 100 Mg Daily/300 Milligram, Qd		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Betamethasone			C	Unknown	Unk		Not Reported	
	Zoledronic Acid			C	Unknown	Unk		Not Reported	
	Valproic Acid			C	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	
	Morphine			C	Unknown	Unk		Not Reported	

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Effentora			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16021272	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010025			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo	
	Abilify			S	Oral	2 Milligram		Not Reported	
	Escitalopram Teva			S	Unknown	20 Milligram, Once A Day		Not Reported	
	Serax			C	Unknown	45 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16043271	EXPEDITED (15-DAY)		OT	PHHY2018CO106563		49 YR	Female	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dry Throat; Dysphonia; Eye Irritation; Furuncle; Headache; Hypertension; Latent Tuberculosis; Malaise; Nasal Congestion; Oropharyngeal Pain; Overweight; Pain; Pyrexia; Subcutaneous Abscess; Tuberculin Test Positive; Weight Increased	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Not Reported	
	Losartan			S	Unknown	50 Mg, Q12h		Novartis	
	Escitalopram Oxalate			S	Unknown	10 Mg, Qd (1 In The Morning)		Not Reported	
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported	
	Hydrochlorothiazide			C	Unknown	1 Df, Qd		Not Reported	
	Trazodon			C	Unknown	50 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16080840	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013878			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Foot Fracture; Headache; Influenza; Stress; Weight	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Omalizumab			S	Subcutaneous	150 Milligram		Not Reported	

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Decreased	Omalizumab	S	Subcutaneous	150 Milligram	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Omalizumab	S	Subcutaneous	150 Milligram	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Claritin	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Pulmicort	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Singulair	C	Unknown	2 Dosage Form, Once A Day	Not Reported
	Singulair	C	Unknown	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16080841	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-014582			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Base Excess Decreased;	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
Confusional State;	Metformin Tablet			S	Unknown	1 Gram, Two Times A Day		Aurobindo
Electrocardiogram T Wave	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
Peaked; Fall;	Gliclazide			S	Unknown	Unk		Not Reported
Hypoglycaemia;	Insulin			S	Unknown	Unk		Not Reported
Hyponatraemia;	Apo-Gliclazide			S	Unknown	Unk		Not Reported
Inappropriate Antidiuretic	Apo-Hydro			S	Unknown	Unk		Not Reported
Hormone Secretion; Lactic	Apo-Metformin			S	Unknown	1 Gram		Not Reported
Acidosis; Pco2 Decreased	Levothyroxine Sodique			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16327846	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027685			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Chronic Spontaneous Urticaria; Urticaria	Escitalopram Tablets			S	Unknown	10 Milligram, Unk		Aurobindo
	Tegretol			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Benadryl			C	Unknown	Unk		Not Reported
	Claritin			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Reactine			C	Unknown	1 Dosage Form, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16327847	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027752			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Decreased; Breath Sounds Abnormal; Cystic Fibrosis; Dizziness; Dyspnoea; Generalised Erythema; Lung Infection; Moaning; Nasal Congestion; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pulmonary Contusion; Pyrexia; Rash Erythematous; Sinus Congestion; Sinus Headache; Sinusitis; Skin Sensitisation; Skin Warm; Smoke Sensitivity; Upper Respiratory Tract	Escitalopram Tablets			S	Oral	1 Dosage Form		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Xolair			S	Subcutaneous	300 Milligram		Not Reported
	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2 Week		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Pulmicort			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Zenhale			C	Unknown	Unk		Not Reported
	Zenhale			C		1 Dosage Form, Two Times A Day		Not Reported

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Congestion

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16327961	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-026637			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo	
Abdominal Distension;	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo	
Abdominal Pain;	Escitalopram Tablets			S	Oral	5 Milligram		Aurobindo	
Arthralgia; Basedow'S	Escitalopram Tablets			S	Oral	20 Milligram		Aurobindo	
Disease; Blood Thyroid	Escitalopram			S	Oral	5 Milligram		Aurobindo	
Stimulating Hormone	Alemtuzumab			S	Intravenous drip	12 Milligram, Once A Day		Not Reported	
Decreased; Blood Urine	Acetaminophen			C	Oral	650 Milligram		Not Reported	
Present; Burning	Acyclovir			C	Oral	200 Milligram		Not Reported	
Sensation; Chest	Benadryl			C	Intravenous (not otherwise specified)	25 Milligram		Not Reported	
Discomfort; Decreased	Benadryl			C	Oral	Unk		Not Reported	
Appetite; Depression;	Dimenhydrinate			C	Oral	50 Milligram		Not Reported	
Diarrhoea; Disturbance In	Gabapentin			C	Unknown	Unk		Not Reported	
Attention; Dizziness; Drug	Losartan			C	Oral	1 Dosage Form, Once A Day		Not Reported	
Hypersensitivity;	Losartan			C	Oral	100 Milligram		Not Reported	
Dysgeusia; Dysphagia;	Methimazole			C	Oral	4 Dosage Form, Once A Day		Not Reported	
Dyspnoea; Dysuria;	Methimazole			C	Oral	2 Dosage Form, Once A Day		Not Reported	
Fatigue; Headache;	Methimazole			C	Oral	5 Milligram, Two Times A Day		Not Reported	
Hyperhidrosis; Influenza;	Methylprednisolone			C	Unknown	Unk		Not Reported	
Insomnia; Migraine; Mood	Pantoprazole			C	Oral	40 Milligram, Once A Day		Not Reported	
Altered; Muscle Spasms;	Propranolol			C	Oral	Unk		Not Reported	
Nasopharyngitis; Nausea;									
Pain In Extremity; Pruritus;									
Rash; Rash									
Erythematous; Rash									
Macular; Somnolence;									
Stress; Swelling Face;									
Temperature Intolerance;									
Throat Irritation; Thyroid									
Hormones Increased;									
Thyroiditis; Urinary Tract									
Infection; Urticaria;									
Vomiting; Weight									
Increased; Wheezing;									
White Blood Cell Count									

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Decreased	Sertraline	C	Oral	100 Milligram, Two Times A Day	Not Reported				
	Sertraline	C	Oral	50 Milligram	Not Reported				
	Zantac	C	Oral	150 Milligram, Once A Day	Not Reported				
	Zantac	C	Oral	150 Milligram	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16327962	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027634			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Escitalopram Tablets			S	Oral	30 Milligram		Aurobindo	
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported	
	Apo-Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported	
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16328198	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027683			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram Tablets			S	Unknown	20 Milligram, Once A Day		Aurobindo	
	Aripiprazole Tablets			S	Oral	2 Milligram		Aurobindo	
	Escitalopram Teva			S	Unknown	20 Milligram, Daily		Not Reported	
	Abilify			S	Oral	2 Milligram		Not Reported	
	Serax			C	Unknown	45 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16328210	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027984			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Lip Ulceration;	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo	

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Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx	S	Subcutaneous	150 Milligram, Every Week	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Povidone-Iodine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	150 Milligram, 1 Month	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Vitamin D3	S	Unknown	Unk	Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Voltaren	S	Unknown	Unk, 1 Every Week	Not Reported
	Enbrel	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16328423	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-027449			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased;	Amlodipine Tablets			S	Oral	150 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Unknown	60 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Potassium Chloride			S	Oral	Unk		Not Reported
	Epinephrine			S	Unknown	30 Microgram		Not Reported
	Dextrose			S	Unknown	Solution Intravenous		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Norepinephrine Bitartrate			S	Unknown	30 Microgram, Liquid Intravenous		Not Reported
	Risperidone			S	Oral	6 Milligram, Once A Day		Not Reported
	Activated Charcoal			C	Unknown	50 Gram		Not Reported

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Electrocardiogram T Wave Inversion;	Amlodipine	C	Unknown	Unk	Not Reported
Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Calcium Gluconate	C	Unknown	Unk	Not Reported
	Dextrose	C	Unknown	Unk	Not Reported
	Glucagon	C	Unknown	Kit	Not Reported
	Insulin	C	Unknown	70 International Unit	Not Reported
	Insulin	C	Intravenous bolus	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16444137	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033470			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Pentasa			S	Unknown	Unk		Not Reported
	Premarin			S	Oral	0.625 Milligram, Once A Day		Not Reported
	Propranolol			S	Oral	40 Milligram, Two Times A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472250	EXPEDITED (15-DAY)		OT	FR-ACCORD-134840		50 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mitral Valve Incompetence	Methotrexate			S	Subcutaneous			Accord
	Gabapentin			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Noctamide			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472316	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034860			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Serotonin Syndrome	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Abilify			S	Oral	2 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472329	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034864			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Trintellix			S	Oral	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported

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	Clonazepam		C	Unknown	Unk			Not Reported	
	Lorazepam		C	Unknown	Unk			Not Reported	
	Quetiapine Fumarate		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472339	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034843			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk; Seizure; Therapeutic Agent Urine Positive; Vomiting	Escitalopram Tablets			S	Transmammary	Unk		Aurobindo	
	Bupropion			S	Transmammary	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472484	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034934			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Musculoskeletal Pain; Neck Pain; Seizure; Tremor	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472487	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035014			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Therapy Change	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472885	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034863			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Inappropriate	Escitalopram Tablets			S	Oral	10 Milligram, 1 Every 1		Aurobindo	

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Antidiuretic Hormone Secretion					Day				
	Baclofen		C	Unknown	Unk			Not Reported	
	Cialis		C	Unknown	Unk			Not Reported	
	Pregabalin		C	Unknown	Unk			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472894	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034855			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cesarean Section; Exposure During Pregnancy; Female Sterilisation; Malaise; Morning Sickness; Nausea; Procedural Pain; Uterine Abscess; Vomiting	Escitalopram			S	Unknown	Unk Unk, Two Times A Day		Aurobindo
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Toradol			S	Unknown	Unk		Not Reported
	Ergocalciferol			C	Oral	800 International Unit, Once A Day		Not Reported
	Folic Acid			C	Oral	Unk Unk, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472897	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034871			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Escitalopram			S	Oral	20 Milligram		Aurobindo
	Gabapentin			S	Oral	300 Milligram, Once A Day		Aurobindo
	Gabapentin			S	Oral	600 Milligram, Once A Day		Aurobindo
	Ferrous Sulfate			S	Unknown	300 Milligram, 3 Every		Not Reported

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Temazepam	S	Oral	Once A Day	Not Reported
Wellbutrin	S	Oral	30 Milligram, Once A Day	Not Reported
Acetaminophen;Codeine Phosphate	S	Oral	150 Milligram, 2 Every Once A Day	Not Reported
Clonazepam	S	Oral	2.0 Dosage Form, 3 Every Once A Day	Not Reported
Domperidone	S	Oral	0.5 Milligram, 3 Every Once A Day	Not Reported
			10 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472899	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034791			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Chest Discomfort; Chronic Obstructive Pulmonary Disease; Cough; Decreased Appetite; Depression; Diarrhoea; Drug Ineffective; Dyspnoea; Fatigue; Feeling Abnormal; Gait Disturbance; General Physical Health Deterioration; Hernia Pain; Hiatus Hernia; Hypoaesthesia; Insomnia; Lung Infection; Malaise; Moaning; Mobility Decreased; Pain; Panic Disorder; Poor Quality Sleep; Pruritus; Restlessness; Skin Discolouration	Escitalopram			S	Unknown	Unk		Aurobindo
	Clarithromycin			S	Unknown	Unk		Not Reported
	Glycopyrronium			S		Unk		Not Reported
	Meloxicam			C	Oral	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Fluticasone			C	Unknown	Unk		Not Reported
	Propionate;Salmeterol Xinafoate							

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472900	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034900			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Hypertension	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472902	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034829			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Asthenia; Blood	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
Alkaline Phosphatase Increased; Blood	Mycophenolate Sodium			S	Oral	Unk, Two Times A Day		Not Reported	
Cholesterol Increased; Diarrhoea; Fatigue; Nephritic Syndrome; Shock	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Ranitidine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472904	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034885			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Olanzapine			S	Unknown	Unk		Aurobindo	
	Bupropion			S	Unknown	Unk		Not Reported	
	Phenytoin			S	Unknown	Unk		Not Reported	
	Primidone			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472906	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035116			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Lorazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472908	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035067			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Shock Symptom	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472925	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-035008			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Depressed Mood; Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis; Poor Quality Sleep	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Pantoprazole			S	Unknown	40 Milligram, Two Times A Day		Aurobindo	
	Telmisartan Tablets			S	Unknown	80 Milligram, Once A Day		Aurobindo	
	Telmisartan Tablets			S				Aurobindo	
	Lorazepam			S	Unknown	1 Milligram, As Required		Not Reported	
	Lorazepam			S	Unknown	1 Milligram, Once A Day		Not Reported	
	Metoprolol			S	Unknown	50 Milligram, Once A Day		Not Reported	
	Metoprolol			S				Not Reported	
	Loperamide			C	Unknown	Unk		Not Reported	
	Prednisolone			C	Unknown	Unk		Not Reported	
	Tamsulosin Cr			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472929	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034903			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Drug Ineffective; Eye Pain; Fear Of Injection; Hereditary Angioedema; Infusion Site Pain; Pharyngeal Swelling; Pharyngitis Streptococcal; Selective Mutism; Vaginal Infection; Vascular Access Site Occlusion	Escitalopram			S	Unknown	Unk		Aurobindo
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	3000 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	3000 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	1500 International Unit		Not Reported
	C1 Esterase Inhibitor (Human)			S	Subcutaneous	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Subcutaneous	1500 International Unit, 3 Times In 1 Week		Not Reported
	C1 Esterase Inhibitor (Human)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Icatibant Acetate			C	Subcutaneous	Unk		Not Reported
	Icatibant Acetate			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472947	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-034730			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Depressed Mood; Dizziness; Fall; Hypotension; Orthostatic Hypotension; Pain; Visual Impairment	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Amlodipine Tablets			S	Unknown	2.5 Milligram, Two Times A Day		Aurobindo
	Oxazepam			S	Unknown	2 Dosage Form, Once A Day		Not Reported

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Furosemide	S	Unknown	40 Milligram, Once A Day	Not Reported
Metoprolol	S	Unknown	25 Milligram, Two Times A Day	Not Reported
Metoprolol	S			Not Reported
Nitroglycerin	S	Transdermal	Unk	Not Reported
Zopiclone	S	Unknown	5 Milligram, Once A Day	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Clopidogrel	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Nitroglycerin	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Polyethylene Glycol	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Acetaminophen;Codeine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472951	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034925			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram Tablets			S	Oral	15 Milligram, Once A Day		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Acacia			C	Unknown	Unk		Not Reported	
	Acetaminophen			C	Unknown	Unk		Not Reported	
	Aczone			C	Unknown	Unk		Not Reported	
	Azithromycin			C	Unknown	Unk		Not Reported	
	Benzaclin			C	Unknown	Unk		Not Reported	
	Calcium			C	Unknown	Unk		Not Reported	
	Canesten Hc			C	Unknown	Unk		Not Reported	

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Cetaphil Acne Principles	C	Unknown	Unk	Not Reported
Cetaphil	C	Unknown	Unk	Not Reported
Cetaphil Cleansers Oily Skin	C	Unknown	Unk	Not Reported
Cipralex	C	Unknown	Unk	Not Reported
Constella	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Epival	C	Unknown	Unk	Not Reported
Flovent Hfa	C	Unknown	Unk	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Nasacort Aq	C	Unknown	Unk	Not Reported
Omega 3 6 9	C	Unknown	Unk	Not Reported
Otrivin Saline	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tears Plus	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	Unk	Not Reported
Zyloprim	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472952	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-034849			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depression; Drug Ineffective; Product Substitution Issue; Suicidal Ideation Escitalopram Tablets S Oral 20 Milligram, Once A Day Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472956	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-034930			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Dizziness; Fall; Hyponatraemia; Hypotension; Hypovitaminosis	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Telmisartan Tablets			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	40 Milligram, Two Times A Day		Aurobindo
	Loperamide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	50 Milligram, Once A Day		Not Reported
	Metoprolol			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tamsulosin Cr			S	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472966	EXPEDITED (15-DAY)		LT, OT	CA-AUROBINDO-AUR-APL-2019-035075			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Depression; Suicidal Ideation	Escitalopram Tablets			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472967	EXPEDITED (15-DAY)		LT, OT	CA-AUROBINDO-AUR-APL-2019-034886			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Depressive Symptom; Sexual Dysfunction; Suicidal Ideation	Escitalopram Tablets	S	Oral	Unk Unk, Once A Day	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472969	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035124			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Feeling Abnormal; Negative Thoughts; Paranoia	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472972	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR- APL-2019-035582			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Escitalopram			S	Oral	30 Milligram		Aurobindo
	Escitalopram			S	Oral	30 Milligram		Aurobindo
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported
	Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472977	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034861			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Insomnia; Pharyngeal Swelling; Product Substitution Issue; Swollen Tongue	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Aldactone			C	Unknown	Unk		Not Reported
	Arthrotec			C	Unknown	Unk		Not Reported

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	Ativan		C	Unknown	Unk			Not Reported	
	Imitrex		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472979	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034814			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Loss Of Consciousness; Seizure	Escitalopram Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Dayquil			S	Unknown	2 Dosage Form, Once A Day		Not Reported	
	Dalacin C			C	Unknown	Unk		Not Reported	
	Stieva-A			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472981	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-034801			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Bone Disorder; Chest Discomfort; Cough; Cyanosis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Drug Ineffective; Dyspnoea Exertional; Emphysema; Fall; Fatigue; Headache; Hiatus Hernia; Hypoaesthesia; Insomnia; Malaise; Overdose; Pain; Panic Reaction; Pneumonia; Pruritus; Pulmonary Mass; Tremor	Escitalopram			S	Unknown	Unk		Aurobindo	
	Atrovent			S	Unknown	Unk		Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Fluticasone			S		Unk, Two Times A Day		Not Reported	
	Propionate;Salmeterol Xinafoate								
	Fluticasone			S		Unk		Not Reported	
	Propionate;Salmeterol Xinafoate								
	Glycopyrronium Bromide			S	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Tiotropium Bromide			S	Unknown	Unk		Not Reported	
	Clonazepam			C	Unknown	Unk		Not Reported	
	Meloxicam			C	Unknown	Unk		Not Reported	
Prednisone			C	Unknown	4 Dosage Form, Unk		Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472984	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035140			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glossodynia	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Pantoloc			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472987	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-035589			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aptyalism; Drug Ineffective; Panic Disorder	Escitalopram Tablets			S	Oral	30 Milligram, Unk		Aurobindo	
	Amitriptyline			S	Oral	20 Milligram, Once A Day		Not Reported	
	Buspirone			S	Oral	5 Milligram, Once A Day		Not Reported	
	Zyprexa			S	Oral	2.5 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035118			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo	
	Vyvanse			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472992	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034945			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Baclofen			C	Unknown	Unk		Not Reported	

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Amlodipine	C	Unknown	Unk	Not Reported
Allopurinol	C	Unknown	Unk	Not Reported
Diltiazem	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16475473	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1068120			Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Intentional Overdose; Suicide Attempt	Serpentil (Escitalopram Oxalate)			S	Oral			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	15826005	EXPEDITED (15-DAY)		HO, OT	SK-MYLANLABS-2019M1002654		30 YR	Male	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abulia; Anhedonia;	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
Antisocial Behaviour;	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported
Apathy; Asthenia;	Olanzapine			S	Oral	15 Milligram, Qd		Not Reported
Bradyphrenia; Delusion;	Olanzapine			S	Oral	10 Milligram, Qd		Not Reported
Depression; Drug	Olanzapine			S	Oral	Unk (Dispersion)		Not Reported
Ineffective; Hypomania;	Olanzapine			S	Oral	Unk		Not Reported
Mania; Mental Impairment;	Valproic Acid			S	Oral	Unk		Not Reported
Off Label Use; Product	Sertraline			S		Unk		Not Reported
Use In Unapproved	Quetiapine			C	Unknown	500 Milligram (Pro Die (Extended-Release Form)		Mylan
Indication; Sleep Disorder;								
Weight Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16327958	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-026303			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis; Interstitial Lung Disease; Pulmonary Fibrosis	Duloxetine			S	Unknown	15 Milligram		Aurobindo
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	37.5 Milligram		Aurobindo
	Paroxetine Tablet			S	Unknown	10 Milligram		Aurobindo
	Mylan Duloxetine			S	Unknown	Unk		Not Reported
	Venlafaxin Mylan			S	Unknown	Unk		Not Reported
	Venlafaxin Mylan			S	Unknown	37.5 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16328325	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027747			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Anxiety; Anxiety Disorder; Breast Cancer; Breast Disorder; Decreased Appetite; Diarrhoea; Ear Discomfort; Frequent Bowel Movements; Hot Flush; Nasopharyngitis; Nausea; Nervousness; Pain; Weight Increased	Escitalopram Tablets			S	Unknown	Unk, Once A Day		Aurobindo
	Tamoxifen			S	Unknown	Unk		Not Reported
	Atezolizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Atezolizumab			S	Intravenous (not otherwise specified)	1200 Milligram		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	Unk, Every 3 Weeks		Not Reported
	Tecentriq			S	Intravenous (not otherwise specified)	1200 Milligram, Every 3 Weeks		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16337161	NON-EXPEDITED		OT	US-PFIZER INC-2019208061		37 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Suicidal Ideation	Zoloft			S	Oral	25 Mg, Unk		Pfizer
	Zoloft			S	Oral	50 Mg, Daily		Pfizer
	Zoloft			S				Pfizer
	Zoloft			S				Pfizer
	Lexapro			S	Oral	20 Mg, Daily		Not Reported
	Lexapro			S		5 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Unk		Not Reported
	Lexapro			S				Not Reported
	Wellbutrin			S		Unk		Not Reported
	Wellbutrin			S				Not Reported
	Wellbutrin			S				Not Reported
	Zyrtec [Cetirizine Hydrochloride]			C		Unk		Not Reported
	Buspirone			C		Unk		Not Reported
	Amphetamine/Dexamphetamine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16468769	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016710		25 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Escitalopram			S	Oral	15 Mg, Qd		Apotex
	Escitalopram			S				Apotex
	Acacia			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aczone			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Benzaclin Topical			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Canesten Hc			C	Unknown	Unk (1 Percentage Cream Powder Mixture)		Not Reported

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Cetaphil Acne Principles	C	Unknown	Unk	Not Reported
Cetaphil /02314901/	C	Unknown	Unk	Not Reported
Cetaphil Cleansers Oily Skin	C	Unknown	Unk	Not Reported
Cipralex /01588501/	C	Unknown	Unk	Not Reported
Constella	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Domperidone	C	Unknown	Unk	Not Reported
Epival /00017001/	C	Unknown	Unk	Not Reported
Flovent	C	Unknown	Unk (Powder)	Not Reported
Flovent Hfa	C	Unknown	Unk (Aerosol)	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Nasacort Aq	C	Unknown	Unk (Metered Dose)	Not Reported
Omega 3 6 9 /01334101/	C	Unknown	Unk	Not Reported
Otrivin Saline	C	Unknown	Unk (Hypertonic Nasal Spray)	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Seroquel	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tears Plus	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Tylenol Extra Strength	C	Unknown	Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	Unk	Not Reported
Zyloprim	C	Unknown	Unk	Not Reported
Benzoyl Peroxide	C	Unknown	Unk	Not Reported
W/Clindamycin Phosphate				
Clotrimazole W/Hydrocortisone	C	Unknown	Unk	Not Reported
Valproate Semisodium	C	Unknown	Unk	Not Reported

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Polyvinyl Alcohol W/Povidone			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476596	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1058202		91 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hyponatraemia	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Hydrochlorothiazide/Irbesartan			S	Oral	Unk		Not Reported	
	Gabapentina			S	Oral	Unk		Mylan	
	Carbamazepina			S	Oral	200 Mg Por Las Mañanas Un Cuarto De Comprimido		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476711	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-211394			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Exposure During Pregnancy; Live Birth	Escitalopram			S	Unknown	Unk		Not Reported	
	Nitrazepam			S	Unknown	Unk		Not Reported	
	Lormetazepam			S	Unknown	Unk		Not Reported	
	Mirtazapine			S	Unknown	Unk		Sun	
	Alprazolam			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476902	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034806			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo	
	Imodium			S	Unknown	Unk		Not Reported	
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported	

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Naevus; Rheumatoid Factor Increased	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 3 Times A Day	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Tecta	S	Unknown	30 Milligram, Once A Day	Not Reported
	Loperamide Hydrochloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476903	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-034783			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dry Mouth; Tension Headache	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Apixabanum			C	Unknown	Unk		Not Reported	
	Rosuvastatin			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476905	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034909			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Therapy Change	Escitalopram Tablets			S	Oral	Unk, Once A Day		Aurobindo	
	Bupropion			C	Unknown	Unk		Not Reported	
	Clonazepam			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476910	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035056			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual; Visual Impairment	Escitalopram Tablets			S	Unknown	5.0 Milligram		Aurobindo	
	Escitalopram			S	Unknown	10.0 Milligram		Aurobindo	
	Lorazepam			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476912	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035575			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram			S	Unknown	Unk, Once A Day		Aurobindo
Arthralgia; Lip Ulceration;	Cosentyx			S	Subcutaneous	150 Milligram, Unk		Not Reported
Lower Respiratory Tract Infection Viral; Malaise;	Cosentyx			S	Unknown	Unk		Not Reported
Mouth Ulceration;	Cosentyx			S	Subcutaneous	150 Milligram, Unk		Not Reported
Musculoskeletal Stiffness;	Diclofenac Diethylamine			S	Unknown	Unk		Not Reported
Nasopharyngitis; Nausea;	Methotrexate			S	Unknown	Unk		Not Reported
Pain; Swollen Tongue;	Vitamin D3			S	Unknown	Unk		Not Reported
Tonsillar Ulcer; Tonsillitis;	Enbrel			C	Unknown	Unk		Not Reported
Vomiting	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034853			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Dizziness; Fatigue; Headache; Heart Rate Increased; Heart Rate Irregular; Myalgia; Nausea; Palpitations	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476914	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034784			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Affective	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo

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Disorder; Condition	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Aggravated; Insomnia;	Candesartan	C	Unknown	Unk	Not Reported
Nasal Dryness	Januvia	C	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476916	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-035005			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Insomnia;	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
Muscle Twitching; Pain In	Norflexacin			S	Oral	400 Milligram, Two Times A Day		Not Reported	
Extremity; Syncope;	Advil			C	Unknown	Unk		Not Reported	
Tachycardia; Tremor									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476917	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR- APL-2019-035636			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo	
Ineffective; Product									
Substitution Issue									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476924	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR- APL-2019-035127			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Product	Escitalopram Tablets			S	Oral	10 Milligram, Unk		Aurobindo	
Substitution Issue									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476925	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR- APL-2019-034807			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Dizziness; Headache; Product Substitution Issue	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476926	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034875			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Withdrawal Syndrome; Arrhythmia; Drug Interaction; Hyperthermia; Intentional Overdose; Intentional Product Misuse; Major Depression; Overdose; Pneumonia; Potentiating Drug Interaction; Sepsis; Serotonin Syndrome; Tachycardia; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo	
	Citalopram Tablets			S	Unknown	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo	
	Olanzapine			S	Oral	Unk		Aurobindo	
	Bupropion			S	Oral	Unk		Not Reported	
	Phenytoin			S	Oral	Unk		Not Reported	
	Primidone			S	Oral	Unk		Not Reported	
	Valproic Acid			S	Unknown	Unk		Not Reported	
	<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>
26-Jun-2019	16476929	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-034790			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder; Depression; Product Substitution Issue; Therapeutic Product Effect Decreased	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476930	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035117			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Fatigue; Obsessive Thoughts; Psychomotor Retardation; Somnolence	Escitalopram Tablets	S	Unknown	10 Milligram, 1 Every 1 Day	Aurobindo
	Escitalopram Tablets	S			Aurobindo
	Citalopram Tablets	S	Oral	50 Milligram, 1 Every 1 Day	Aurobindo
	Citalopram Tablets	S			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476931	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035628			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Urine Present; Chills; Condition Aggravated; Dizziness; Dyspnoea; Fatigue; Heart Rate Increased; Heart Rate Irregular; Hyperhidrosis; Loss Of Consciousness; Nausea; Photophobia	Escitalopram Tablets			S	Oral	10.0 Milligram, Daily		Aurobindo
	Diclofenac Sodium			C	Unknown	Unk		Not Reported
	Dayquil			C	Unknown	Unk		Not Reported
	Ferrous Sulphate			C	Unknown	Unk		Not Reported
	Misoprostol			C	Unknown	Unk		Not Reported
	Vitamin C			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476934	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034821			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Product Substitution Issue; Restlessness; Therapeutic Product Effect Decreased	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo
	Lorazepam			C	Unknown	Unk		Not Reported
	Olanzapine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476935	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR- APL-2019-034834			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Mental Status	Escitalopram Tablets			S	Oral	10 Milligram		Aurobindo

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Changes	Lorazepam			S	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476937	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034958			Unknown	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476938	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-034929			Unknown	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Overdose; Suicide Attempt	Escitalopram Tablets			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Duloxetine			S	Unknown	Unk		Not Reported	
	Bupropion			C	Unknown	Unk		Not Reported	
	Cetirizine			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476939	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034949			Unknown	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Altered State Of Consciousness; Anxiety; Confusional State;	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo	
Confusional State; Insomnia; Pain In Jaw; Somnolence; Speech Disorder; Vision Blurred	Lorazepam			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476940	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034990			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Caesarean Section; Exposure During Pregnancy	Escitalopram			S	Unknown	Unk		Aurobindo	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Bupropion			S	Unknown	Unk		Not Reported	
	Domperidone			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram, 1 Every 8 Weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476941	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034728			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Product Substitution Issue	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476944	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035626			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476945	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR- APL-2019-035134			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Temazepam			S	Unknown	Unk		Not Reported	
	Tylenol With Codein #3			S	Unknown	Unk		Not Reported	
	Advair			C	Unknown	Unk		Not Reported	
	Atrovent			C	Unknown	Unk		Not Reported	

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	Gabapentin	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Ranitidine	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16476948	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035149			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Cosentyx			S	Subcutaneous	150 Milligram, 1 Month		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	150 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk, 1 Every Week		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16477900	EXPEDITED (15-DAY)		OT	HR-ACCORD-135040		15 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Suicide Attempt	Aripiprazole			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16477904	EXPEDITED (15-DAY)		OT	IT-ACCORD-135171		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Therapeutic Product Ineffective	Escitalopram			S	Oral			Not Reported	
	Xanax			S	Oral	Strength: 0,5 Mg Prolonged-Release Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16477911	EXPEDITED (15-DAY)		CA	DE-ACCORD-135008		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Premature Baby	Escitalopram			S	Transplacental	Dosage Text: 10 Mg/D		Not Reported	
	Femi Baby			C	Transplacental	Dosage Text: 0.6 Mg/D (Bis 0.8 Mg/D)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16477912	EXPEDITED (15-DAY)		HO	FR-ACCORD-134957		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Spinal Fracture	Escitalopram			S	Oral			Not Reported	
	Agomelatine			S	Oral			Not Reported	
	Phenergan			S	Oral			Not Reported	
	Clotiazepam			S	Oral			Not Reported	
	Risperidone			S	Oral			Not Reported	
	Lormetazepam			S	Oral			Not Reported	
	Tilcotil			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Kardegic			C				Not Reported	
	Esomeprazole			C				Not Reported	

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Ramipril			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16477979	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035598			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Cough; Dyspnoea; Interstitial Lung Disease; Secretion Discharge; Wheezing	Duloxetine			S	Unknown	15 Milligram		Aurobindo	
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo	
	Venlafaxine			S	Unknown	37.5 Milligram, Once A Day		Aurobindo	
	Venlafaxine Xr Extended Release Capsule			S	Unknown	37.5 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16478018	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035620			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Duloxetine			S	Unknown	15.0 Milligram		Aurobindo	
	Duloxetine			S				Aurobindo	
	Escitalopram Tablets			S	Unknown	5.0 Milligram		Aurobindo	
	Escitalopram Tablets			S				Aurobindo	
	Venlafaxine			S	Unknown	37.5 Milligram		Aurobindo	
	Venlafaxine			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16478197	EXPEDITED (15-DAY)		OT	KR-ALLERGAN- 1926084US			Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dementia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16478470	EXPEDITED (15-DAY)		HO	IT-MYLANLABS- 2019M1058084		84 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertension; Medication Error	Escitalopram			S	Oral	25 Milligram, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16478845	EXPEDITED (15-DAY)		HO	ES-DSJP-DSE-2019-123684			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Balzak Plus			S	Oral	40/10/25 Mg, Qd		Daiichi	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Apixaban			C	Oral	2.5 Mg, Once Every 12hr		Not Reported	
	Atenolol			C	Oral	25 Mg, Qd		Not Reported	
	Potassium Citrate			C	Oral	1.08 G, Qd		Not Reported	
	Omeprazole			C	Oral	20 Mg, Once Every 12hr		Not Reported	
	Paracetamol			C	Oral	1 G, Once Every 8hr		Not Reported	
	Glimepiride			C	Oral	4 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16487616	DIRECT	Y	OT			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dry Mouth	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16487691	DIRECT		OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fatigue; Hypotension	Escitalopram 20 Mgs Tablet			S	Oral	Quantity:30 Tablet(S);		Accord	
	Ranitidine			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Wellbutrin XL			C				Not Reported	
	Albuterol			C				Not Reported	

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Multi Vitamin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16487784	DIRECT		DS			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysgeusia	Escitalopram Oxalate			S	Oral	Quantity:1 Tablet(S);		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16368484	EXPEDITED (15-DAY)		HO, LT, OT	US- GLAXOSMITHKLINE- US2019AMR095883		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Ineffective; Jaundice; Liver Transplant; Nausea; Sexual Dysfunction	Wellbutrin XI			S	Unknown	150 Mg, Unk		Glaxosmithkline	
	Wellbutrin XI			S	Unknown	150 Mg, Unk		Glaxosmithkline	
	Wellbutrin Sr			S	Unknown	100 Mg, Unk		Glaxosmithkline	
	Wellbutrin Sr			S				Glaxosmithkline	
	Wellbutrin Sr			S				Glaxosmithkline	
	Lexapro			S	Unknown	10 Mg, Unk		Not Reported	
	Escitalopram			C	Unknown	10 Mg, Unk		Glaxosmithkline	
	Escitalopram			C				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16482311	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE- 1069598			Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Depressed Level Of Consciousness; Dyskinesia; Intentional Overdose; Intentional Self- Injury; Tachycardia	Ibuprofen			S	Oral			Actavis	
	Paracetamol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Ivax	
	Lergigan (Promethazine Hydrochloride)			S	Oral			Not Reported	

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27-Jun-2019	16482674	EXPEDITED (15-DAY)		HO	FR-ACCORD-135441		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Allopurinol			S	Oral			Accord
	Seroplex			S	Oral	Strength: 10 Mg		Not Reported
	Smofkabiven E			S	Intravenous drip			Not Reported
	Lyrica			S	Oral	Strength: 50 Mg		Not Reported
	Imovane			S	Oral	Strength: 3.75 Mg		Not Reported
	Methotrexate/Methotrexate Sodium			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Vincristine			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Doxorubicin			C	Intravenous (not otherwise specified)	Variable		Not Reported
	Prednisone/Prednisone Acetate			C	Oral	Variable		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Variable		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16482734	EXPEDITED (15-DAY)		OT	US-ACCORD-135190		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Sleep Paralysis; Treatment Failure; Withdrawal Syndrome	Bupropion/Bupropion Hydrochloride			S				Not Reported
	Escitalopram			S				Not Reported
	Mirtazapine			S				Not Reported
	Fluoxetine			C				Not Reported
	Venlafaxine/Venlafaxine Hydrochloride			C				Not Reported

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27-Jun-2019	16482893	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1069922		21 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Dizziness	Escitalopram			S		25 Mg		Ivax	
	Atarax (Hydroxyzine)			S		25 Mg 7 St- 175 Mg		Not Reported	
	Lergigan (Promethazine Hydrochloride)			S	Oral	7 St 25 Mg - 125 Mg		Not Reported	
	Propavan			S		5 St -25 Mg - 125 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16483605	NON-EXPEDITED			US-PFIZER INC-2019272084		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Pregabalin			S		Unk		Pfizer	
	Indomethacin			S		Unk		Unknown	
	Midazolam			S		Unk		Pfizer	
	Sertraline Hcl			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Sedinal			S		Unk		Not Reported	
	Escitalopram [Escitalopram Oxalate]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16483676	EXPEDITED (15-DAY)		HO, LT, OT	US-ELI_LILLY_AND_COMP ANY-US201906012656		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperemesis Gravidarum;	Prozac			S	Unknown	Unk, Unknown		Eli Lilly And Co	

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Live Birth; Maternal	Cymbalta	S	Unknown	Unk Unk, Unknown	Eli Lilly And Co
Exposure During	Duloxetine Hydrochloride	S	Unknown	Unk, Unknown	Not Reported
Pregnancy; Morning	Fluoxetine Hydrochloride	S	Unknown	Unk Unk, Unknown	Eli Lilly And Co
Sickness; Nausea;	Clonazepam	S			Not Reported
Placenta Praevia; Pre-	Methylphenidate	S	Unknown		Not Reported
Eclampsia; Premature	Quetiapine	S	Unknown	50 Mg, Prn	Not Reported
Delivery; Premature	Quetiapine	S	Unknown	25 Mg, Prn	Not Reported
Rupture Of Membranes;	Seroquel	S	Unknown	25 Mg, Prn	Not Reported
Premature Separation Of	Seroquel	S	Unknown	50 Mg, Prn	Not Reported
Placenta	Zoloft	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown		Not Reported
	Prevacid	S	Unknown	Unk	Not Reported
	Topamax	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Concerta	S	Unknown	Unk	Not Reported
	Klonopin	S	Unknown	Unk	Not Reported
	Klonopin	S			Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Aripiprazole	S	Unknown	2.5 Mg, Unk	Not Reported
	Prazosin	S	Unknown	Unk	Not Reported
	Ambien	S	Unknown	Unk	Not Reported
	Wellbutrin	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Ativan	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Zofran [Ondansetron	S	Unknown	Unk	Not Reported
	Hydrochloride]				
	Lorazepam	S	Unknown		Not Reported
	Celexa [Celecoxib]	S	Unknown	Unk	Not Reported

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Sertraline	S	Unknown	Unk	Not Reported
Vitamin B Complex	C	Unknown	Unk	Not Reported
Prenatal Vitamins [Ascorbic Acid;Calcium Pant	C	Unknown	Unk	Not Reported

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27-Jun-2019	16484229	EXPEDITED (15-DAY)		CA, HO, LT, OT	US- ELI_LILLY_AND_COMP ANY-US201906012676			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apgar Score Low; Blood Glucose Decreased; Body Temperature Abnormal; Bradycardia Neonatal; Congenital Foot Malformation; Continuous Positive Airway Pressure; Dyspnoea; Foetal Exposure During Pregnancy; Gastrooesophageal Reflux Disease; Heart Rate Decreased; Hydrocele; Hyperbilirubinaemia Neonatal; Hypotonia Neonatal; Infantile Apnoea; Large For Dates Baby; Macrocephaly; Neonatal Respiratory Distress; Plagiocephaly; Premature Baby; Selective Eating Disorder	Cymbalta			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Transplacental	Unk Unk, Unknown		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Seroquel			S	Transplacental	100 Mg, Unk		Not Reported
	Ambien			S	Transplacental	Unk Unk, Unknown		Not Reported
	Ursodiol			S	Transplacental	Unk, Unknown		Not Reported
	Insulin			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lexapro			S	Transplacental	Unk Unk, Unknown		Not Reported
	Metformin Hydrochloride			S	Transplacental	Unk Unk, Unknown		Not Reported
	Colace			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lovaza			S	Transplacental	Unk, Unknown		Not Reported
	Lithium Carbonate			S	Transplacental	Unk Unk, Unknown		Not Reported
	Amoxicillin			S	Transplacental	Unk Unk, Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]			S	Transplacental	75 Mg, Unk		Not Reported
	Lithium			S	Transplacental	900 Mg, Unk		Not Reported
	Lamictal			S	Transplacental	Unk Unk, Unknown		Not Reported
	Levothyroxine			S	Transplacental	Unk Unk, Unknown		Not Reported
	Lisinopril			S	Transplacental	Unk Unk, Unknown		Not Reported
	Simponi			S	Transplacental	Unk Unk, Unknown		Not Reported
	Effexor			S	Transplacental	300 Mg, Unk		Not Reported

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Reglan [Metoclopramide Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Lamotrigine	S	Transplacental	Unk, Unknown	Not Reported
Levemir	S	Transplacental	Unk Unk, Unknown	Not Reported
Trazodone	S	Transplacental	Unk Unk, Unknown	Not Reported
Clonazepam	S	Transplacental	Unk Unk, Unknown	Not Reported
Wellbutrin	S	Transplacental	Unk Unk, Unknown	Not Reported
Victoza	S	Transplacental	Unk Unk, Unknown	Not Reported
Venlafaxine Xr	S	Transplacental	300 Mg, Unk	Not Reported
Zolpidem	S	Transplacental	Unk Unk, Unknown	Not Reported
Zofran [Ondansetron Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	S	Transplacental	Unk Unk, Unknown	Not Reported
Quetiapine	S	Transplacental	100 Mg, Unk	Not Reported
Lovenox [Enoxaparin Sodium]	S	Transplacental	Unk Unk, Unknown	Not Reported
Adderall	S	Transplacental	Unk Unk, Unknown	Not Reported
Metoclopramide	S	Transplacental	Unk Unk, Unknown	Not Reported
Aripiprazole	S	Transplacental	5 Mg, Unk	Not Reported
Novolog	S	Transplacental	Unk Unk, Unknown	Not Reported
Amoxicillin Trihydrate	S	Transplacental	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16487996	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059475		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haemorrhagic Stroke	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Qd		Mylan
	Inegy			C	Oral	1 Dosage Form, Qd		Mylan
	Spironolactone			C	Oral	75 Milligram, Qd		Mylan
	Cardensiel			C	Oral	1 Dosage Form, Qd		Mylan

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Lasilix /00032601/	C	Oral	60 Milligram, Qd	Mylan
Esomeprazole	C	Oral	20 Milligram, Qd	Mylan

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28-Jun-2019	13895603	NON-EXPEDITED			US-PFIZER INC-2017361004		81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paroxetine Hcl			S		Unk		Not Reported
	Nitrofurantoin Monohyd/M-Cryst			S		Unk		Not Reported
	Amoxicillin-Pot Clavulanate			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16455973	EXPEDITED (15-DAY)		DE, HO, OT	CH-GLAXOSMITHKLINE-CH2019109286		78 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aplasia; Febrile	Wellvone			S	Oral	1500 Mg In The Morning		Glaxosmithkline
Neutropenia;	Diflucan			S	Unknown	400 Mg, Qd		Not Reported
Oesophageal Candidiasis;								

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Off Label Use; Oral Candidiasis; Pseudomonal Sepsis	Benerva	S	Unknown	300 Mg, Qd	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg Unique Total	Not Reported
	Amlodipin	S	Unknown	10 Mg, Unk	Not Reported
	Cipralex	S	Unknown	10 Mg, Unk	Not Reported
	Brufen (Ibuprofen)	S	Unknown	400 Mg, Unk	Not Reported
	Imodium	S	Unknown	2 Mg, Unk	Not Reported
	Novorapid	S	Unknown	Unk	Not Reported
	Levemir	S	Unknown	100 Unk, Unk	Not Reported
	Cefepime	C	Unknown	Unk	Glaxosmithkline
	Bactrim Ds	C	Unknown	Unk	Glaxosmithkline
	Dafalgan	C	Unknown	1 G, Tid	Not Reported
	Aspirin Cardio	C	Unknown	100 Mg, Qd	Not Reported
	Diovan	C	Unknown	80 Mg, Qd	Not Reported
	Diovan	C	Unknown	160 Mg, Qd	Not Reported
	Spiricort	C	Unknown	50 Mg, Qd	Not Reported
	Piperacillin Sodium And Tazobactam Sodium	C	Unknown	Unk	Not Reported
	Esomep	C	Unknown	20 Mg, Qd	Not Reported
	Fragmin	C	Unknown	Unk	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
	Mestinon	C	Unknown	60 Mg, 6 Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16494695	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR- APL-2019-035641			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Paroxetine Tablet			S	Unknown	5 Milligram, Once A Day		Aurobindo
Arthralgia; Bradykinesia;	Paroxetine Tablet			S	Unknown	10 Milligram, Once A Day		Aurobindo
Cogwheel Rigidity;								

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Confusional State; Drug Ineffective; Drug Intolerance; Hyperhidrosis; Myalgia; Parkinsonism; Resting Tremor; Therapy Non-Responder	Paroxetine Tablet	S	Unknown	15 Milligram, Once A Day	Aurobindo
	Olanzapine	S	Oral	15 Milligram, Once A Day	Aurobindo
	Sertraline Capsules	S	Unknown	50 Milligram	Aurobindo
	Citalopram Tablets	S	Oral	10 Milligram, Two Times A Day	Aurobindo
	Citalopram Tablets	S	Oral	100 Milligram, Once A Day	Aurobindo
	Quetiapine Film-Coated Tablet	S	Unknown	25 Milligram, Once A Day	Aurobindo
	Haloperidol	S	Unknown	1 Milligram, Once A Day	Not Reported
	Trazodone	S	Unknown	100 Milligram, Once A Day	Not Reported
	Aricept	S	Unknown	10 Milligram, Once A Day	Not Reported
	Clomipramine	S	Oral	100 Milligram, Once A Day	Not Reported
	Clomipramine	S	Oral	25 Milligram, Once A Day	Not Reported
	Ciprallex	S	Unknown	10 Milligram, Two Times A Day	Not Reported
	Valproic Acid	S	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16497680	EXPEDITED (15-DAY)		CA, HO, OT	US-ELI_LILLY_AND_COMP ANY-US201906012718		2 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chordee; Deformity; Developmental Delay; Drug Withdrawal Syndrome Neonatal; Emotional Distress; Encephalopathy; Eustachian Tube Dysfunction; Foetal Exposure During Pregnancy; Muscular Weakness; Otitis Media Acute; Pain; Penile Torsion; Periventricular	Cymbalta			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Cymbalta			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Bentyl			S	Transplacental	Unk, Unknown		Not Reported
	Bentyl			S	Transplacental	Unk, Unknown		Not Reported
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Transplacental	Unk, Unknown		Not Reported
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Transplacental	Unk, Unknown		Not Reported
	Lortab [Hydrocodone Bitartrate;Paracetamol]			S	Transplacental	Unk, Unknown		Not Reported

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Leukomalacia; Premature Baby; Prepuce Redundant; Skull Malformation; Social Avoidant Behaviour; Tachypnoea	Lortab [Hydrocodone Bitartrate;Paracetamol] Neurontin Neurontin Dilaudid Hp Dilaudid Hp Percocet [Oxycodone Hydrochloride;Paracetamol] Percocet [Oxycodone Hydrochloride;Paracetamol] Topamax Topamax Dulcolax [Bisacodyl] Dulcolax [Bisacodyl] Zofran [Ondansetron] Zofran [Ondansetron] Methadone Methadone Reglan [Metoclopramide] Reglan [Metoclopramide] Lexapro Lexapro Stadol Stadol Miralax Miralax Prenatal Vitamins [Minerals Nos;Vitamins Nos] Prenatal Vitamins [Minerals Nos;Vitamins Nos]	S S S S S S S S S S S S S S S S S S S S S S C C	Transplacental Transplacental	Unk, Unknown Unk, Unknown	Not Reported Not Reported

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28-Jun-2019	16497681	EXPEDITED (15-DAY)		HO	US- ELI_LILLY_AND_COMP ANY-US201906012594		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Disorder; Exposure During Pregnancy; Premature Labour	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co	
	Lexapro			S	Unknown	Unk Unk, Unknown		Not Reported	
	Dulcolax [Bisacodyl]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Dilaudid			S	Unknown	Unk Unk, Unknown		Not Reported	
	Lortab [Hydrocodone Bitartrate;Paracetamol]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Zofran [Ondansetron]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Zofran [Ondansetron]			S				Not Reported	
	Percocet [Oxycodone Hydrochloride;Paracetamol]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Stadol			S	Unknown	Unk, Unknown		Not Reported	
	Miralax			S	Unknown	Unk, Unknown		Not Reported	
	Bentyl			S	Unknown	Unk, Unknown		Not Reported	
	Reglan [Metoclopramide]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Neurontin			S	Unknown	Unk, Unknown		Not Reported	
	Methadone			S	Unknown	Unk, Unknown		Not Reported	
	Topamax			S	Oral	Dosage Form: Unspecified		Not Reported	
	Protonix [Pantoprazole Sodium Sesquihydrate]			S	Unknown	Unk Unk, Unknown		Not Reported	
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16707175	DIRECT		OT				Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Fear; Panic Reaction; Restlessness;	Escitalopram Generic For Lexapro			S	Oral	1 Pill Per Day Mouty	1 MTH	Forest	

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Tension

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2019	16498543	NON-EXPEDITED		OT	US-TEVA-2019-US-1069069			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2019	16502109	DIRECT		OT			29 YR	Transgender	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Psychosexual Disorder	Lexapro			S	Oral	Quantity:30 Tablet(S);		Not Reported
	Invega Sustenna			C				Not Reported
	Cymbalta			C				Not Reported
	Spironlactone			C				Not Reported
	Progesterone			C				Not Reported
	Vitamin D			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	15083465	NON-EXPEDITED			US-CLOVIS ONCOLOGY-CLO-2018-000580		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rubraca			S	Oral	600mg Am/ 300mgpm		Clovis Oncology
Arthralgia; Blood	Rubraca			S	Oral	600 Mg, Bid		Clovis Oncology
Cholesterol Increased;	Rubraca			S	Oral	600 Mg, Bid		Clovis Oncology
Constipation; Cough;	Rubraca			S	Oral	600 Mg Am/300 Mg Pm		Clovis Oncology
Diarrhoea; Dizziness;	Rubraca			S	Oral	600 Mg Am/300 Mg Pm		Clovis Oncology
Fatigue; Increased Upper	Lexapro			S		Unk		Not Reported
Airway Secretion; Joint	Wellbutrin			C				Not Reported
Stiffness; Myalgia;	Trintellix			C				Not Reported
Nasopharyngitis; Nausea;								
Product Dose Omission;								
Rhinorrhoea; Unevaluable								
Event								

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01-Jul-2019	15667650	EXPEDITED (15-DAY)		OT	PHHY2018DE151907		38 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Mg, Qd		Not Reported	
	Levetiracetam			S	Oral	1500 Mg, Qd		Novartis	
	Paroxetine Hydrochloride			S	Oral	30 Mg, Qd		Not Reported	
	Escitalopram			S	Oral	20 Mg, Qd		Not Reported	
	Candesartan Cilexetil			S	Oral	16 Mg, Qd		Not Reported	
	Keppra			S	Unknown	1 Df, Qd		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	L-Thyroxine			C	Oral	Unk		Not Reported	
	Cytotec			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16452191	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1056386		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Faeces; Contraindicated Product Administered; Feeling Hot; Hyperhidrosis; Hypotension; Malaise; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Rash; Respiratory Distress	Aripiprazole			S	Unknown	2 Milligram, Qd		Not Reported	
	Seroplex			S	Unknown	20 Milligram, Qd		Mylan	
	Selincro			S	Oral	1 Dosage Form, Qd		Mylan	
	Loxen /00639802/			C	Unknown	1 Dosage Form, Qd		Mylan	
	Theralene			C	Unknown	2 Dosage Form, Qd		Mylan	
	Corgard			C	Unknown	80 Milligram, Qd		Mylan	
	Methadone			C	Unknown	80 Milligram, Qd		Mylan	
	Lexomil			C	Unknown	1 Dosage Form, Qd		Mylan	
	Kardegic			C	Unknown	Unk Unk, Qd		Mylan	
	Ventolin /00139501/			C	Unknown	Unk		Mylan	

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01-Jul-2019	16457530	EXPEDITED (15-DAY)		HO, OT	RO-MYLANLABS-2019M1056582		54 YR	Male	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Bronchitis; Chest Discomfort; Chronic Gastritis; Condition Aggravated; Decreased Appetite; Depressed Mood; Depression; Depressive Symptom; Dizziness; Drug Ineffective; Dyspnoea; Fatigue; Feeling Guilty; Headache; Helplessness; Hypertension; Illness Anxiety Disorder; Insomnia; Libido Decreased; Loss Of Personal Independence In Daily Activities; Memory Impairment; Obsessive-Compulsive Personality Disorder; Self Esteem Decreased; Somatic Symptom Disorder; Treatment Noncompliance; Weight Decreased	Olanzapine			S	Unknown	15 Milligram, Qd		Not Reported
	Duloxetine			S	Unknown	60 Milligram, Qd		Not Reported
	Quetiapine			S	Unknown	800 Milligram, Qd		Mylan
	Quetiapine			S	Unknown	300 Milligram, Qd		Mylan
	Mirtazapine			S	Unknown	30 Milligram, Qd		Mylan
	Clonazepam			S	Unknown	0.5 Milligram, Qd		Mylan
	Risperidone			S	Unknown	6 Milligram, Qd		Mylan
	Escitalopram			S	Unknown	10 Milligram, Qd		Mylan
	Doxepine			S	Unknown	100 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16458217	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC-2019261492		78 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Aplasia; Febrile Neutropenia; Off Label Use; Product Use	Diflucan			S		400 Mg, 1x/Day		Pfizer	
	Wellvone			S	Oral	1500 Mg, 1x/Day (In The		Not Reported	

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Issue									
	Mabthera	S	Intravenous (not otherwise specified)	Morning)	1000 Mg, Single (1000 Mg Once; In Total)				Not Reported
	Benerva	S			300 Mg, 1x/Day				Not Reported
	Amlodipin Generics	S			10 Mg, Unk				Not Reported
	Ciprallex [Escitalopram Oxalate]	S			10 Mg, Unk				Not Reported
	Brufen	S			400 Mg, Unk (2-3x/Day)				Not Reported
	Imodium	S			2 Mg, Unk (2-3x/Day)				Not Reported
	Novorapid	S			Unk				Not Reported
	Levemir	S			Unk				Not Reported
	Bactrim Ds	C			Unk				Not Reported
	Cefepime	C			Unk				Not Reported
	Piperacillin Sodium And Tazobactam Sodium	C			Unk				Not Reported
	Dafalgan	C			1 G, 3x/Day				Not Reported
	Esomep [Esomeprazole]	C			20 Mg, 1x/Day (1-0-0)				Not Reported
	Fragmin	C			Unk				Not Reported
	Aspirin Cardio	C			100 Mg, 1x/Day (1-0-0)				Not Reported
	Beloc Zok	C			25 Mg, Daily				Not Reported
	Beloc Zok	C			50 Mg, Daily (1-0-0)				Not Reported
	Diovan	C			80 Mg, Daily				Not Reported
	Diovan	C			160 Mg, Daily				Not Reported
	Atorvastatin Pfizer	C			40 Mg, Daily				Not Reported
	Spiricort	C			50 Mg, Daily				Not Reported
	Mestinon	C			60 Mg, 6x/Daily				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16499090	EXPEDITED (15-DAY)		OT	AR-ABBVIE-19K-007-2837340-00			Female	ARG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Epilepsy; Fatigue; Rash	Humira 40mg/0.4ml	S	Subcutaneous	Not Reported
Generalised; Somnolence	Meridian (Escitalopram Oxalate)	S	Unknown	Not Reported

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01-Jul-2019	16499167	EXPEDITED (15-DAY)	HO		SE-JNJFOC-20190631084			Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Depressed	Ipren Unspecified			S	Oral			Not Reported	
Level Of Consciousness;	Lergigan (Promethazine			S	Oral			Not Reported	
Dyskinesia; Intentional	Hydrochloride)			S	Oral			Not Reported	
Overdose; Intentional Self-	Paracetamol			S	Oral			Not Reported	
Injury; Tachycardia	Escitalopram			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16502629	NON-EXPEDITED			US-TEVA-2019-US-1062920			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram			S	Unknown			Ivax	
	Sertraline			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16507491	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1059284		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of	Aripiprazole			S	Oral	10 Milligram, Qd		Not Reported	
Consciousness;	Seresta			S	Oral	1/2cp-1/2cp-/1cp		Mylan	
Rhabdomyolysis;	Tercian /00759302/			S	Oral	1/2cp-1/2cp-/1cp/J		Mylan	
Somnolence	Zyprexa			S	Oral	2 Dosage Form, Qd		Mylan	
	Dafalgan Codeine			S		3 Dosage Form, Qd		Mylan	
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan	
	Oxycontin			S	Oral	2 Dosage Form, Qd		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16508747	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2019M1059727		72 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Respiratory Depression	Escitalopram			S	Oral	Escitalopram 15 Efg: 1 Comprimido/Día Con El Desayuno. Durante El Ingreso En Histórico De Líneas De		Not Reported	
	Neurontin			S	Oral	Neurontín 300: 1 Comprimido Con El Desayuno, Comida Y Cena		Mylan	
	Trankimazin			S	Oral	Trankimazín 1: 1 Comprimido/Día 30 Minutos Antes De Acostarse.		Mylan	
	Durogesic			S	Transdermal	Durogesic: 1 Parche Transdérmico De 100 Microgrs. Y Otro De 50 Microgrs. Cada 72 Horas		Mylan	
	Sevredol			S	Oral	Sevredol 10: 1 Comprimido Si Dolores Importantes A Pesar Del Tratamiento Con Neurontín 300 Y Duroges		Mylan	
	Zovirax /00587301/			S		Unk		Mylan	
	Nolotil /00473101/			C		Unk		Mylan	
	Paracetamol			C		Unk		Mylan	
	Zyloric			C		Unk		Mylan	
	Seguril			C		Unk		Mylan	
	Binocrit			C	Subcutaneous	Unk		Mylan	
	Clexane			C	Subcutaneous	Unk		Mylan	
	Pantoprazol /01263201/			C		Unk		Mylan	

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Natecal D	C	Unk	Mylan
Mycostatin	C	Unk	Mylan
Hidroxil B12 B6 B1	C	Unk	Mylan
Seretide Accuhaler	C	Unk	Mylan
Borea	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16509421	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059420			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Muscle Rigidity; Myoclonus; Salivary Hypersecretion; Serotonin Syndrome	Escitalopram			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16513595	EXPEDITED (15-DAY)		HO, LT	PHHY2019JP150225		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alcohol Interaction; Discomfort; Disorientation; Hyperhidrosis; Hyperreflexia; Muscle Rigidity; Muscular Weakness; Myoclonus; Serotonin Syndrome; Tremor	Clomipramine			S	Unknown	50 Mg, Qd		Novartis	
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Flunitrazepam			C	Unknown	2 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16513980	EXPEDITED (15-DAY)			US-ROCHE-2301395		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Sedation Complication	Clonazepam	S	Unknown		Not Reported
	Lorazepam	S	Unknown		Not Reported
	Escitalopram	S	Unknown		Not Reported
	Clobazam	C	Unknown	15 Mg In The Morning 15mg In The Afternoon 40mg At Night	Not Reported
	Clonidine	C	Unknown	At Night	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16709357	DIRECT	Y	HO			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Obstructive Pulmonary Disease; Pneumonia	Tadalafil Tab			S				Mylan
	Albuterol			C				Not Reported
	Aricept			C				Not Reported
	Escitalopam			S				Not Reported
	Gabapentin			C				Not Reported
	Ipratropium/Sol Albuter			S				Not Reported
	Laxative Tab			C				Not Reported
	Levetiraceta SI			C				Not Reported
	Losartan Pot Tab			C				Not Reported
	Metamucil Pow			C				Not Reported
	Mometasne Cre			C				Not Reported
	Montelukast Tab			C				Not Reported
	Omega-3 Cap			C				Not Reported
	Stool Softner			C				Not Reported
	Synthroid			C				Not Reported
	Tadalafil			C				Not Reported
	Tolterodine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16510697	EXPEDITED (15-DAY)		OT	BR-TORRENT-00005031		43 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gynaecomastia; Nodule; Swelling; Tremor	Espran			S	Oral	Unknown		Torrent

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Addera D3	C		One Capsule Every Monday, Wednesday And Friday	Unknown
Magnesium	C		One Tablet Every Monday, Wednesday, Saturday And Sunday	Unknown
Xenical	C		Unknown	Unknown
Vitamin C	C		Unknown	Unknown
Noripurum	C	Intramuscular	1 Ampoule Of 100 Mg/2ml	Unknown
Aripiprazole	C		One Tablet Of 10 Mg In The Morning	Sandoz
Decan Haloper	C		1 Ampoule Monthly	Unknown
Flavenos	C		2 Tablets In The Morning	Not Reported
Chlorthalidone	C		1 Tablet Daily	Unknown
Zinpass	C		2 Tablets	Not Reported
Cronobe	C		Unknown	Unknown
Omega 3	C		One Tablet Daily, 500/400 Mg	Not Reported
Garlic Oil	C		700 Mg 1 Or 2 Capsules Daily	Unknown
Hidrion	C		1 Tablet Daily	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16514372	EXPEDITED (15-DAY)		DE, HO, OT	CH-JNJFOC-20190627136		78 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Aplasia; Febrile Neutropenia; Off Label Use; Product Use Issue	Fluconazole			S	Unknown	400 Mg, 1x/Day		Not Reported
	Imodium			S	Unknown	2 Mg, Unk (2-3x/Day)		Not Reported
	Wellvone			S	Oral	1500 Mg, 1x/Day (In The Morning)		Not Reported
	Benerva			S	Unknown	300 Mg, 1x/Day		Not Reported
	Mabthera			S	Intravenous (not	1000 Mg, Single (1000 Mg		Not Reported

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			otherwise specified)	Once; In Total)	
Amlodipin Generics	S	Unknown	10 Mg, Unk		Not Reported
Ciprallex [Escitalopram Oxalate]	S	Unknown	10 Mg, Unk		Not Reported
Brufen /00109201/	S		400 Mg, Unk (2-3x/Day)		Not Reported
Novorapid	S	Unknown	Unk		Not Reported
Levemir	S	Unknown	Unk		Not Reported
Bactrim Ds	C	Unknown			Not Reported
Cefepime	C	Unknown			Not Reported
Piperacillin Sodium And Tazobactam Sodium	C	Unknown			Not Reported
Dafalgan	C		1 G, 3x/Day		Not Reported
Esomep [Esomeprazole]	C	Unknown	20 Mg, 1x/Day (1-0-0)		Not Reported
Fragmin	C	Unknown			Not Reported
Aspirin Cardio	C	Unknown	100 Mg, 1x/Day (1-0-0)		Not Reported
Beloc Zok	C	Unknown	25 Mg, Daily		Not Reported
Beloc Zok	C	Unknown	50 Mg, Daily (1-0-0)		Not Reported
Diovan	C	Unknown	80 Mg, Daily		Not Reported
Diovan	C	Unknown	160 Mg, Daily		Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Daily		Not Reported
Spiricort	C	Unknown	50 Mg, Daily		Not Reported
Mestinon	C	Unknown	60 Mg, 6x/Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16522112	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1060827		89 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion	Candesartan			S	Oral	4 Milligram, Qd		Not Reported
	Pantoprazole			S	Oral	40 Milligram, Qd		Not Reported
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Furosemide			S	Oral	10 Milligram, Qd		Not Reported

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Alprazolam	C	Mylan
Spagulax Mucilage Pur	C	Mylan
Gaviscon /00480201/	C	Mylan
Voltarene /00372303/	C	Mylan
Levothyrox	C	Mylan
Rilmenidine	C	Mylan
Eupressyl /00631801/	C	Mylan
Loxen L P	C	Mylan
Uvedose	C	Mylan
Doliprane	C	Mylan
	Unk	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	12696910	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP010675		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Mg, Unk		Apotex
	Clonazepam			S	Oral	0.5 Mg, Tid		Apotex
	Domperidone Maleate Tablets			S	Oral	10 Mg, Bid		Apotex
	Apc-Ferrous Sulfate			S	Oral	300 Mg, Tid		Not Reported
	Gabapentin			S	Oral	300 Mg, Qd		Apotex
	Gabapentin			S	Oral	600 Mg, Bid		Apotex
	Temazepam			S	Oral	30 Mg, Qd		Not Reported
	Acetaminophen W/Codeine Phosphate			S	Oral	2 Df, Tid		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported
	Multivitamins W/Minerals			S	Oral	2 Df, Qd		Not Reported
	Cipralex /01588501/			S	Oral			Not Reported
	Cipralex /01588501/			S	Oral	20 Mg, Unk		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid, 3 Every 1 Day		Not Reported
	Vitalux /01586901/			S	Oral	Unk, Bid, Two Times A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	15710328	NON-EXPEDITED			US-PFIZER INC-2018507704		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Tramadol			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Benadryl			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16469396	EXPEDITED (15-DAY)		CA, HO	CA-APOTEX-2019AP016709		1 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; High-Pitched Crying; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram			S	Transplacental	20 Mg, Qd, 1 Every 1 Day		Apotex	
	Gabapentin			S	Transplacental	1800 Mg, Qd, 1 Every 1 Day		Apotex	
	Nortriptyline			S	Transplacental	20 Mg, Qd, 1 Every 1 Day		Not Reported	
	Quetiapine			S	Transplacental	300 Mg, Q.12h, 1 Every 12 Hours		Apotex	
	Rabeprazole			S	Transplacental	Unk		Apotex	
	Zopiclone			S	Transplacental	Unk		Not Reported	
	Benzotropine			S	Transplacental	1.5 Mg, Qd, 1 Every 1 Day		Not Reported	
	Benzotropine			S	Transplacental	1.5 Mg, Qd		Not Reported	
	Methadone			S	Transplacental	70 Mg, Qd, 1 Every 1 Day		Not Reported	
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Mg, Qd		Not Reported	

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03-Jul-2019	16503964	EXPEDITED (15-DAY)		DE, HO	CH-MYLANLABS-2019M1061082		78 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aplasia; Febrile Neutropenia; Off Label Use	Brufen			S		400 Milligram, (2 -3 Per Day)		Mylan
	Wellvone			S	Oral	1500 Milligram (Morgens)		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram, Total (1st And Only Administration)		Mylan
	Diflucan			S		400 Milligram, Qd		Mylan
	Benerva			S		300 Milligram, Qd		Mylan
	Amlodipin Generics			S		10 Milligram		Mylan
	Cipralex /01588502/			S		10 Milligram		Mylan
	Imodium			S		2 Milligram, (2-3 Per Day)		Mylan
	Novorapid			S		Unk		Mylan
	Novorapid			S		Unk		Mylan
	Levemir			S		Unk		Mylan
	Levemir			S		Unk		Mylan
	Esomep /01479301/			C		20 Milligram, Qd		Mylan
	Fragmin			C		5000 International Unit		Mylan
	Aspirin Cardio			C		100 Milligram, Qd		Mylan
	Beloc Zok			C		25 Milligram		Mylan
	Beloc Zok			C		50 Milligram, Qd		Mylan
	Diovan			C		80 Milligram, Qd		Mylan
	Diovan			C		160 Milligram, Qd		Mylan
	Atorvastatin Pfizer			C		40 Milligram, Qd		Mylan
	Spiricort			C		50 Milligram, Qd		Mylan
	Mestinon			C	Oral	60 Milligram, 6xd		Mylan
	Bactrim Ds			C		Unk		Mylan

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	Cefepime		C		Unk		Mylan		
	Piperacillin Sodium And Tazobactam Sodium		C		Unk		Mylan		
	Dafalgan		C		1 Gram, Tid		Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16528763	NON-EXPEDITED			US-TEVA-2019-US-1062613			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Gluten Sensitivity	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16532558	DIRECT					30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia; Arthralgia; Contusion; Erythema; Joint Swelling	Escitalopram			S	Oral	Quantity:1 Tablet(S);		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16489399	EXPEDITED (15-DAY)		OT	CH-ALKEM LABORATORIES LIMITED-CH-ALKEM-2019-05886		46 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Esomeprazole Magnesium			S	Unknown	40 Milligram, Qd		Alkem	
	Escitalopram			S	Unknown	10 Milligram, Bid		Not Reported	
	Ritonavir-Boosted Darunavir			S	Unknown	Darunavir 600 Mg/Ritonavir 100 Mg, Bid		Not Reported	
	Ritonavir-Boosted Darunavir			S				Not Reported	
	Emtricitabine/Tenofovir			C	Unknown	200 Mg/245 Mg, Qd		Not Reported	
	Emtricitabine/Tenofovir			C				Not Reported	

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04-Jul-2019	16527442	EXPEDITED (15-DAY)		OT	IT-SA-2019SA176219		73 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Sodium Decreased	Aprovel			S	Oral	1 Df, Qd		Sanofi	
	Coaprovel			S	Oral	1 Df, Qd		Sanofi	
	Escitalopram Oxalate			S		1 Df, Qd		Not Reported	
	Lorazepam			C				Not Reported	
	Debridat [Trimebutine]			C				Not Reported	
	Movicol [Macrogol;Potassium Chloride;Sodium Bicarbonate;Sodium Chlorid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16529852	EXPEDITED (15-DAY)		OT	FR-ACCORD-137015		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16530009	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1071938			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Acetaminophen/Codeine Phosphate			S	Oral	6 Dosage Forms Daily;		Actavis	
	Clonazepam			S	Unknown	1.5 Milligram Daily;		Teva	
	Domperidone			S	Unknown	20 Milligram Daily;		Not Reported	
	Gabapentin			S	Oral	300 Milligram Daily;		Actavis	
	Gabapentin			S	Oral	1200 Milligram Daily;		Actavis	
	Cipralext [Escitalopram]			S	Oral			Not Reported	
	Co Temazepam			S	Oral	30 Milligram Daily;		Not Reported	

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Ferrous Sulfate	S	Unknown	900 Milligram Daily;	Not Reported
Wellbutrin XL	S	Oral	300 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16530844	EXPEDITED (15-DAY)		DE, HO, OT	PL-LUPIN PHARMACEUTICALS INC.-2019-03940		69 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antiphospholipid Antibodies; Pulmonary Embolism	Mirtazapine			S	Unknown	30 Milligram, Qd		Not Reported
	Mirtazapine			S	Unknown	45 Milligram, Qd (Another 12 Months To The Second Vte Episode)		Not Reported
	Paroxetine			S	Unknown	20 Milligram, Qd		Lupin
	Sertraline			S	Unknown	100 Milligram, Qd		Lupin
	Venlafaxine			S	Unknown	225 Milligram, Qd		Not Reported
	Quetiapine			S	Unknown	100 Milligram, Qd		Lupin
	Quetiapine			S		300 Milligram, Qd (Another 12 Months To The Second Vte Episode))		Lupin
	Escitalopram			S	Unknown	20 Milligram, Qd		Lupin
	Olanzapine			S	Unknown	5 Milligram, Qd		Not Reported
	Reboxetine			S	Unknown	4 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16531290	EXPEDITED (15-DAY)		OT	KR-ROCHE-2344679		35 YR	Male	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parkinsonism	Clonazepam			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

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Zolpidem	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16532026	EXPEDITED (15-DAY)	HO		SE-ACCORD-136791			Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Depressed Level Of Consciousness;	Escitalopram			S	Oral			Not Reported
Dyskinesia; Intentional Overdose; Intentional Self-Injury; Tachycardia	Paracetamol			S	Oral			Accord
	Ibuprofen			S	Oral			Accord
	Lergigan (Promethazine)			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	15585112	EXPEDITED (15-DAY)	HO		JP-ALLERGAN-1851976US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Muscle Spasms; Thirst; Vomiting	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Sulpiride			S	Oral	Unk		Not Reported
	Desmopressin			C	Nasal			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16450184	EXPEDITED (15-DAY)	OT		US-TORRENT-00008900		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Choking; Condition Aggravated; Drug Ineffective; Dysphagia; Extrapyramidal Disorder; Oesophageal Obstruction	Olanzapine			S	Oral	At Bedtime		Unknown
	Escitalopram			S	Oral			Unknown
	Lorazepam			C	Oral			Unknown
	Mirtazapine			S	Oral	At Bedtime		Unknown
	Temazepam			C	Oral	At Bedtime As Needed (Prn)		Unknown

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Levothyroxine	C	Oral		Unknown
Metoprolol Tartrate	C	Oral	25 Mg Every 12 Hours	Unknown
Potassium Chloride	C			Unknown
Pantoprazole	C	Oral		Unknown
Losartan	C	Oral		Unknown
Benzotropine	C		Unknown	Unknown
Haloperidol	C	Intramuscular	2 To 4 Mg Prn	Unknown
Docusate	C		Unknown	Unknown
Olanzapine	S	Intramuscular	As Needed (Maximum Of 5 Mg Im Per Day)	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16534660	NON-EXPEDITED			US-SUNOVION-2019SUN002768		23 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sexual Dysfunction	Latuda			S	Oral	40 Mg		Sunovion
	Lexapro			S	Unknown	Unk (Decreased)		Not Reported
	Lexapro			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16534702	EXPEDITED (15-DAY)		OT	PHHY2019KR152143		35 YR	Male	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Freezing Phenomenon;	Clonazepam			S	Unknown	0.5 Mg, Qd		Not Reported
Gait Disturbance;	Zolpidem			S	Unknown	12.5 Mg, Qd		Novartis
Movement Disorder;	Escitalopram			S	Unknown	5 Mg, Qd		Not Reported
Parkinsonism; Product	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
Use In Unapproved	Risperidone			S	Unknown	1.5 Mg, Qd		Not Reported
Indication; Reduced Facial	Risperidone			S	Unknown	1.5 Mg, Qd		Not Reported
Expression; Speech	Lorazepam			S	Unknown	1 Mg, Qd		Not Reported
Disorder								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16535621	NON-EXPEDITED			US-PFIZER INC-2019286122			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown	
	Flagyl			S		Unk		Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Nitrofurantoin			S		Unk		Not Reported	
	Paroxetine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16535753	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-137117		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning, Started On 5mg Increasing To 15mg Once A Day In The Morning		Not Reported	
	Evorel Conti			C				Not Reported	
	Diazepam			C		At Night.		Not Reported	
	Ropinirole/Ropinirole Hydrochloride			C				Not Reported	
	Fexofenadine/Fexofenadine Hydrochloride			C				Not Reported	
	Codeine			C				Not Reported	
	Phosphate/Paracetamol							Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16535831	EXPEDITED (15-DAY)		OT	KR-STRIDES ARCOLAB LIMITED-2019SP005710		35 YR	Male	KOR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gait Disturbance; Movement Disorder; Parkinsonism; Reduced Facial Expression; Speech Disorder	Zolpidem			S	Unknown	12.5 Mg/Day, Unk		Strides
	Clonazepam			S	Unknown	0.5 Mg/Day, Unk		Not Reported
	Risperidone			S	Unknown	3 Mg/Day, Unk		Not Reported
	Risperidone			S	Unknown	1.5 Mg/Day, Unk,(Dose Decreased)		Not Reported
	Lorazepam			S	Unknown	1 Mg/Day, Unk		Not Reported
	Escitalopram			S	Unknown	5 Mg/Day, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16536095	NON-EXPEDITED			US-PFIZER INC- 2019284124		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Confusional State; Cough; Decreased Appetite; Depression; Disturbance In Attention; Dysphonia; Fatigue; Insomnia; Memory Impairment; Muscle Tightness; Musculoskeletal Stiffness; Peripheral Swelling; Speech Disorder; Weight Decreased	Desvenlafaxine Succinate Monohydrate			S	Oral	10 Mg, Daily		Pfizer
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2019	15603666	EXPEDITED (15-DAY)		OT	DE-ALLERGAN- 1852706US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Pregnancy	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan
	Paroxetine			S	Oral	30 Mg, Qd		Not Reported
	Levetiracetam			S	Oral	1500 Mg, Qd		Not Reported

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	Nepresol (Dihydralazine Sulfate)	S	Oral	25 Mg, Qd	Not Reported
	Candesartan	S	Oral	16 Mg, Qd	Not Reported
	L-Thyroxin	C	Oral		Not Reported
	Cytotec	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2019	15605519	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2018-054457			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Maternal Exposure During Pregnancy; Off Label Use	Levetiracetam			S	Oral	1500 Milligram, Once A Day		Aurobindo
	Paroxetine			S	Oral	30 Milligram, Once A Day Stopped On 03-Nov-2017		Aurobindo
	Candesartan			S	Oral	16 Milligram, Once A Day Stopped On 03-Nov-2017		Not Reported
	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Nepresol (Dihydralazine Sulfate)			S	Oral	25 Milligram, Once A Day		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	L-Thyroxin			C	Oral	Unk		Not Reported
	Cytotec			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2019	16540282	DIRECT		DS			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Manufacturing Materials Issue; Product Quality Issue; Product Substitution Issue; Symptom Recurrence	Escitalopram 20 Mg Tab - Shape Round, Color White, Side 1 P20			S	Oral	Quantity:1 Tablet(S);		Prinston Pharmaceutical

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	15932618	EXPEDITED (15-DAY)		DE, HO, LT	CA-PFIZER INC-2019050581		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Ibuprofen			S	Oral	400 Mg, As Needed		Pfizer	
	Ciprallex [Escitalopram]			S	Oral	10 Mg, 1x/Day		Not Reported	
	Diclofenac			S	Oral	50 Mg, 2x/Day		Not Reported	
	Diclofenac			S	Oral	2 Df(Dosage Form), 1x/Day		Not Reported	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Eliquis			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16366044	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020591		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Mood Altered; Product Substitution Issue; Sleep Disorder	Mirtazapine			S	Oral	30 Mg, Qd		Apotex	
	Mirtazapine			S				Apotex	
	Ciprallex /01588501/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539264	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP017589			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematemesis	Azathioprine			S	Unknown	Unk		Apotex	
	Propranolol			S	Oral	40 Mg, Bid		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Marijuana			S	Unknown	Unk, Qd		Not Reported	
	Pentasa			S	Unknown	Unk		Not Reported	

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Premarin			S	Oral	0.625 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539562	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1034664			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Drug Abuse; Fall; Malaise; Overdose; Presyncope	Olanzapine			S	Oral	20 Mg, Total		Not Reported	
	Olanzapine			S		10 Mg, Qd		Not Reported	
	Mirtazapine			S	Oral	60 Mg, Total		Not Reported	
	Mirtazapine			S		30 Mg, Qd		Not Reported	
	Cipralex /01588502/			S	Oral	2 Df, Total		Mylan	
	Cipralex /01588502/			S		20 Mg, Qd		Mylan	
	Lyrica			C		Unk		Mylan	
	Folina /00024201/			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539901	NON-EXPEDITED			US-PFIZER INC-2019287635		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Spirolonolactone			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16540000	EXPEDITED (15-DAY)		DE, HO, OT	CH-NOVOPROD-670240		78 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia; Febrile Neutropenia; Oesophageal Candidiasis; Off Label Use; Oral	Levemir			S	Unknown	Unk		Novo Nordisk	
	Levemir			S	Unknown	Unk		Novo Nordisk	
	Levemir			S	Unknown	100ie/MI		Novo Nordisk	

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Candidiasis;	Novorapid	S	Unknown	Unk	Novo Nordisk
Pneumocystis Jirovecii	Novorapid	S	Unknown	Unk	Novo Nordisk
Pneumonia; Pseudomonal	Novorapid	S	Unknown	100iu/MI	Novo Nordisk
Sepsis	Wellvone	S	Oral	1500 Mg, Qd	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg, Single	Not Reported
	Diflucan	S	Unknown	400 Mg, Qd	Not Reported
	Benerva	S	Unknown	300 Mg	Not Reported
	Amlodipin Generics	S	Unknown	10 Mg	Not Reported
	Cipralex [Escitalopram Oxalate]	S	Unknown	10 Mg	Not Reported
	Ibuprofen	S	Unknown	400 Mg 2- 3/Per Day	Not Reported
	Loperamide	S	Unknown	2mg 2-3/Per Day	Not Reported
	Dafalgan	C	Unknown	1 G, Tid	Not Reported
	Esomep [Esomeprazole]	C	Unknown	20 Mg, Qd	Not Reported
	Fragmin	C	Unknown	5000 Ui Admission Medication From Rehab	Not Reported
	Aspirin Cardio	C	Unknown	100 Mg, Qd	Not Reported
	Beloc Zok	C	Unknown	25 Mg, Qd	Not Reported
	Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
	Diovan	C	Unknown	40 Mg, Qd	Not Reported
	Diovan	C	Unknown	160 Mg, Qd	Not Reported
	Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
	Spiricort	C		50 Mg, Qd	Not Reported
	Mestinon	C		60 Mg 6x/Per Day	Not Reported
	Neostigmine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16541333	EXPEDITED (15-DAY)		DE, HO, LT	DE-ASTRAZENECA-2019SE95881		74 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Depressed Mood; Gastrointestinal Haemorrhage; Haematochezia; Hypertension; Hyponatraemia; Product Prescribing Error; Suicidal Ideation	Brilique Aspirin Protect Cipralelex Mirtazapine Aprovel Beloc-Zok Pantoprazol Spironolactone Torasemide Sortis Zopiclon	S S S C C C C C C C C C	Oral Oral Oral Oral Oral Oral Oral Oral Oral Oral Oral Oral	20 Mg, Pause, Drops 50 Mg, 0.5-0-0-0 7.5 Mg, On Demand	Astrazeneca Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16541939	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS- 2018M1026098		68 YR	Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Food Interaction; Haemodynamic Instability; Haemorrhage	Escitalopram Emconcor Simvastatin Hibor Cipralelex /01588501/			S C C C C	Unknown Oral Oral Subcutaneous C	Unk At Breakfast And Dinner, Every 12 Hours At Dinner 3500 Iu Anti-Xa/0.2 MI Solution For Injection In Pre-Filled Syringe; In The Evening At Breakfast, For Several Years		Not Reported Mylan Mylan Mylan Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16739027	DIRECT		HO			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Affect Lability; Anxiety;	Escitalopram 20 Mg Daily	S	Teva
Depression; Fear;	Escitalopram 20 Mg Daily	S	Teva
Hyperhidrosis;	Nexium	S	Not Reported
Palpitations; Panic Attack;			
Product Substitution Issue;			
Sleep Disorder;			
Withdrawal Syndrome			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16460905	EXPEDITED (15-DAY)			FR-ALLERGAN-1925506US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Aripiprazole			S	Unknown	20 Mg, Qd		Not Reported	
	Aripiprazole			S	Unknown	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16542776	EXPEDITED (15-DAY)		HO, OT	GB-CIPLA LTD.-2019GB04929			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	5 Milligram Increasing To 15mg Once A Day In The Morning		Invagen	
	Escitalopram			S	Oral	15 Milligram, Qd (Morning)		Invagen	
	Diazepam			C	Unknown	2 Milligram, Qd At Night		Not Reported	
	Ropinirole			C	Unknown	0.5 Milligram, Unk		Not Reported	
	Fexofenadine			C	Unknown	Unk		Not Reported	
	Co-Codamol			C	Unknown	Unk		Not Reported	
	Evorel Conti			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16543445	EXPEDITED (15-DAY)		OT	SE-ACCORD-137661		63 YR	Male	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram			S				Not Reported	
	Phenylephrine			S		Strength 2.5% One Drop Per Eye		Not Reported	
	Selokenzoc			C				Not Reported	
	Trombyl			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16545328	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1062450		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura; Rash Pruritic	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Alprazolam			S	Oral	0.25 Milligram, Qd		Not Reported	
	Xgeva			S	Subcutaneous	120 Milligram, Total		Mylan	
	Aromasine			C	Oral	25 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16545728	EXPEDITED (15-DAY)		OT	SE-TEVA-2019-SE-1074200		63 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram			S	Unknown	10mg		Ivax	
	Phenylephrine Hydrochloride			S		"2.5% Strength" One Drop Per Eye		Not Reported	
	Selokenzoc			C		50mg		Not Reported	
	Trombyl			C		75mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16547007	EXPEDITED (15-DAY)		HO	PHHY2019DE155948		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Pregabalin			S	Unknown	75 Mg, Unk		Not Reported	

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Zolpidem	S	Unknown	10 Mg, Qd (0-0-1-0)	Novartis
Mirtazapine	S	Unknown	45 Mg, Qd (0-0-1-0)	Not Reported
Lamotrigine	S	Unknown	50 Mg, Qd (1-0-1-0)	Not Reported
Cipralext	S	Unknown	10 Mg, Qd (1-0-0-0)	Not Reported
Elontril	S	Unknown	150 Mg, Qd (1-0-0-0)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16548302	EXPEDITED (15-DAY)	HO		IT-ALLERGAN-1923145US			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Overdose; Vertigo	Escitalopram Oxalate - Bp			S	Oral	40 Gtt		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16167699	EXPEDITED (15-DAY)	CA, HO		CA-MALLINCKRODT-T201902873		1 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Methadose			S	Transplacental	Unk		Mallinckrodt	
	Benzotropine Mesylate			S	Transplacental	Unk		Not Reported	
	Escitalopram			S	Transplacental	Unk		Not Reported	
	Gabapentin			S	Transplacental	Unk		Not Reported	
	Nortriptyline			S	Transplacental	Unk		Not Reported	
	Quetiapine			S	Transplacental	Unk		Not Reported	
	Rabeprazole			S	Transplacental	Unk		Not Reported	
	Zopiclone			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16245265	EXPEDITED (15-DAY)	HO		CA-GLAXOSMITHKLINE-CA2019GSK069199			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Asthma; Blood Count	Salbutamol Sulphate	S	Unk	Glaxosmithkline
Abnormal; Chest	Breo Ellipta	S	Unk	Glaxosmithkline
Discomfort; Chest X-Ray	Levothyroxine	S	Unk	Glaxosmithkline
Abnormal; Condition	Theophylline	S	Unk	Glaxosmithkline
Aggravated; Cough; Drug	Escitalopram	S	Unk	Glaxosmithkline
Ineffective; Dyspnoea;	Zantac	S	Unk	Glaxosmithkline
Forced Expiratory Volume	Singular	S	Unk	Glaxosmithkline
Decreased; Forced Vital	Solu-Medrol	S	Unk	Not Reported
Capacity Decreased;	Zithromax	S	Unk	Not Reported
Gastrooesophageal Reflux	Tazocin	S	Unk	Not Reported
Disease; Lung Disorder;	Cipralex	S	Unk	Not Reported
Lung Hyperinflation;	Inspiolto	S	Unk	Not Reported
Malaise; Nasal	Atrovent	S	Unk	Not Reported
Congestion; Obstructive	Amlodipine	S	Unk	Not Reported
Airways Disorder;	Uniphyl	S	Unk	Not Reported
Obstructive Airways	Synthroid	S	Unk	Not Reported
Disorder; Oropharyngeal	Spiriva	S	Unk	Not Reported
Pain; Pain In Extremity;	Prednisone	S	Unk	Not Reported
Rhinorrhoea; Sputum				
Discoloured; Therapeutic				
Product Effect Incomplete;				
Total Lung Capacity				
Abnormal; Weight				
Increased; Wheezing				

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10-Jul-2019	16551432	EXPEDITED (15-DAY)		HO, OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022017			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged;	Escitalopram			S	Oral	5 Milligram, Started On		Macleods	
Breast Swelling; Breast						5mg Increasing To 15mg			
Tenderness; Gingival						Once A Day In The			
Bleeding; Postmenopausal						Morning			
Haemorrhage; Spider	Escitalopram			S	Oral	15 Milligram, Qd Morning		Macleods	
Naevus	Diazepam			C	Unknown	2 Milligram, Qd At Night		Not Reported	

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Ropinirole	C	Unknown	0.5 Milligram	Not Reported
Fexofenadine	C	Unknown	Unk	Not Reported
Co-Codamol	C	Unknown	Unk	Not Reported
Evorel Conti	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16551464	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1063264		68 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Food Intolerance; Gastrointestinal Pain; Migraine; Nausea; Nervous System Disorder; Serotonin Syndrome	Escitalopram			S	Oral	Startdosis 5mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16551538	EXPEDITED (15-DAY)			US-ELI_LILLY_AND_COMP ANY-US201906009777			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Nausea; Oropharyngeal Pain; Pruritus; Psoriasis; Vomiting	Prozac			S	Unknown	Unk, Unknown		Eli Lilly And Co	
	Abilify			S	Unknown	Unk, Unknown		Not Reported	
	Lexapro			S	Unknown	Unk, Unknown		Not Reported	
	Lithium			S	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16553002	NON-EXPEDITED			US-TEVA-2019-US-1073310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax	

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11-Jul-2019	13047349	EXPEDITED (15-DAY)		OT	DE-GILEAD-2016-0249810		48 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Ledipasvir/Sofosbuvir			S	Oral	90 Mg, Qd		Gilead	
	Ribavirin			S	Oral	600 Mg, Bid		Not Reported	
	Ribavirin			S	Oral	400 Mg, Bid		Not Reported	
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Braunovidon			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	14319717	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2017539420		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Loratadine			S	Oral	Unk		Pfizer	
	Levothyroxine Sodium			S	Oral	Unk		Pfizer	
	Folic Acid			S	Oral	Unk		Pfizer	
	Furosemide			S	Oral	Unk		Not Reported	
	Escitalopram			S	Oral	Unk		Not Reported	
	Ethylene Glycol			S	Oral	Unk		Not Reported	
	Vitamin B-1			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16372916	EXPEDITED (15-DAY)		HO	ES-ALLERGAN-1922523US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypomagnesaemia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Trazodone			S	Unknown	Unk		Not Reported	

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Enalapril, Hydrochlorothiazida	S	Unknown	Unk	Not Reported
Aristo	S	Unknown	Unk	Not Reported
Omeprazole	C	Unknown	Unk	Not Reported
Metformin				

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11-Jul-2019	16557136	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038411			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Prescribed Overdose; Rash; Vasculitis	Terbinafine			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Cipraxel			S	Oral	30 Milligram, Once A Day		Not Reported	
	Cipraxel			S				Not Reported	
	Trintellix			S	Oral	10 Milligram, Once A Day		Not Reported	
	Trintellix			S				Not Reported	
	Amitriptyline			C	Oral	100 Milligram, Once A Day		Not Reported	
	Clonazepam			C	Oral	1 Milligram, 3 Times A Day		Not Reported	
	Clonazepam			C				Not Reported	
	Isophane Insulin			C	Subcutaneous	Unk		Not Reported	
	Nozinan			C	Oral	37.5 Milligram, Once A Day		Not Reported	
	Rosuvastatin Calcium			C	Oral	5 Milligram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16557650	EXPEDITED (15-DAY)		LT	PHHY2019FR158972		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	20 Mg, Unk		Novartis	
	Escitalopram			S	Oral	60 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16557660	EXPEDITED (15-DAY)		HO	PHHY2019FR158989		94 YR	Female	FRA

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Haemorrhage	Pantoprazole			S	Oral	10 Mg, Qd		Novartis	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Coumadine			S	Oral	6 Mg, Qd		Not Reported	
	Coumadine			S	Oral	6 Mg, Qd		Not Reported	
	Doliprane			S	Oral	3 G, Qd		Not Reported	
	Lasilix			C	Oral	60 Mg, Qd		Not Reported	
	Diffu K			C	Oral	600 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16557692	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019295009		92 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Interstitial Lung Disease	Venlafaxine Hcl			S		37.5 Mg, 1x/Day		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Duloxetine Dr			S		15 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16557971	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-213363		35 YR	Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Risperidone			S	Unknown	3 Milligram, Daily		Ranbaxy	
	Risperidone			S	Unknown	Tappered Off Gradually Over 4 Weeks		Ranbaxy	
	Risperidone			S	Unknown	1.5 Milligram, Daily		Not Reported	
	Lorazepam			S	Unknown	1 Milligram, Daily		Sun	
	Lorazepam			S	Unknown	Tappered Off Gradually Over 4 Weeks		Sun	
	Zolpidem			S	Unknown	12.5 Milligram, Daily		Sun	

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Zolpidem	S	Unknown	Tapered Off Gradually Over 4 Weeks	Sun
Escitalopram	S	Unknown	5 Milligram, Daily	Not Reported
Escitalopram	S	Unknown	Tapered Off Gradually Over 4 Week	Not Reported
Clonazepam	S	Unknown	0.5 Milligram, Daily	Sun
Clonazepam	S	Unknown	Tapered Off Gradually Over 4 Weeks	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16558187	EXPEDITED (15-DAY)		HO, OT	GB-TORRENT-00021359		61 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning		Unknown
	Diazepam			C		At Night		Unknown
	Ropinirole			C		Unknown		Unknown
	Fexofenadine			C		Unknown		Unknown
	Co-Codamol			C		Unknown		Unknown
	Evorel Conti			C		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16558365	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS-2019M1063208		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Ciprofloxacin			S	Oral	500 Milligram, Qd,1000 Milligram		Not Reported
	Pamidronate			S	Intravenous drip	30 Milligram, Qd		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Seroplex			S	Oral	1 Dosage Form, Qd		Mylan
	Augmentin /00756801/			S	Oral	1 Gram, Qd,3 Gram		Mylan
	Dexamethasone			S	Oral	40 Milligram, Qw,5.7143		Mylan

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			Milligram	
Zyloric	S	Oral	300 Milligram, Qd	Mylan
Revlimid	S	Oral	25 Milligram, Q28d,25 Milligram	Mylan
Paracetamol	C	Unknown	Unk	Mylan
Zelitrex	C	Oral	Unk	Mylan
Zelitrex	C	Oral	1 Dosage Form, Qd	Mylan
Zelitrex	C	Oral	500 Milligram, Qd,1000 Milligram	Mylan
Lyrica	C	Oral	Unk	Mylan
Lyrica	C	Oral	25 Milligram, Qd,50 Milligram	Mylan
Durogesic	C	Unknown	Unk	Mylan
Gaviscon /01405501/	C	Unknown	Unk	Mylan
Movicol /01749801/	C	Unknown	Unk	Mylan
Lovenox	C	Subcutaneous	Unk	Mylan
Lovenox	C	Subcutaneous	7000 International Unit, Qd,14000 lu (International Unit)	Mylan
Bactrim	C	Oral	400 Milligram, Qw,400 Milligram	Mylan
Bactrim	C	Oral	Unk	Mylan
Seresta	C	Oral	Unk	Mylan
Seresta	C	Oral	10 Milligram, Qd	Mylan
Mianserine /00390602/	C	Oral	30 Milligram, Qd,30 Milligram	Mylan
Mianserine /00390602/	C	Oral	Unk	Mylan
Tamiflu	C	Unknown	Unk	Mylan
Furosemide	C	Unknown	20 Milligram	Mylan
Previscan /00261401/	C	Unknown	15 Milligram, Qd,15 Milligram	Mylan

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Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16558713	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2019M1063232			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Transposition Of The Great Vessels	Escitalopram			S	Transplacental	10 [Mg/D (5)]		Not Reported	
	Skinoren			C	Transplacental	Unk		Mylan	
	Folic Acid			C	Transplacental	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16561413	NON-EXPEDITED			US-TEVA-2019-US-1073765			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity; Rash Macular; Reaction To Excipient; Urticaria	Hydralazine			S	Unknown			Actavis	
	Benazepril Hydrochloride Tablet 20 Mg			S	Oral	20 Milligram Daily;		Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Metoprolol Succinate Er			C	Unknown			Not Reported	
	Synthroid			C				Not Reported	
	Premarin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16561955	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2019-GB-1074942		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Morning, 15mg		Ivax	
	Escitalopram			S	Oral	Started On 5mg Increasing To 15mg Once A Day In The Morning		Ivax	
	Diazepam			C		At Night.		Not Reported	
	Ropinirole			C				Not Reported	

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		Fexofenadine		C					Not Reported
		Co-Codamol		C					Not Reported
		Evorel Conti		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562012	NON-EXPEDITED			US-PFIZER INC-2019292527		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Hyperhidrosis; Impaired Work Ability; Memory Impairment; Panic Attack; Tremor	Gabapentin			S		Unk		Pfizer	
	Abilify			S		Unk		Not Reported	
	Abilify			S		2 Mg, Unk		Not Reported	
	Aripiprazole			S		5 Mg, Unk		Not Reported	
	Rexulti			S		Unk		Not Reported	
	Rexulti			S				Not Reported	
	Lexapro			S		Unk		Not Reported	
	Paxil [Piroxicam]			C		Unk		Not Reported	
	Lithium			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1064151			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Macular Fibrosis; Varicose Vein; Visual Acuity Reduced	Escitalopram			S		5 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562494	EXPEDITED (15-DAY)		HO, LT	DE-ALLERGAN-1928164US		74 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Gastrointestinal Haemorrhage;	Escitalopram Oxalate - Bp			S	Oral	Actual: 20 Mg, Pause, Tropfen20mg/MI		Allergan	

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Haematochezia; Hypertension; Hyponatraemia; Product Prescribing Error; Suicidal Ideation	Brilique	S	Oral	Actual: 90 Mg, 1-0-1-0, Tabletten	Not Reported
	Aspirin Protect	S	Oral	Actual: 100 Mg, 1-0-0-0, Tabletten	Not Reported
	Mirtazapin Hexal	C	Oral	7.5 Mg, 1-0-0-0, Tabletten	Not Reported
	Aprovel	C	Oral	75 Mg, 1-0-0-0, Tabletten	Not Reported
	Beloc-Zok	C	Oral	47.5 Mg, 1-0-0-0, Retard- Tabletten	Not Reported
	Pantoprazol	C	Oral	40 Mg, 1-0-0-0, Tabletten	Not Reported
	Spironolacton	C	Oral	50 Mg, 0.5-0-0-0, Tabletten	Not Reported
	Torasemid	C	Oral	5 Mg, 1-0-0-0, Tabletten	Not Reported
	Sortis	C	Oral	20 Mg, 0-0-1-0, Tabletten	Not Reported
	Zopiclon	C	Oral	7.5 Mg, Bedarf, Tabletten	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16008673	EXPEDITED (15-DAY)		OT	US-ALLERGAN- 1906192US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affect Lability; Anxiety; Breast Cancer Recurrent; Depression; Disturbance In Attention; Fatigue; Feeling Abnormal; Panic Attack; Therapy Cessation	Escitalopram Oxalate 10mg Tab (Tbd)			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate 10mg Tab (Tbd)			S				Allergan
	Clonopine			C				Not Reported
	Clonopine			C				Not Reported
	Atenolol			C	Oral	50 Mg Qam, 25 Mg Qhs		Not Reported
	Hctz			C	Oral	12.5 Mg, Unk		Not Reported
	Hydroxyzine			C		5 Mg, Unk		Not Reported
	Hydroxyzine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16564382	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-137985		67 YR	Male	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Mg / Day		Not Reported	
	Warfarin			S				Not Reported	
	Perindopril			C				Not Reported	
	Metformin			C				Not Reported	
	Isosorbide			C				Not Reported	
	Atorvastatin/Ezetimibe			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16564464	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR- APL-2019-040005			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram			S	Oral	Started On 5mg Increasing To 15mg Once A Day In The Morning		Aurobindo	
	Escitalopram			S	Oral	Morning		Aurobindo	
	Diazepam			C	Unknown	At Night.		Not Reported	
	Ropinirole			C	Unknown	0.5 Milligram		Not Reported	
	Fexofenadine			C	Unknown	Unk		Not Reported	
	Co-Codamol			C	Unknown	Unk		Not Reported	
	Evorel Conti			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16564674	EXPEDITED (15-DAY)		HO	DE-ACCORD-138161		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S		20 Mg, 1-0-0-0		Not Reported	
	Loratadine			S		10 Mg, 1-0-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16566596	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019293275		51 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Infusion Related Reaction; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Methotrexate Sodium			S		14 Mg, Weekly		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Ciprallex [Escitalopram]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abilify			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Fluoxetine			C	Unknown	Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Oxycontin			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Sertraline Hydrochloride			C		Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16567136	EXPEDITED (15-DAY)		HO, OT	GB-ALLERGAN-1928503US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bleeding Time Prolonged; Breast Swelling; Breast Tenderness; Gingival Bleeding; Postmenopausal Haemorrhage; Spider Naevus	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qam		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qam		Allergan	
	Diazepam			C	Unknown	2 Mg, Qpm		Not Reported	
	Ropinirole			C	Unknown	0.5 Mg, Unknown		Not Reported	

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	Fexofenadine	C	Unknown	Unk, Unknown				Not Reported	
	Co-Codamol	C	Unknown	Unk, Unknown				Not Reported	
	Evorel Conti	C	Unknown	Unk, Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16567185	NON-EXPEDITED			US-TEVA-2019-US-1073307			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Teva Escitalopram			S		10 Milligram Daily;		Ivax	
	Amiodarone Zydus			S		400 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16567320	NON-EXPEDITED			US-TEVA-2019-US-1073411			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram Oxalate			S	Oral	10 Milligram Daily; Daily By Mouth		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16567343	EXPEDITED (15-DAY)		OT	KR-BAUSCH-BL-2019-019339		35 YR	Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Lorazepam			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Zolpidem			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16568275	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1064167		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported	
	Eliquis			S	Oral	2 Dosage Form, Qd		Mylan	
	Digoxine			C		Unk		Mylan	
	Loxen L P			C		Unk		Mylan	
	Lopressor			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2019	16568864	EXPEDITED (15-DAY)		DS	GB-TEVA-2019-GB-1076110		55 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bladder Disorder; Bowel Movement Irregularity; Burning Sensation; Decreased Appetite; Extrasystoles; Eye Irritation; Fear; Feeling Cold; Headache; Hyperhidrosis; Hypersensitivity; Insomnia; Intracranial Mass; Irritability; Memory Impairment; Muscle Spasms; Musculoskeletal Stiffness; Myalgia; Nail Disorder; Nervousness; Panic Reaction; Paraesthesia; Presyncope; Sneezing; Social Anxiety Disorder; Tinnitus	Escitalopram Oxalate			S	Oral			Ivax	
	Nelson Bach Rescue Remedy			C				Not Reported	
	Paracetamol			C				Not Reported	
	Aconite			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	9321374	EXPEDITED (15-DAY)		HO, LT	JP-FRI-1000045519			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Anafranil			S	Oral	25 Mg, Q12h		Not Reported	
	Anafranil			S	Oral	Unk		Not Reported	
	Rohypnol			S	Oral	2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16569610	EXPEDITED (15-DAY)		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2019-04375		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Lamotrigine			S	Unknown	50 Milligram, Bid (1-0-1-0)		Lupin	
	Zolpidem			S	Unknown	10 Milligram, Qd (0-0-1-0)		Lupin	
	Mirtazapine			S	Unknown	45 Milligram, Qd (0-0-1-0)		Not Reported	
	Pregabalin			S	Unknown	75 Milligram, Unk		Not Reported	
	Elontril			S	Unknown	150 Milligram, Qd (1-0-0-0)		Not Reported	
	Cipralex [Escitalopram]			S	Unknown	10 Milligram, Qd (1-0-0-0)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16569669	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR- APL-2019-036079			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Epilepsy; Galactorrhoea; Parkinsonism; Product Use In Unapproved	Escitalopram			S	Unknown	10 Milligram		Aurobindo	
	Lamotrigine			S	Unknown	200 Milligram		Aurobindo	
	Quetiapine Film Coated Tablets			S	Unknown	800 Milligram, Once A Day		Aurobindo	

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Indication; Somnolence	Clozapine	S	Unknown	500 Milligram	Not Reported
	Clozapine	S	Unknown	Unk	Not Reported
	Clozapine	S	Unknown	900 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	600 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	200 Milligram, Once A Day	Not Reported
	Clozapine	S	Unknown	200 Milligram, Once A Day	Not Reported
	Citalopram	S	Unknown	20 Milligram, Once A Day	Not Reported
	Haloperidol	S	Unknown	13 Milligram	Not Reported
	Ziprasidone Hydrochloride	S	Unknown	160 Milligram, Once A Day	Not Reported
	Chlorpromazine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Perphenazine	S	Unknown	100 Milligram, Every 2 Weeks	Not Reported
	Risperidone	S	Unknown	50 Milligram (Every 2 Weeks)	Not Reported
	Sertindole	S	Unknown	12 Milligram, Once A Day	Not Reported
	Valproic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16569870	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1076454		70 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Pregabalin			S	Unknown	75 Mg, Discontinued		Not Reported
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0		Teva
	Lamotrigin			S	Unknown	50 Mg, 1-0-1-0		Teva
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0		Teva
	Cipralex			S	Unknown	10 Mg, 1-0-0-0		Not Reported
	Elontril			S	Unknown	150 Mg, 1-0-0-0		Not Reported

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15-Jul-2019	16570641	EXPEDITED (15-DAY)		OT	IT-ACCORD-138436		54 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
	Depakin Chrono			C		Strength: 300 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16570686	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2019-CA-1075160		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved Indication	Diclofenac			S	Oral			Actavis	
	Ibuprofen			S	Oral			Actavis	
	Ciprallex			S	Oral	10 Milligram Daily;		Not Reported	
	Eliquis Film Coated			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16570781	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2019126413		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Rhabdomyolysis	Seroplex			S	Oral	10 Mg, Qd		Glaxosmithkline	
	Lamictal			S	Oral	100 Mg, Qd		Glaxosmithkline	
	Vitamin B12			C	Oral	250 ?G, Qd		Glaxosmithkline	
	Speciafoldine			C	Oral	5 Mg, Qd		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16571653	EXPEDITED (15-DAY)		HO	DE-BAYER-2019-130565		19 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Loratadine			S		10 Mg, Qd		Bayer	
	Escitalopram			S		20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16572814	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1076698		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Mg, 1-0-0-0		Ivax	
	Loratadine			S	Unknown	10 Mg, 1-0-0-0		Actavis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16573034	EXPEDITED (15-DAY)		LT	FR-009507513-1907FRA005031		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Milligram		Merck	
	Alprazolam			S	Oral	20 Milligram		Not Reported	
	Escitalopram			S	Oral	60 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16573047	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1063563		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness; Nuchal Rigidity; Suicide Attempt	Escitalopram			S	Oral	3920 Milligram, Total		Not Reported	
	Felison			S	Oral	900 Milligram, Total		Mylan	
	Seroquel			S	Oral	6 Gram, Total		Mylan	
	Tavor /00273201/			S	Oral	50 Milligram, Total		Mylan	
	Zoloft			S	Oral	6 Gram, Total		Mylan	

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15-Jul-2019	16573067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1075123			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac Diethylamine			S	Unknown			Actavis	
Arthralgia; Lip Ulceration;	Escitalopram Oxalate			S	Unknown			Ivax	
Lower Respiratory Tract Infection Viral; Malaise;	Methotrexate			S	Unknown			Barr	
Mouth Ulceration;	Cosentyx			S	Subcutaneous			Not Reported	
Musculoskeletal Stiffness;	Cosentyx			S	Unknown			Not Reported	
Nasopharyngitis; Nausea;	Cosentyx			S	Subcutaneous			Not Reported	
No Adverse Event; Pain;	Vitamin D3			S	Unknown			Not Reported	
Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Enbrel			C	Unknown			Not Reported	
	Humira			C	Subcutaneous			Not Reported	
	Remicade			C	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16574742	EXPEDITED (15-DAY)		DS	GB-ALLERGAN-1928505US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bladder Disorder; Bowel Movement Irregularity;	Escitalopram Oxalate - Bp			S	Oral	5 Mg		Allergan	
Burning Sensation; Decreased Appetite;	Paracetamol			C	Unknown			Not Reported	
Extrasystoles; Eye Irritation; Fear; Feeling Cold; Headache; Hyperhidrosis; Hypersensitivity; Insomnia; Intracranial Mass; Irritability; Memory Impairment; Muscle	Aconite			C	Unknown			Not Reported	

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Spasms; Musculoskeletal
Stiffness; Myalgia; Nail
Disorder; Nervousness;
Panic Reaction;
Paraesthesia;
Paraesthesia;
Presyncope; Sneezing;
Social Anxiety Disorder;
Tinnitus

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15-Jul-2019	16575138	EXPEDITED (15-DAY)		HO	PHHY2019FR159171		95 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Esidrex			S	Oral	0.5 Df, Unk		Novartis
	Escitalopram			S	Oral	0.5 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	9285538	NON-EXPEDITED			US-PFIZER INC- 2013145521		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Talwin			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Deconamine			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Provigil			S		Unk		Not Reported
	Opana			S		Unk		Not Reported

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16-Jul-2019	16569351	EXPEDITED (15-DAY)		LT	FR-ASTRAZENECA-2019SE99251		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Coma; Electrocardiogram Qt Prolonged; Miosis; Toxicity To Various Agents	Xeroquel			S	Oral	1.8g Unknown		Zeneca	
	Depakote			S	Oral	1.5g Unknown		Not Reported	
	Depakote			S	Oral	3.0g Unknown		Not Reported	
	Seroplex			S	Oral	30.0mg Unknown		Not Reported	
	Seresta			S	Oral	100.0mg Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16575394	EXPEDITED (15-DAY)		HO, OT	DE-HETERO-HET2019DE00938		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Mg, Q.D.(1-0-0-0)		Hetero	
	Loratadin			S	Unknown	10 Mg, Q.D.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16575685	EXPEDITED (15-DAY)		OT	JP-SA-2019SA190909		81 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Harnal			S	Oral	Unk		Sanofi	
	Aripiprazole			S	Oral	Unk		Not Reported	
	Escitalopram Oxalate			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16576876	NON-EXPEDITED		OT	US-APOTEX-2019AP018249		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Seizure;	Bupropion	S	Unknown	Unk	Apotex
Sleep Paralysis;	Bupropion	S	Unknown	300 Mg, Unk	Apotex
Therapeutic Product Effect	Fluoxetine	S	Unknown	Unk	Apotex
Incomplete; Weight	Escitalopram	S	Unknown	Unk	Apotex
Increased; Withdrawal	Mirtazapine	S	Unknown	15 Mg, Unk	Apotex
Syndrome	Venlafaxine Xr	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577204	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2019-025994			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Fatigue; Hypersomnia	Prednisone Tablet 10 Mg			S	Oral	1 Tablet Every Other Day		Aurobindo	
	Valacyclovir Hydrochloride Tablets 1g			S	Oral	1/2 Tablet Every 12 Hrs		Aurobindo	
	Sulfamethoxazole And Trimethoprim Tablets Usp 800/160 Mg			S	Oral	1 Tablet Twice A Day On Saturday And Sunday		Aurobindo	
	Premarin			S	Oral	1.25 Milligram, Once A Day For 28 Days Out Of The Month		Not Reported	
	Provera			S	Oral	1 Tablet , Once A Day, 10 Days Out Of Each Month		Not Reported	
	Tacrolimus			S	Oral	2.5 Milligram, Two Times A Day		Not Reported	
	Genotropin			S	Subcutaneous	2.6 Milligram Three Times A Week		Not Reported	
	Mg-Plus-Protein [Dietary Supplement]			S	Oral	1 Tablet Twice A Day		Not Reported	
	Jakafi			S	Oral	1 Tablet Twice A Day		Not Reported	
	Lexapro			S	Oral	1 Tablet Once A Day		Not Reported	
	Cyproheptadine Hcl			S	Oral	1 Tablet Twice A Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577757	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1065754			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Malaise; Nasopharyngitis	Asmol (Salbutamol)			S		Up To 12 Puffs Per Day As Necessary		Mylan	
	Nucala			S	Subcutaneous	100 Milligram		Mylan	
	Spiriva			S		2 Puffs Each Night		Mylan	
	Seretide			S		250/25mg/2 Puffs Twice A Day		Mylan	
	Prednisone			S		10 Milligram, Qd		Mylan	
	Ondansetron			S		10 Milligram When Required,		Mylan	
	Omeprazole			S		20 Milligram, Qd		Mylan	
	Lexamil			S		10 Milligram, Qd		Mylan	
	Hypertonic Saline Solution			S		Via Nebuliser Qd		Mylan	
	Colistimethate Sodium			S		Unk Via Nebuliser		Mylan	
	Azithromycin			S		500 Milligram, Mon/Wed/Fri		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16578273	EXPEDITED (15-DAY)		HO	FR-009507513-1907FRA004833		62 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Hypotension; Poisoning Deliberate	Aerius (Desloratadine)			S	Oral	35 Milligram		Merck	
	Escitalopram			S	Oral			Not Reported	
	Lexomil			S	Oral			Not Reported	
	Doliprane			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16580854	NON-EXPEDITED			US-TEVA-2019-US-1077840		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Intolerance; Restlessness	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S				Ivax	
	Fluoxetine			S	Unknown			Barr	
	Fluoxetine			S				Barr	
	Sertraline			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Methylphenidate			S	Unknown			Not Reported	
	Methylphenidate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16580951	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR122610		30 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Salbutamol			S		Unk		Glaxosmithkline	
	Escitalopram Oxalate			S		10 Mg, Unk		Glaxosmithkline	
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Every 8 Weeks		Not Reported	
	Acetaminophen + Codeine Phosphate			S		Unk		Not Reported	
	Imodium			S		Unk		Not Reported	
	Pantoprazole Magnesium			S		30 Mg, Qd		Not Reported	
	Loperamide Hydrochloride			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16581455	EXPEDITED (15-DAY)		HO, LT, OT	PT-ALLERGAN-1928854US			Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Ischaemic Stroke	Escitalopram Oxalate - Bp	S	Oral	10 Mg/Dia	Allergan
	Warfarin	S	Unknown		Not Reported
	Perindopril	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Isosorbide Mononitrate	C	Unknown		Not Reported
	Atorvastatina + Ezetimiba	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16581460	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1928853US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram Oxalate - Bp			S		20 Mg, 1-0-0-0		Allergan	
	Loratadin			S		10 Mg, 1-0-0-0		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16581596	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1928833US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Hypotension; Overdose; Poisoning Deliberate	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan	
	Doliprane			S	Oral			Not Reported	
	Aerius (Desloratadine)			S	Oral			Not Reported	
	Lexomil			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16581643	NON-EXPEDITED			US-US WORLDMEDS, LLC-USW201904-000820		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dizziness; Drug Interaction; Dyskinesia; Flushing; Mania	Xadago			S				Us Worldmeds	
	Lexapro			S				Not Reported	
	Simvastatin			C				Not Reported	
	Botox			C				Not Reported	

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Xanax	C	Not Reported
Diclofenac	C	Not Reported
Omeprazole	C	Not Reported

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17-Jul-2019	10013343	NON-EXPEDITED			US-PFIZER INC-2014073917		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Methocarbamol			S		Unk		Pfizer
	Amrix			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16567148	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074914			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Diclofenac Potassium			S	Unknown			Actavis
	Escitalopram			S	Oral	20 Milligram Daily;		Ivax
	Naproxen			S	Unknown			Teva
	Naproxen Sodium			S	Unknown	1000 Milligram Daily;		Teva
	Nortriptyline			S	Oral	25 Milligram Daily;		Teva
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Tylenol			S	Topical			Not Reported
	Voltaren			S	Topical			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

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Infliximab	C	Intravenous (not otherwise specified)	Not Reported
Infliximab	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16582124	EXPEDITED (15-DAY)	HO		FR-AUROBINDO-AUR-APL-2019-040714			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Esomeprazole			S	Oral	40 Milligram, Once A Day		Aurobindo	
	Gabapentin			S	Oral	1200 Milligram, Once A Day		Aurobindo	
	Lamotrigine			S	Oral	200 Milligram, Once A Day		Aurobindo	
	Oxynormoro			S	Oral	Unk		Not Reported	
	Nefopam			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16582801	EXPEDITED (15-DAY)	HO		CA-BAYER-2019-132892		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Neutropenia; Pleural Effusion	Cipro 1000 Mg			S	Oral	1000 Mg		Bayer	
	Cipro			S	Intravenous (not otherwise specified)	Unk		Bayer	
	Avastin [Simvastatin]			S	Intravenous (not otherwise specified)	15 Mg		Not Reported	
	Carboplatin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Cipralext [Escitalopram]			S	Unknown	10 Mg, Qd		Not Reported	
	Codeine			C	Unknown	Unk		Not Reported	

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Docetaxel	S	Intravenous (not otherwise specified)	75.0 Mg/M2	Not Reported
Docetaxel	S		75.0 Mg/M2	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Docusate	C		Unk	Not Reported
Lactulose	C	Unknown	Unk	Not Reported
Laxasene	C	Unknown	Unk	Not Reported
Morphine	S	Unknown	2.5 Mg, Q4hr	Not Reported
Piperacillin Sodium;Tazobactam Sodium	S	Unknown	Unk	Not Reported
Trastuzumab	S	Intravenous (not otherwise specified)	8 Mg	Not Reported
Trazodone	C		Unk	Not Reported
Tylenol [Paracetamol]	S	Unknown	Unk	Not Reported
Tylenol No.1 Forte	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16583260	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019022095			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram Oxalate			S	Unknown	20 Milligram, Qd		Macleods	
	Loratadin			S	Unknown	10 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16583819	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1078074		75 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Dizziness; Hypertension	Diazepam-Ratiopharm 10mg/ML			S	Oral	5 Gtt, Need, Drops		Barr	
	Trimipramin			S	Oral	25 Mg, Pause, Solution		Not Reported	
	Concor 2,5 Mg			S	Oral	2.5 Mg, 1-0-0-0, Tablets		Not Reported	

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Ciprallex	S	Oral	10 Mg, 1-0-0-0, Tabletten	Not Reported
Ximovan	C	Oral	0.5-1-0-0, Tablets	Not Reported
Ass 100	C	Oral	100 Mg, 1-0-0-0, Tablets	Not Reported
L-Thyroxin 125µg	C	Oral	125 Mg, 1-0-0-0, Tablets	Not Reported
Magnesium Verla	C	Oral	0-0-1-0	Not Reported
Lexotanil 6mg	C	Oral	6 Mg, 0.25-0-0.25-0, Tablets	Not Reported
Tromcardin Complex	C	Oral	1-1-0-0, Tablets	Not Reported
Diovan 80	C			Not Reported
Nitrolingual	C	Respiratory (inhalation)	Need, Spray	Not Reported

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17-Jul-2019	16586416	EXPEDITED (15-DAY)		HO, LT, OT	PT-TEVA-2019-PT-1077464		67 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Mg/Dia		Ivax	
	Warfarin			S	Unknown			Not Reported	
	Perindopril			C				Not Reported	
	Metformin			C				Not Reported	
	Isosorbide Mononitrate			C				Not Reported	
	Atorvastatina + Ezetimiba			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16586502	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1078027		52 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Screen Positive; Electrocardiogram Qt Prolonged; Hyperkalaemia; Loss Of Consciousness; Overdose; Sinus Tachycardia	Escitalopram Oxalate			S	Unknown			Ivax	
	Escitalopram Oxalate			S	Unknown			Ivax	
	Citalopram Hydrobromide			S	Unknown			Not Reported	
	Acetaminophen/Oxycodone Hydrochloride			S	Unknown			Actavis	

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Lorazepam	S	Unknown	Actavis
Morphine	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Oxycodone	S	Unknown	Actavis
Oxycodone	S	Unknown	Actavis
Zopiclone	S	Oral	Not Reported
Diazepam	S	Unknown	Not Reported

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17-Jul-2019	16586791	NON-EXPEDITED			US-TEVA-2019-US-1079107			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Flushing	Escitalopram			S	Unknown			Ivax
	Escitalopram			S	Unknown			Ivax

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17-Jul-2019	16586815	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1078145		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Escitalopram			S	Oral	10mg Per Day		Ivax
	Lamotrigine			S	Oral	Unknown		Teva
	Alprazolam			C				Not Reported
	Verapamil (Chlorhydrate De)			C				Not Reported
	Trandolapril			C				Not Reported

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17-Jul-2019	16587676	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019126580		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Fall	Escitalopram	S	Oral	10 Mg, Qd	Glaxosmithkline
	Lamotrigine	S	Oral	200 Mg, Qd	Glaxosmithkline
	Clopidogrel	S	Oral	75 Mg, Qd	Glaxosmithkline
	Ramipril	S	Oral	5 Mg, Qd	Glaxosmithkline
	Furosemide	S	Oral	40 Mg, Qd	Glaxosmithkline
	Bisoprolol Fumarate	S	Oral	10 Mg, Qd	Not Reported
	Amlodipine	S	Oral	5 Mg, Qd	Not Reported
	Gabapentine	S	Oral	1200 Mg, Qd	Not Reported
	Alprazolam	S	Oral	0.5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	8432641	NON-EXPEDITED			US-PFIZER INC-2012051184		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Interaction	Norvasc			S	Oral	Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Cardura			S	Oral	Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Zolof			S	Oral	Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Lotensin			S		Unk		Not Reported
	Lotensin Hct			S		Unk		Not Reported
	Benazepril And Hydrochlorothiazide			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Symbyax			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16209808	EXPEDITED (15-DAY)		CA	FR-ALLERGAN-1916581US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Bilateral; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16388241	EXPEDITED (15-DAY)		HO, OT	PHHY2019ES122146		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left;	Escitalopram			S	Unknown	Unk		Not Reported	
Dyspnoea Exertional;	Trazodone			S	Unknown			Not Reported	
Electrocardiogram Qt Prolonged; Extrasystoles;	Omeprazole			S	Unknown			Novartis	
Hypocalcaemia;	Enalapril, Hydrochlorothiazide			S	Unknown			Not Reported	
Hypomagnesaemia;	Metformin			C	Unknown	Unk		Not Reported	
Ventricular Extrasystoles									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16535430	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1071927		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Clonazepam			S	Oral	1.5 Milligram Daily;		Teva	
Dehydration; Dysphagia;	Domperidone			S	Oral	20 Milligram Daily;		Not Reported	
Mental Disorder; Product Use In Unapproved Indication	Escitalopram			S	Oral	20 Milligram		Ivax	
	Gabapentin			S	Oral	1200 Milligram Daily;		Actavis	
	Temazepam			S	Oral	30 Milligram Daily;		Actavis	
	Ferrous Sulfate			S	Oral	900 Milligram Daily;		Not Reported	
	Tylenol With Codeine			S	Oral	6 Dosage Forms Daily;		Not Reported	
	Vitalux [Ascorbic Acid;Betacarotene;Coug;Tocofe			S	Oral			Not Reported	

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r Wellbutrin XL		S		Oral		300 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16588621	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR- APL-2019-040411			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Pregabalin			S	Unknown	75 Mg, Abgesetzt		Not Reported	
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0		Aurobindo	
	Cipralex			S	Unknown	10 Mg, 1-0-0-0		Not Reported	
	Elontril			S	Unknown	150 Mg, 1-0-0-0		Not Reported	
	Lamotrigin			S	Unknown	50 Mg, 1-0-1-0		Not Reported	
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16589188	EXPEDITED (15-DAY)		HO	FR-ACCORD-138603		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram			S	Oral			Not Reported	
	Lamotrigine			S	Oral			Not Reported	
	Alprazolam			C				Not Reported	
	Verapamil			C				Not Reported	
	Trandolapril			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16589873	EXPEDITED (15-DAY)		HO, LT, OT	PT-MACLEODS PHARMACEUTICALS US LTD- MAC2019022117			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Ischaemic Stroke	Escitalopram			S	Oral	10 Milligram, Qd, 10 Mg/Daily		Macleods	

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Warfarin	S	Unknown	Not Reported
Perindopril	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Isosorbide Mononitrate	C	Unknown	Not Reported
Atorvastatina/Ezetimiba	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16590757	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR- APL-2019-040695			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram			S	Unknown	20 Milligram, Once A Day,20 Mg, 1-0-0-0		Aurobindo
	Loratadine			S	Unknown	10 Milligram, Once A Day,10 Mg, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16590955	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC- 2019300028		70 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Pregabalin			S		75 Mg, Unk		Pfizer
	Zolpidem			S		10 Mg, 1x/Day		Not Reported
	Ciprallex Meltz [Escitalopram]			S		10 Mg, 1x/Day		Not Reported
	Elontril			S		150 Mg, 1x/Day		Not Reported
	Lamotrigin			S		50 Mg, 1x/Day		Not Reported
	Mirtazapin			S		45 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16592964	EXPEDITED (15-DAY)		HO	JP- ELI_LILLY_AND_COMP ANY-JP201907006822		59 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Locked-In Syndrome; Withdrawal Syndrome	Duloxetine Hydrochloride	S	Oral	20 Mg, Daily	Eli Lilly And Co
	Adco Mirteron	S	Oral	45 Mg, Daily	Not Reported
	Lexapro	S	Oral	5 Mg, Daily	Not Reported
	Myslee	C	Oral	32 International Unit	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16593087	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1077324		62 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Hypotension; Poisoning Deliberate	Escitalopram			S	Oral	140 Milligram		Ivax	
	Doliprane			S	Oral	4 Gram		Not Reported	
	Aerius (Desloratadine)			S	Oral	35 Milligram		Not Reported	
	Lexomil Roche			S	Oral	30 Dosage Forms		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16594176	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1066848		56 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyarrhythmia; Circulatory Collapse	Escitalopram			S	Oral	10 Milligram		Not Reported	
	Elleste-Solo			C	Transdermal	80 Microgram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16594746	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929126US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16594778	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1929281US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Haemorrhagic Stroke	Escitalopram Oxalate - Bp	S	Oral	5 Mg	Allergan
	Kardegic	S	Oral		Not Reported
	Dacryoserum	C	Unknown	Unk	Not Reported
	Diffu K	C	Unknown	Unk	Not Reported
	Dafalgan	C	Unknown	Unk	Not Reported
	Keppra	C	Unknown	Unk	Not Reported
	Zymad	C	Unknown		Not Reported
	Cokenzen	C	Unknown		Not Reported
	Hemifumarate Bisoprolol	C	Unknown		Not Reported
	Tramadol (Chlorhydrate De)	C	Unknown		Not Reported
	Macrogol 4000	C	Unknown		Not Reported
	Levemir	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16594902	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1929293US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Electrocardiogram Qt Prolonged; Overdose; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	Overdose: 60mg Unit Dose		Allergan
	Mirtazapine			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	15551355	EXPEDITED (15-DAY)		CA, HO, OT	CA-GLENMARK PHARMACEUTICALS-2018GMK037887			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby;	Gabapentin			S	Transplacental	1800 Mg, Od		Glenmark
	Benztrapine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported
	Benztrapine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported

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Sleep Disorder; Tremor; Trismus	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Escitalopram	S	Transplacental	20 Mg, Od	Not Reported
	Methadone	S	Transplacental	70 Mg, Od	Not Reported
	Nortriptyline	S	Transplacental	20 Mg, Od	Not Reported
	Quetiapine	S	Transplacental	300 Mg, Bid, (One Every 12 Hours)	Not Reported
	Rabeprazole	S	Transplacental	Unk	Not Reported
	Zopiclone	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	15569031	EXPEDITED (15-DAY)		DE	CA-TEVA-2018-CA- 967648		35 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Clonazepam			S	Oral	1.5 Milligram Daily;		Teva
	Clonazepam			S				Teva
	Clonazepam			S				Teva
	Escitalopram			S	Oral			Ivax
	Escitalopram			S				Ivax
	Escitalopram			S				Ivax
	Zopiclone			S	Oral	15 Milligram Daily;		Not Reported
	Zopiclone			S				Not Reported
	Zopiclone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	15626479	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA- 976639		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Unknown			Ivax
	Hydrochlorothiazide			S	Unknown			Ivax
	Gliclazide			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported

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	Metformin			C					Not Reported
	Telmisartan			C					Not Reported
	Trazodone			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	15668447	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980609			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram Hydrobromide			S	Unknown			Actavis	
	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S	Unknown			Ivax	
	Escitalopram			S	Unknown			Ivax	
	Trintellix			S	Unknown	10 Milligram Daily;		Not Reported	
	Trintellix			S				Not Reported	
	Trintellix			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	15679889	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-981621		32 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Teva-Escitalopram			S	Unknown			Ivax	
	Teva-Escitalopram			S				Ivax	
	Teva-Escitalopram			S				Ivax	
	Quetiapine Fumarate			S	Unknown			Teva	
	Levothyroxine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16530957	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-037455			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Dementia; Fatigue; Insomnia; Loss Of Libido; Nausea; Weight	Auro-Escitalopram Tablets			S	Unknown	10 Milligram, Daily		Aurobindo	
	Auro-Paroxetine 20 Tablets			S	Unknown	20 Milligram, Daily		Aurobindo	

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Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16536622	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1073053		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Measurement; Delirium; Diabetes Mellitus; Drug Level Increased; Fall; Myocardial Infarction; Neuroleptic Malignant Syndrome; Rhabdomyolysis; Sedation; Serotonin Syndrome	Teva-Quetiapine Xr			S	Oral	30 Milligram Daily;		Teva
	Teva-Quetiapine Xr			S				Teva
	Escitalopram			S	Unknown	20 Milligram Daily;		Ivax
	Lorazepam 2 Mg			C		6 Milligram Daily; (As Needed)		Not Reported
	Lorazepam 2 Mg			C				Not Reported
	Triazide 50-25			C		50-25		Not Reported
	Baclofen 10mg			C		30 Milligram Daily; Prn		Not Reported
	Anacin 325-30mg			C		325-30mg		Not Reported
	T3			C		Patient States Took About Once A Week Leg Pain		Not Reported
	Spiriva 18mcg			C		18 Microgram Daily;		Not Reported
	Ventolin			C		1-2 Puffs Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595619	EXPEDITED (15-DAY)		HO, LT, OT	PT-AUROBINDO-AUR-APL-2019-040988			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ischaemic Stroke	Escitalopram			S	Oral	10 Milligram, Once A Day, 10 Mg/Dia		Aurobindo
	Warfarin			S	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			C	Unknown	Unk		Not Reported
	Atorvastatin;Ezetimibe			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595867	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040308			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Escitalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Unknown	20 Milligram, 1 Every 24 Hour(S)		Aurobindo	
	Aripiprazole			S	Oral	2 Milligram, Unk		Aurobindo	
	Serax			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595880	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041034			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Hypotension; Poisoning Deliberate	Escitalopram			S	Oral	140 Milligram		Aurobindo	
	Doliprane			S	Oral	4 Gram		Not Reported	
	Aerius (Desloratadine)			S	Oral	35 Milligram		Not Reported	
	Lexomil			S	Oral	30 Dosage Form		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16596079	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-041423			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Escitalopram			S	Oral	200 Milligram, Total		Aurobindo	
	Depakin Chrono			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16596265	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1078887		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Traumatic Haemothorax	Escitalopram	S	Oral	10 Milligram Daily;	Ivax
	Eliquis	S	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597036	EXPEDITED (15-DAY)		LT	FR-TEVA-2019-FR-1078465		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram	Mirtazapine			S	Oral			Teva	
Qt Prolonged; Toxicity To	Alprazolam			S	Oral			Actavis	
Various Agents	Escitalopram			S	Oral			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597072	EXPEDITED (15-DAY)		HO	PHHY2019FR162638		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Furosemide			S	Oral	40 Mg, Qd		Not Reported	
	Bisoprolol			S	Oral	10 Mg, Qd		Not Reported	
	Amlodipine			S	Oral	5 Mg, Qd		Novartis	
	Lamotrigine			S	Oral	200 Mg, Qd		Not Reported	
	Ramipril			S	Oral	5 Mg, Qd		Not Reported	
	Gabapentin			S	Oral	1200 Mg, Qd		Not Reported	
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported	
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597077	EXPEDITED (15-DAY)		OT	IE-TEVA-2019-IE-1069498		37 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Escitalopram			S	Oral	15 Milligram Daily;		Ivax	

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Adverse Drug Reaction;
Bruxism; Restless Legs
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597223	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019306999		94 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage	Pantoprazole			S	Oral	10 Milligram, Qd		Pfizer	
	Doliprane			S	Oral	3 Gram, Qd		Not Reported	
	Coumadine			S	Oral	6 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Lasilix [Furosemide]			C	Oral	60 Milligram, Qd		Not Reported	
	Diffu K			C	Oral	600 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597732	EXPEDITED (15-DAY)		LT	FR-PFIZER INC- 2019304485		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Alprazolam			S	Oral	20 Mg, Unk		Pfizer	
	Mirtazapine			S	Oral	30 Mg, Unk		Not Reported	
	Escitalopram			S	Oral	60 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597937	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA- 1077702		18 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
	Escitalopram			S	Oral	5 Milligram Daily;		Ivax	

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19-Jul-2019	16598161	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1077998		35 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Jittery; Nervousness; Panic Attack	Escitalopram			S	Oral	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16599092	EXPEDITED (15-DAY)		OT	PH-OTSUKA-2019_026259		22 YR	Female	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Inflammation	Abilify			S	Unknown	5 Mg, Qd		Otsuka	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16599506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1078045		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis;	Escitalopram Oxalate			S	Oral	1 Dosage Forms Daily;		Ivax	
Cough; Diabetes Mellitus;	Methotrexate			S	Unknown			Barr	
Herpes Zoster;	Pantoprazole Magnesium			S	Oral	1 Dosage Forms Daily;		Teva	
Hypertension; Joint	Celebrex			S	Unknown			Not Reported	
Stiffness; Joint Swelling;	Enbrel			S	Unknown			Not Reported	
Liver Disorder; Liver	Humira			S	Subcutaneous			Not Reported	
Function Test Increased;	Orencia			S	Unknown			Not Reported	
Rheumatoid Arthritis;	Sulfasalazine			S	Unknown			Not Reported	
Therapeutic Product Effect	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported	
Decreased; Therapeutic	Prednisone			C		5 Milligram Daily;		Not Reported	
Product Effect Decreased									

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19-Jul-2019	16599852	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929188US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan	
	Lamotrigine			S	Oral	Unk		Not Reported	
	Alprazolam			C				Not Reported	
	Verapamil			C				Not Reported	
	Trandolapril			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16601747	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019AMR127715			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspirin-Exacerbated Respiratory Disease; Asthma; Blood Count Abnormal; Condition Aggravated; Drug Hypersensitivity; Dyspnoea; Eczema; Nasal Polyps; Therapeutic Product Effect Incomplete	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, 1 Month		Glaxosmithkline	
	Ventolin			S		Unk, Prn		Glaxosmithkline	
	Incruse Ellipta			S		Unk		Glaxosmithkline	
	Avamys			S		Unk		Glaxosmithkline	
	Rhinocort			S		2 Puff(S) In To Each Nostrilat Bedtime Prn		Glaxosmithkline	
	Bupropion			S		300 Mg, Qd		Glaxosmithkline	
	Levothyroxine			S		150 Mg, Qd		Glaxosmithkline	
	Pantoprazole			S		40 Mg, Qd		Glaxosmithkline	
	Escitalopram			S		20 Mg, Qd		Glaxosmithkline	
	Singulair			S		Unk		Glaxosmithkline	
	Fluticasone			S		Unk		Glaxosmithkline	
	Zenhale			S		2 Puff(S), Bid		Not Reported	
	Spiriva			S		2 Puff(S), Qd		Not Reported	
	Gabapentin			S		100 Mg, Qd		Not Reported	

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Symbicort

S

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16081411	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-014149			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis;	Escitalopram			S	Oral	1 Dosage Form, Daily		Aurobindo
Contraindicated Product	Pantoprazole			S	Oral	1 Dosage Form, Daily		Aurobindo
Administered; Cough;	Celebrex			S	Unknown	Unk		Not Reported
Diabetes Mellitus; Herpes	Enbrel			S	Unknown	Unk		Not Reported
Zoster; Hypertension;	Humira			S	Subcutaneous	Unk		Not Reported
Joint Stiffness; Joint	Methotrexate			S	Unknown	Unk		Not Reported
Swelling; Liver Disorder;	Methotrexate			S	Unknown	Unk		Not Reported
Liver Function Test	Methotrexate			S	Unknown	Unk		Not Reported
Increased; Rheumatoid	Orencia			S	Unknown	Unk		Not Reported
Arthritis; Therapeutic	Sulfasalazine			S	Unknown	Unk		Not Reported
Product Effect Decreased	Xeljanz			S	Oral	1 Dosage Form, Two Times A Day		Not Reported
	Prednisone			C	Unknown	5 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16328202	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-027687			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extradural Haematoma;	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
Haemorrhage;	Heparin Sodium			S	Subcutaneous	5000 International Unit		Not Reported
Hypotension;	Heparin Sodium			S				Not Reported
Hypovolaemia; Motor	Heparin Sodium			S				Not Reported
Dysfunction; Oedema;	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
Paralysis; Platelet	Rivaroxaban			S				Not Reported
Aggregation Inhibition;	Rivaroxaban			S				Not Reported
Platelet Count Decreased;	Rivaroxaban			S				Not Reported
Spinal Cord Compression;	Xarelto			S	Unknown	15 Milligram, Once A Day		Not Reported
Spinal Cord Oedema								

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	Xarelto	S							Not Reported
	Bupivacaine	C	Unknown	Unk, Sloution Block/Infiltration					Not Reported
	Epinephrine	C	Unknown	Unk					Not Reported
	Hydromorphone	C	Unknown	Unk					Not Reported
	Lidocaine	C	Unknown	3 MI					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16599634	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-041935			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	0.5 Dosage Form		Aurobindo	
	Esidrex			S	Oral	0.5 Dosage Form		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16599642	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-041955			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage	Escitalopram			S	Oral	10 Milligram, Daily (1-0-0)		Aurobindo	
	Pantoprazole			S	Oral	10 Milligram, Daily (0-0-1)		Aurobindo	
	Coumadine			S	Oral	6 Milligram, Daily (0-0-1)		Not Reported	
	Doliprane			S	Oral	3 Gram, Daily		Not Reported	
	Lasilix			C	Oral	60 Milligram, Daily (1-0-0)		Not Reported	
	Diffu K			C	Oral	600 Milligram, Daily (1-0-0)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16600117	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2019-042396			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram	Mirtazapine			S	Oral	30 Milligram, Unk		Aurobindo	

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Qt Prolonged; Toxicity To Various Agents		Alprazolam	S	Oral	20 Milligram, Unk	Aurobindo			
		Escitalopram	S	Oral	60 Milligram, Unk	Aurobindo			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16600533	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041959			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Lamotrigine			S	Oral	Unk		Aurobindo	
	Alprazolam			C	Unknown	Unk		Not Reported	
	Verapamil Hydrochloride			C	Unknown	Unk		Not Reported	
	Trandolapril			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16600710	EXPEDITED (15-DAY)		OT	FR-ACCORD-138747		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Pregabalin			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Metoject			S	Subcutaneous			Not Reported	
	Xanax			S	Oral			Not Reported	
	Pantoprazole			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16600739	EXPEDITED (15-DAY)		HO	FR-ACCORD-139256		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Amlodipine			S	Oral			Accord	
	Bisoprolol			S	Oral			Not Reported	
	Clopidogrel			S	Oral			Not Reported	

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Escitalopram	S	Oral	Not Reported
Furosemide	S	Oral	Accord
Ramipril	S	Oral	Accord
Oxynormoro	S	Oral	Not Reported
Nefopam	S	Oral	Not Reported
Gabapentin	S	Oral	Not Reported
Alprazolam	S	Oral	Not Reported
Lamotrigine	S	Oral	Not Reported
Esomeprazole/Esomeprazole	S	Oral	Not Reported
Magnesium/Esomeprazole			
Sodium			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	12889556	NON-EXPEDITED			US-PFIZER INC-2016499444		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Xanax Xr			S		Unk		Pfizer
	Doxepin Hcl			S		Unk		Pfizer
	Nexium 24hr			S		Unk		Unknown
	Neurontin			S		Unk		Pfizer
	Hydroxyzine Pamoate			S		Unk		Pfizer
	Lorazepam			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Mevacor			S		Unk		Not Reported
	Nefazodone			S		Unk		Not Reported
	Oxycontin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paxil	S	Unk	Not Reported
Paxil Cr	S	Unk	Not Reported
Reglan	S	Unk	Not Reported
Risperidone	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported
Ultram	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Zofran	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16108617	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-114227		26 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Rhabdomyolysis; Serotonin Syndrome	Escitalopram			S	Oral			Not Reported
	Clomipramine			S	Oral			Not Reported
	Flunitrazepam			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16467630	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2019AP016748		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram			S	Unknown	Unk, Qd		Apotex
	Cosentyx			S	Subcutaneous	150 Mg, Q.M.T.		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	150 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Voltaren /00372301/			S	Unknown	Unk, Q.Wk.		Not Reported
	Voltaren /00372301/			S	Unknown	Unk		Not Reported

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	Diclofenac Diethylamine	S	Unknown	Unk		Not Reported			
	Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported			
	Humira	C	Subcutaneous	Unk		Not Reported			
	Enbrel	C	Unknown	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16566795	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP008950		16 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Suicidal Ideation; Therapy Change	Escitalopram			S	Unknown	20 Mg, Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607009	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040986			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Confusional State; Dizziness; Flushing; Heart Rate Increased; Loss Of Consciousness; Nausea	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607031	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-040880			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram			S	Unknown	Unk		Aurobindo	
	Metformin Tablet			S	Unknown	1 Gram		Aurobindo	
	Metformin Tablet			S	Unknown	1 Gram, Two Times A Day		Aurobindo	
	Apo-Gliclazide			S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported	

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Insulin	S	Unknown	Unk	Not Reported
Insulin	S	Unknown	Unk	Not Reported
Gliclazide	C	Unknown	Unk	Not Reported
Levothyroxine Sodium	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Telmisartan	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607532	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-041633			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Neutropenia; Pleural Effusion	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Aurobindo
	Ciprofloxacin			S	Oral	1000 Milligram		Aurobindo
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, 1 Every 3 Weeks		Not Reported
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter		Not Reported
	Morphine			S	Unknown	2.5 Milligram, 1 Every 4 Hours		Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Trastuzumab			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 3 Weeks		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Avastin			S	Intravenous (not otherwise specified)	15 Milligram/Kilogram, 1 Every 3 Weeks		Not Reported
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported
	Cipralelex			S	Unknown	10 Milligram, Once A Day		Not Reported

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Codeine	C	Unknown	Unk	Not Reported
Docusate	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Lactulose	C	Unknown	Unk	Not Reported
Laxasene	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607541	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-040870			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Escitalopram			S	Unknown	10 Milligram		Aurobindo
	Pantoprazole			S	Unknown	30 Milligram, Once A Day		Aurobindo
	Acetaminophen;Codeine Phosphate			S	Unknown	Unk		Not Reported
	Imodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Week		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Loperamide Hydrochloride			C	Unknown	Unk		Not Reported
	Multi Vitamin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607753	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-214229		70 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Pregabalin			S	Unknown	75 Mg, Abgesetzt ()		Not Reported
	Mirtazapin			S	Unknown	45 Mg, 0-0-1-0 ()		Sun
	Zolpidem			S	Unknown	10 Mg, 0-0-1-0 ()		Not Reported

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	Cipralex	S	Unknown	10 Mg, 1-0-0-0 ()	Not Reported
	Elontril	S	Unknown	150 Mg, 1-0-0-0 ()	Not Reported
	Lamotrigin	S	Unknown	50 Mg, 1-0-1-0 ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16608068	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019022174			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Pancreatitis; Skin Ulcer	Escitalopram			S	Oral	10 Milligram, Qd		Macleods
	Ledipasvir/Sofosbuvir			S	Oral	90 Milligram, Qd		Not Reported
	Ribavirin			S	Oral	600 Milligram, Bid		Not Reported
	Ribavirin			S	Oral	400 Milligram, Bid		Not Reported
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported
	Braunovidon			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16609116	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2019AP018478		23 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mania	Escitalopram			S	Unknown	Unk		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16610207	EXPEDITED (15-DAY)		LT	FR-ALLERGAN- 1929466US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Coma; Electrocardiogram Qt Prolonged; Miosis; Product Use In Unapproved Indication; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan
	Depakote			S	Oral	3 G		Not Reported
	Depakote			S	Unknown	1.5 G		Not Reported
	Seresta			S	Oral	100 Mg		Not Reported

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Xeroquel Lp			S	Oral	1.8 G	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16611681	EXPEDITED (15-DAY)	CA		DE-MYLANLABS-2019M1067348			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Hydronephrosis; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 [Mg/D]		Not Reported	
	L-Thyroxin /00068002/			C	Transplacental	112 [Mg/D (Bis 75 Mg/D)]		Mylan	
	Progestan			C	Transplacental	600 [Mg/D (3 X 200 Mg/D)]		Mylan	
	Dekristol			C	Transplacental	2000 [I.E./D (Bis 1000 I.E./D)]		Mylan	
	Progynova /00045402/			C	Transplacental	3 [Mg/D (3 X 1 Mg/D)]		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	13550558	EXPEDITED (15-DAY)	HO, OT		CA-APOTEX-2017AP011838		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram			S	Unknown			Apotex	
	Hydrochlorothiazide			S	Unknown			Apotex	
	Gliclazide			S	Unknown			Not Reported	
	Metformin			S	Unknown	1 G, Bid		Apotex	
	Metformin			S	Unknown	1 G, Unk		Apotex	
	Insulin			S	Unknown			Not Reported	
	Insulin			S	Unknown			Not Reported	
	Levothyroxine Sodium			C	Unknown			Not Reported	
	Levothyroxine Sodium			C	Unknown			Not Reported	
	Telmisartan			C	Unknown			Not Reported	
	Telmisartan			C	Unknown			Not Reported	
	Trazodone			C	Unknown			Not Reported	
	Insulin			C	Unknown			Not Reported	

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		Metformin	C	Unknown				Not Reported	
		Metformin	C					Not Reported	
		Gliclazide	C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	15203873	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1837101US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Deafness; Ototoxicity; Tympanometry; Vertigo	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Lyrica			C	Unknown			Not Reported	
	Wellbutrin			C	Unknown			Not Reported	
	Xenical			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	15222340	EXPEDITED (15-DAY)		DS	CA-ALLERGAN-1837599US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Flushing; Joint Stiffness; Sensory Disturbance; Tremor	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Hctz			C	Unknown	Unk		Not Reported	
	Imovane			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	15316856	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1841138US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphonia; Aphonia; Arthritis; Asthma; Blood Pressure Increased; Blood	Escitalopram Oxalate Unk			S	Unknown	1 Df, Qd		Allergan	
	Amlodipine			S	Oral	1 Df, Qd		Not Reported	

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Pressure Systolic Increased; Bone Density Abnormal; Cardiac Murmur; Chest Discomfort; Dysgraphia; Dyspnoea; Fall; Forced Expiratory Volume Decreased; Malaise; Malaise; Mental Disorder; Post-Traumatic Stress Disorder; Rib Fracture; Weight Decreased	Ranitidine	S	Oral	2 Df, Qd	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Q2weeks	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Advair	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Arava	C		Unk	Not Reported
	Darifenacin	C	Oral	1 Df, Qd	Not Reported
	Levothyroxine Sodium	C	Oral	1 Df, Qd	Not Reported
	Plaquenil	C		Unk	Not Reported
	Prednisone	C		2.5 Mg, Qd	Not Reported
	Prednisone	C		15 Mg, Qd	Not Reported
	Prednisone	C		20 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Qvar	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df, Q12h	Not Reported
	Ventolin	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Mirtazapine	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	15625848	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018207113		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cholestasis	Lasilix	S	Oral	20 Mg, Qd	Glaxosmithkline
	Ramipril	S	Oral	2.5 Mg, Qd	Glaxosmithkline
	Lamotrigine	S	Oral	100 Mg, Qd	Glaxosmithkline
	Seroplex	S	Oral	5 Mg, Qd	Glaxosmithkline
	Gabapentine	S	Oral	200 Mg, Qd	Not Reported
	Aspirine Protect	S	Oral	100 Mg, Qd	Not Reported
	Bisoce	S	Oral	1.25 Mg, Qd	Not Reported
	Exemestane	S	Oral	25 Mg, Qd	Not Reported
	Levothyroxine Sodium	C	Oral	30 Gtt, Qd	Glaxosmithkline
	Fluidabak	C	Ophthalmic	3 Gtt, Qd	Not Reported
	Macrogol 3350	C	Oral	11.8 G, Qd	Not Reported
	Potassium Gluconate	C	Oral	1 Cs Per Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16076723	EXPEDITED (15-DAY)		CA, HO	CA-AUROBINDO-AUR-APL-2019-013708			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Milligram, Once A Day		Aurobindo
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Quetiapine Film-Coated Tablet			S	Transplacental	300 Milligram, Two Times A Day		Aurobindo
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported
	Methadone			S	Transplacental	70 Milligram, Once A Day		Not Reported
	Nortriptyline			S	Transplacental	20 Milligram, Once A Day		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16080820	EXPEDITED (15-DAY)		CA, HO, OT	CA-AUROBINDO-AUR-APL-2019-013670			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; High-Pitched Crying; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo	
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo	
	Escitalopram Tablets			S	Transplacental	20 Milligram, Once A Day		Aurobindo	
	Gabapentin			S	Transplacental	1800 Milligram, Once A Day		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Transplacental	300 Milligram, Two Times A Day		Aurobindo	
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Milligram, Once A Day		Not Reported	
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported	
	Benztropine Mesylate			S	Transplacental	1.5 Milligram, Once A Day		Not Reported	
	Nortriptyline			S	Transplacental	20 Milligram, Once A Day		Not Reported	
Rabeprazole			S	Transplacental	Unk		Not Reported		
Zopiclone			S	Transplacental	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16613909	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018482		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Diarrhoea	Apo-Escitalopram			S	Oral	10 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614269	EXPEDITED (15-DAY)		LT	FR-ZYDUS-038803		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral			Zydus Pharm	
	Alprazolam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Cadila	

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23-Jul-2019	16617512	EXPEDITED (15-DAY)		HO	CA-APOTEX-2019AP018471		18 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Jaundice; Nausea; Vomiting	Escitalopram			S	Oral	10 Mg, Qd		Apotex	
	Escitalopram			S	Oral	5 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16618494	EXPEDITED (15-DAY)		HO	FR-SA-2019SA198700		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Ramipril			S	Oral	5 Mg, Qd		Sanofi	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Furosemide			S	Oral	40 Mg, Qd		Sanofi	
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported	
	Bisoprolol Fumarate			S		Unk		Not Reported	
	Amlodipine (Salt Not Specified)			S	Oral	5 Mg, Qd		Not Reported	
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported	
	Clopidogrel Bisulfate			S	Oral	75 Mg, Qd		Sanofi	
	Gabapentin			S	Oral	1200 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16620220	NON-EXPEDITED			US-OTSUKA-2019_010527			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Incorrect Dose Administered; Migraine; Product Use In Unapproved Indication	Rexulti			S	Unknown	1/4 Of A Tablet Or 1/2 A Tablet		Otsuka	
	Rexulti			S				Otsuka	
	Abilify			S	Unknown	Unk		Otsuka	

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	Lexapro		S	Unknown	Unk			Not Reported	
	Latuda		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16620243	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1068219		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Logorrhoea; Seizure; Tachycardia; Toxicity To Various Agents	Escitalopram			S	Oral	Unk		Not Reported	
	Valium			S	Oral	Unk		Mylan	
	Lithium			S	Oral	1.2 Gram, Qd		Mylan	
	Tercian /00759301/			S	Oral	250 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16620339	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1080623		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Pregabaline			S	Oral	225mg Per Day		Not Reported	
	Escitalopram			S	Oral	10mg Per Day		Ivax	
	Metoject			S	Subcutaneous	25mg Per Weeks		Not Reported	
	Xanax 0,25 Mg, Comprimé			S	Oral	0.25mg Per Day		Not Reported	
	Sécable								
	Pantoprazole			C	Oral	40mg Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16621156	EXPEDITED (15-DAY)		OT	US-OTSUKA-2018_031126		20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Depressed Mood; Fatigue; Incorrect Dose Administered; Lethargy; Suicidal Ideation	Rexulti			S	Oral	2 Mg, Qd		Otsuka	
	Rexulti			S				Otsuka	
	Lexapro			S	Unknown	Unk		Not Reported	

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23-Jul-2019	16621694	NON-EXPEDITED			US-OTSUKA-2018_038821			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Rexulti			S	Oral	2mg Once Daily By Mouth		Otsuka	
	Rexulti			S				Otsuka	
	Effexor			S	Unknown	Unk		Not Reported	
	Effexor			S				Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Lexapro			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16622092	NON-EXPEDITED			US-OTSUKA-2019_023477			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Homeless; Hyperhidrosis; Impaired Work Ability; Inability To Afford Medication; Insurance Issue; Memory Impairment; Panic Attack; Tremor	Abilify			S	Unknown	Unk		Otsuka	
	Abilify			S	Unknown	2 Mg, Unk		Otsuka	
	Abilify			S	Unknown	5 Mg, Unk		Otsuka	
	Aripiprazole			S	Unknown	5 Mg, Unk		Otsuka	
	Rexulti			S	Unknown	Unk		Otsuka	
	Rexulti			S				Otsuka	
	Gabapentin			S	Unknown	Unk		Not Reported	
	Lexapro			S	Unknown	Unk		Not Reported	
	Paxil			C	Unknown	Unk		Not Reported	
	Lithium			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16622749	NON-EXPEDITED			US-OTSUKA-2019_009346		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Agitation; Anxiety; Blood	Rexulti	S	Oral	3 Mg, Qd	Otsuka
Glucose Increased;	Rexulti	S	Oral	0.5 Mg, Qd	Otsuka
Diabetes Mellitus;	Trazodone	S	Unknown	Unk	Not Reported
Glycosylated Haemoglobin	Deplin	S	Unknown	Unk	Not Reported
Increased; Weight	Lamictal	S	Unknown	Unk	Not Reported
Increased	Prozac	S	Unknown	Unk	Not Reported
	Trintellix	S	Oral	10 Mg, Unk	Not Reported
	Lexapro	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16622781	EXPEDITED (15-DAY)		OT	US-OTSUKA-2019_018144			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Burning	Rexulti			S	Unknown	Low Dose Once Daily		Otsuka	
Sensation; Dysphagia;	Lexapro			S	Unknown	Unk		Not Reported	
Hypersensitivity; Insomnia;									
Nervousness; Overdose;									
Pain; Rash Pruritic;									
Therapy Cessation;									
Tinnitus; Urticaria									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16623076	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR129774			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal;	Mepolizumab			S		100 Mg, Z(Months)		Glaxosmithkline	
Bronchial Secretion	Ventolin			S		Unk, Prn		Glaxosmithkline	
Retention; Cough; Drug	Ventolin Nebules			S		Unk		Glaxosmithkline	
Ineffective; Dyspnoea;	Escitalopram			S		10 Mg, Qd		Glaxosmithkline	
Eosinophil Count	Crestor			S		10 Mg, Qd		Glaxosmithkline	
Increased; Multiple	Rosuvastatin			S		Unk		Glaxosmithkline	
Allergies; Obstructive									
Airways Disorder;									
Pneumonia; Pulmonary									

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Mass; Respiratory Tract Infection; Reversible Airways Obstruction; Sputum Culture; Sputum Culture Positive; Upper-Airway Cough Syndrome; Vital Capacity Decreased	Diazepam	S	Unk	Glaxosmithkline
	Spirolactone	S	Unk	Glaxosmithkline
	Ferrous Gluconate	S	0.125 Mg, Qd	Glaxosmithkline
	Singulair	S	Unk	Glaxosmithkline
	Symbicort	S	2 Puff(S), Qd	Not Reported
	Spiriva Respimat	S	2 Puff(S), Qd	Not Reported
	Pulmicort	S	Unk Unk, Qd	Not Reported
	Rabeprazole	S	10 Mg, Qd	Not Reported
	Bisoprolol	S	5 Mg, Qd	Not Reported
	Triazide (Trichlormethiazide)	S	Unk, Qd(50/25)	Not Reported
	Xolair	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Alendronate	S	Unk	Not Reported
	Meloxicam	S	Unk	Not Reported
	Tylenol	S	Unk	Not Reported
	Lasix	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16623309	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1081030		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Furosemide			S	Oral	40mg		Not Reported	
	Escitalopram			S	Oral	10mg		Ivax	
	Bisoprolol (Fumarate De)			S	Oral	10mg		Teva	
	Amlodipine			S	Oral	5mg		Teva	
	Lamotrigine			S	Oral	200mg		Teva	
	Ramipril			S	Oral	5mg		Actavis	
	Gabapentine			S	Oral	1200mg		Actavis	

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Clopidogrel Base	S	Oral	75mg	Teva
Alprazolam	S	Oral	0.5mg	Actavis

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24-Jul-2019	15302825	EXPEDITED (15-DAY)	DS		CA-ALLERGAN-1840798US			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Dysaesthesia; Fatigue; Nausea	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Allopurinol			C	Oral	300 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Qd		Not Reported
	Amlodipine			C	Oral	10 Mg, Q8hr		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Diltiazem			C	Oral	240 Mg, Qd		Not Reported
	Gabapentin			C	Unknown	300 Mg, Q8hr		Not Reported
	Ramipril			C	Oral	10 Mg, Qd		Not Reported
	Tylenol With Codein #3			C	Oral	1 Df, Q8hr		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16510059	EXPEDITED (15-DAY)	HO		FR-MYLANLABS-2019M1059587		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Electrocardiogram Abnormal; Miosis; Somnolence; Toxicity To Various Agents	Paroxetine			S	Oral	28 Dosage Form, Total		Not Reported
	Escitalopram			S	Oral	14 Dosage Form, Total		Not Reported
	Prazepam			S	Oral	20 Dosage Form, Total		Mylan
	Cocaine			S	Unknown	0.5 Gram		Mylan
	Tercian /00759302/			S	Oral	16 Dosage Form, Total		Mylan
	Atarax /00058402/			S	Oral	10 Dosage Form, Total		Mylan
	Valium			S	Oral	3 Dosage Form, Total		Mylan
	Alcool			S	Oral	Non Renseign��e		Mylan
	Diazepam			S	Oral	8 Dosage Form, Total		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16588485	EXPEDITED (15-DAY)		HO	IT-ACCORD-138806		6 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Tremor	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16624784	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-042924			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Lamotrigine			S	Oral	200 Milligram, Once A Day		Aurobindo	
	Gabapentin			S	Oral	1200 Milligram, Once A Day		Aurobindo	
	Alprazolam			S	Oral	0.5 Milligram, Once A Day		Aurobindo	
	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Bisoprolol			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Clopidogrel			S	Oral	75 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Furosemide			S	Oral	40 Milligram, Once A Day		Aurobindo	
	Ramipril			S	Oral	5 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16624889	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019309914		46 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Xanax			S	Oral	0.25 Mg, 1x/Day		Pfizer	
	Pregabalin			S	Oral	225 Mg, 1x/Day		Pfizer	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Metoject			S	Subcutaneous	25 Mg, Weekly		Not Reported	

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Pantoprazole			C	Oral	40 Mg, 1x/Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16624966	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2019310014		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Gabapentin			S	Oral	1200 Mg, Daily		Pfizer	
	Alprazolam			S	Oral	0.5 Mg, Daily		Pfizer	
	Esomeprazole Magnesium			S	Oral	40 Mg, Daily		Unknown	
	Oxynormoro			S	Oral	Unk		Not Reported	
	Nefopam [Nefopam Hydrochloride]			S	Oral	Unk		Not Reported	
	Lamotrigine			S	Oral	200 Mg, Daily		Not Reported	
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16627925	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2019317215		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Ramipril			S	Oral	5 Mg, Qd		Pfizer	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Furosemide			S	Oral	40 Mg, Qd		Unknown	
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported	
	Bisoprolol Fumarate			S		Unk		Not Reported	
	Amlodipine			S	Oral	5 Mg, Qd		Pfizer	
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported	
	Clopidogrel			S	Oral	75 Mg, Qd		Not Reported	
	Gabapentin			S	Oral	1200 Mg, Unk		Pfizer	
	Alprazolam			S	Oral	0.5 Mg, Qd		Pfizer	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	16627997	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1929768US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Pregabalin			S	Oral	225 Mg, Qd		Not Reported	
	Metoject			S	Subcutaneous	25 Mg, Q Week		Not Reported	
	Xanax			S	Oral	0.25 Mg, Qd		Not Reported	
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	12922283	NON-EXPEDITED			US-ASTRAZENECA-2016SF13739		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Nexium 24 Hr			S	Oral	Unknown Dose Of Frequency		Astrazeneca	
	Aspirin			S	Oral	Unknown Dose Of Frequency		Not Reported	
	Escitalopram Oxalate			S	Unknown	Unknown Dose Of Frequency		Not Reported	
	Paxil			S	Unknown	Unknown Dose Of Frequency		Not Reported	
	Zoloft			S	Unknown	Unknown Dose Of Frequency		Not Reported	
	Doxepin Hydrochloride			S	Oral	Unknown Dose Of Frequency		Not Reported	
	Depakote			S	Unknown	Unknown Dose Of Frequency		Not Reported	
	Flexeril			S	Unknown	Unknown Dose Of Frequency		Not Reported	
	Nefazodone			S	Unknown	Unknown Dose Of Frequency		Not Reported	

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Oxycontin	S	Unknown	Unknown Dose Of Frequency	Not Reported
Risperidone	S	Unknown	Unknown Dose Of Frequency	Not Reported
Trazodone	S	Unknown	Unknown Dose Of Frequency	Not Reported
Zofran	S	Unknown	Unknown Dose Of Frequency	Not Reported
Xanax Xr	S	Unknown	Unknown Dose Of Frequency	Not Reported
Lorazepam	S	Unknown	Unknown Dose Of Frequency	Not Reported
Hydroxyzine Pamoate	S	Unknown	Unknown Dose Of Frequency	Not Reported
Wellbutrin	S	Unknown	Unknown Dose Of Frequency	Not Reported
Mevacor	S	Unknown	Unknown Dose Of Frequency	Not Reported
Paxil Cr	S	Unknown	Unknown Dose Of Frequency	Not Reported
Reglan	S	Unknown	Unknown Dose Of Frequency	Not Reported
Ultram	S	Unknown	Unknown Dose Of Frequency	Not Reported
Neurontin	S	Unknown	Unknown Dose Of Frequency	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16208883	EXPEDITED (15-DAY)		HO	IT-TAKEDA-2019TUS023263		53 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Glaucoma; Headache; Vertigo	Brintellix			S	Oral	10 Milligram, Qd		Takeda
	Escitalopram Zentiva			S	Unknown	10 Milligram, Qd		Not Reported

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Lormetazepam			C	Oral	40 Gtt Drops, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16548532	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1928174US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Metrorrhagia	Escitalopram Oxalate - Bp			S	Oral	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16628108	NON-EXPEDITED			US-TEVA-2019-US-1080283			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Escitalopram Tablet			S	Unknown			Ivax	
	Adderall Teva			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16628907	EXPEDITED (15-DAY)		DE, HO, OT	CH-TAKEDA-2019TEU008739		78 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease; Respiratory Failure	Dexilant			S	Oral	Unk		Takeda	
	Atorvastatin Pfizer			S	Unknown	Unk		Not Reported	
	Metoprolol Succinate			S	Oral	Unk		Not Reported	
	Cipralext /01588502/			S	Oral	Unk		Not Reported	
	Aspirin Cardio			C	Oral	Unk		Not Reported	
	Pregabalin Pfizer			C	Oral	Unk		Not Reported	
	Toviaz			C	Oral	Unk		Not Reported	
	Mirtazapin			C		Unk		Not Reported	
	Temesta /00273201/			C		Unk		Not Reported	
	Brilique			C		Unk		Not Reported	
	Mst Continus			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16629838	EXPEDITED (15-DAY)		CA	NL-MYLANLABS-2019M1068148			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fallot'S Tetralogy; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	1 Dd 10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16630694	EXPEDITED (15-DAY)		HO	FR-ACCORD-148607		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Amlodipine			S	Oral			Accord	
	Escitalopram			S	Oral			Not Reported	
	Zopiclone			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Mirtazapine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16630844	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1069474		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Bisoprolol			S	Oral	10 Milligram, Qd		Not Reported	
	Bisoprolol			S	Oral	Dose Reduced		Not Reported	
	Furosemide			S	Oral	40 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Amlodipine			S	Oral	5 Milligram, Qd		Not Reported	
	Lamotrigine			S	Oral	200 Milligram, Qd		Not Reported	
	Ramipril			S	Oral	5 Milligram, Qd		Not Reported	
	Gabapentin			S	Oral	1200 Milligram, Qd		Not Reported	

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		Clopidogrel		S	Oral	75 Milligram, Qd			Not Reported
		Alprazolam		S	Oral	0.5 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631043	EXPEDITED (15-DAY)		OT	FR-BAYER-2019-135344		87 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Thrombocytopenia	Glucobay			S	Oral	150 Mg, Qd		Bayer	
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Alfuzosin Hydrochloride			S	Oral	10 Mg, Qd		Not Reported	
	Risperdal			C	Oral	1 Mg/MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631224	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000926			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebellar Haemorrhage; Drug Interaction; Serotonin Syndrome	Tramadol			S	Unknown	Unk		Ipca	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631443	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1929780US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Ischaemic Syndrome	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Trimipramine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631597	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019309871		80 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Alprazolam			S	Oral	0.5 Mg, Daily		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, Daily		Pfizer
	Gabapentin			S	Oral	1200 Mg, Daily		Pfizer
	Furosemide			S	Oral	40 Mg, Daily		Not Reported
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Daily		Not Reported
	Lamotrigine			S	Oral	200 Mg, Daily		Not Reported
	Ramipril			S	Oral	5 Mg, Daily		Not Reported
	Clopidogrel Basics			S	Oral	75 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16632766	NON-EXPEDITED			US-SUNOVION-2019SUN002975			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Withdrawal Syndrome	Latuda			S	Oral	Unk		Sunovion
	Xanax			S				Not Reported
	Lexapro			S				Not Reported
	Vyvanse			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16632845	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1068840		50 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Central Nervous System Lymphoma	Escitalopram			S	Unknown	Unk		Not Reported
	Bromazepam			S	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16633799	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1929807US			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Medication Error; Product Administered To Patient Of Inappropriate Age; Tremor	Escitalopram Oxalate - Bp	S	Oral	12 Gtt	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	8114669	EXPEDITED (15-DAY)		DE, OT	PHHY2011PL76431		69 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Deep Vein Thrombosis; Embolism Venous; Embolism Venous; Pulmonary Embolism	Mirtazapine			S	Unknown	45 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Novartis
	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Reboxetine			S	Unknown	4 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	25 Mg, Qd		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16635509	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039007		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Furosemide			S	Oral			Not Reported
	Escitalopram			S	Oral			Cadila
	Bisoprolol			S	Oral			Not Reported
	Amlodipine			S	Oral			Zydus Pharm
	Lamotrigine			S	Oral			Not Reported
	Ramipril			S	Oral			Zydus Pharm
	Gabapentin			S	Oral			Not Reported
	Clopidogrel			S	Oral			Cadila

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	Alprazolam		S	Oral				Not Reported	
	Bisoprolol		S	Oral	Reduced Dose			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16636726	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-215324		45 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Coma; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Mirtazapine			S	Oral	30 Milligram Unk		Sun	
	Escitalopram			S	Oral	60 Milligram Unik		Not Reported	
	Alprazolam			S	Oral	20 Milligram		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639417	EXPEDITED (15-DAY)		DS, OT	BE-ALLERGAN- 1930163US			Female	BEL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tourette'S Disorder	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Trazolan			S	Unknown	Unk		Not Reported	
	Rodizen			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639433	EXPEDITED (15-DAY)		OT	AU-ALLERGAN- 1930164US			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cholelithiasis; Pancreatitis	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Valium			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	14269725	EXPEDITED (15-DAY)		OT	CA-OTSUKA- 2015_005094		58 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Agitation; Energy Increased; Euphoric Mood; Hypomania; Impulsive Behaviour; Insomnia; Restlessness	Abilify Ciprallex Serax	S S C	Oral Unknown Unknown	2 Mg, Unk 20 Mg, Qd Unk	Otsuka Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16559973	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1063293		1 DAY	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Small For Dates Baby	Escitalopram			S	Transplacental	5 [Mg/D]		Not Reported	
	Tetanus Vaccine			C	Transplacental	Unk		Mylan	
	L-Thyroxin /00068002/			C	Transplacental	50 [Mg/D]		Mylan	
	Folic Acid			C	Transplacental	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16640554	EXPEDITED (15-DAY)		OT	GB-ACCORD-149358		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16642038	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2019022259			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal	Escitalopram			S	Oral	5 Milligram		Macleods	
	Livial			C	Unknown	Unk		Not Reported	
	Candesartan			C	Unknown	Unk		Not Reported	
	Ezetimibe			C	Unknown	Unk		Not Reported	

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29-Jul-2019	16642498	NON-EXPEDITED			US-PFIZER INC-2019318210			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxepin Hcl			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	
	Piroxicam			S		Unk		Pfizer	
	Lodine			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Savella			S		Unk		Not Reported	
	Nucynta			S		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16642590	NON-EXPEDITED			US-MYLANLABS-2019M1065555			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Tramadol			S	Oral	Unk		Not Reported	
	Escitalopram			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643033	EXPEDITED (15-DAY)		HO	FR-009507513-1907FRA013465		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Mirtazapine			S		30 Milligram, Qd		Merck	
	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported	
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported	

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	Seresta		S	Oral		5 Milligram, Qd			Not Reported
	Amlodipine		S	Oral		5 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643447	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1070445		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Haemorrhagic Diathesis; Injection Site Haemorrhage; Product Use In Unapproved Indication	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Fluanxol Depot			C	Unknown	0.5 Milliliter		Mylan	
	Nebivolol			C	Unknown	5 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643869	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019320764		38 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Drug Ineffective	Effexor			S		225 Mg, Unk		Pfizer	
	Jzoloft			S				Pfizer	
	Lexapro			S				Not Reported	
	Cymbalta			S				Not Reported	
	Mirtazapine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16644242	EXPEDITED (15-DAY)		LT	FI-ASTRAZENECA-2019SF06175		51 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcoholic Pancreatitis	Ketipinor			S	Oral	Unknown, Every 12 Hours		Zeneca	
	Ketipinor			S	Oral	Unknown, Every 12 Hours		Zeneca	
	Escitalopram			S		Strength: 5mg		Not Reported	
	Melatonin			S	Unknown	Strength: 3mg		Not Reported	
	Burana			S	Unknown	As Needed		Not Reported	

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Paracetamol			C			Not Reported			
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29-Jul-2019	16644493	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2019M1069893		22 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Obstruction; Product Use In Unapproved Indication	Aripiprazole			S	Unknown	400 Milligram		Not Reported	
	Sipralexa			S	Unknown	20 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16644535	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1930304US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrapyramidal Disorder; Overdose	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan	
	Trevicta			S	Intramuscular			Not Reported	
	Esidrex			C	Oral			Not Reported	
	Irbesartan			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16644772	EXPEDITED (15-DAY)		HO	KR-ANIPHARMA-2019-KR-000023		35 YR	Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parkinsonism	Lorazepam (Non-Specific)			S		1 Mg Daily		Ani	
	Risperidone			S		3 Mg Daily		Not Reported	
	Escitalopram			S		5 Mg Daily		Not Reported	
	Zolpidem			S		12.5 Mg Daily		Not Reported	
	Clonazepam			S		0.5 Mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16463162	NON-EXPEDITED			US-PFIZER INC-2019266999			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Pristiq			S		Unk		Pfizer
	Wellbutrin Sr			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16503672	EXPEDITED (15-DAY)		OT	PHHY2019LT148490		40 YR	Female	LTU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Cough; Drug Reaction With Eosinophilia And Systemic Symptoms; Febrile Neutropenia; Hepatic Enzyme Increased; Intentional Self-Injury; Leukopenia; Liver Injury; Pneumonia; Product Use In Unapproved Indication; Pyrexia; Rash Maculo- Papular; Rash Pruritic; Thrombocytopenia	Carbamazepine			S	Unknown	600 Mg, Qd		Not Reported
	Carbamazepine			S	Unknown	300 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	15 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qhs		Novartis
	Olanzapine			S	Unknown	5 Mg, Qd		Novartis
	Olanzapine			S	Unknown	10 Mg, Qd		Novartis
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	9 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	3 Mg, Unk		Not Reported
	Zuclopentixol			S	Unknown	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16648085	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1071215		25 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Drug Abuse; Dry Mouth; Slow Speech	Lorazepam			S	Oral	20 Milligram, Total		Not Reported
	En 2 Mg Comprese			S	Oral	40 Milligram, Total		Mylan
	Cipralext /01588501/			S	Oral	300 Milligram, Total		Mylan

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30-Jul-2019	16648818	EXPEDITED (15-DAY)		OT	PHHY2019BR148441		43 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Lip Disorder; Memory Impairment; Nodule; Speech Disorder; Swelling; Tremor; Tremor; Weight Increased	Aripiprazole Sandoz			S	Unknown	10 Mg, Unk		Not Reported
	Aripiprazole Sandoz			S	Oral	15 Mg, Bid		Not Reported
	Aripiprazole Sandoz			S	Unknown	25 Mg, Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Rosuvastatin			S	Oral	10 Mg, Qd		Novartis
	Vitamin D			C	Oral	70000 Iu, Bid		Not Reported
	Xenical			C	Oral	120 Mg, Qd		Not Reported
	Omega 3			C	Oral	Unk, Qd		Not Reported
	Garlic			C	Oral	500 Mg, Bid		Not Reported
	Bio C			C	Oral	1000 Mg, Qd		Not Reported
	Citoneurin			C	Intramuscular	1 Df, Qmo		Not Reported
	Chlorthalidone			C	Oral	12.5 Mg, Qd		Not Reported
	Chlorthalidone			C				Not Reported
	Noripurum			C	Intramuscular	Unk Unk, Qmo (One Vial)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16649208	EXPEDITED (15-DAY)		DE	BE-MYLANLABS-2019M1071760		38 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Off Label Use	Escitalopram			S		1 Dosage Form, Qy		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16465592	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2019M1057781		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Accidental Death;	Venlafaxine	S	Unknown	Unk	Not Reported
Agitation; Delirium;	Venlafaxine	S	Unknown	Unk	Not Reported
Dissociative Amnesia;	Mirtazapine	S	Oral	Unk	Not Reported
Drug Intolerance;	Seroplex	S	Unknown	Unk	Mylan
Psychotic Disorder;	Seroplex	S	Unknown	Unk	Mylan
Suicidal Ideation;	Seroplex	S	Unknown	Unk	Mylan
Withdrawal Syndrome	Lysanxia	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16650061	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-215817		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Amlodipine			S	Oral	5 Milligram, Daily		Sun
	Bisoprolol			S	Oral	10 Milligram, Daily		Sun
	Clopidogrel			S	Oral	75 Milligram, Daily		Sun
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Gabapentin			S	Oral	1200 Milligram, Daily		Ranbaxy
	Ramipril			S	Oral	5 Milligram, Daily		Ranbaxy
	Furosemide			S	Oral	40 Milligram, Daily		Not Reported
	Lamotrigine			S	Oral	200 Milligram, Daily		Not Reported
	Alprazolam			S	Oral	0.5 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16650451	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-215818		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Esomeprazole			S	Oral	40 Milligram, Daily		Sun
	Gabapentin			S	Oral	1200 Milligram, Daily		Ranbaxy

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	Oxynormoro 5 Mg, Comprime Orodispersible	S	Oral	()	Not Reported
	Nefopam (Chlorhydrate De)	S	Oral	()	Not Reported
	Alprazolam	S	Oral	0.5 Milligram, Daily	Not Reported
	Lamotrigine	S	Oral	200 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16650467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-215800		87 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Thrombocytopenia	Escitalopram			S	Oral	1/Jour		Not Reported	
	Alfuzosin			S	Oral	1/Jour		Sun	
	Acarbose			S	Oral	150 Milligram, Daily		Not Reported	
	Risperdal 1 Mg/ML, Solution Buvable			C	Oral	25/Jour (1), Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16650918	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-044150			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal	Escitalopram			S	Oral	5 Milligram		Aurobindo	
	Livial			C	Unknown	Unk		Not Reported	
	Candesartan			C	Unknown	Unk		Not Reported	
	Ezetimibe			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16652354	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC- 20190740604		89 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage;	Rivaroxaban			S	Oral	15.0 Mg, Qd		Not Reported	

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Hypotension;	Rivaroxaban	S				Not Reported
Hypovolaemia; Motor	Heparin Sodium	S	Subcutaneous	Unk, Bid		Not Reported
Dysfunction; Oedema;	Heparin Sodium	S				Not Reported
Paralysis; Platelet	Escitalopram	S	Unknown	Unk		Not Reported
Aggregation Inhibition;	Bupivacaine	C		Unk		Not Reported
Platelet Count Decreased;	Epinephrine	C		Unk		Not Reported
Spinal Cord Compression;	Lidocaine	C	Topical	3.0 MI		Not Reported
Spinal Cord Oedema	Hydromorphone	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653725	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2019VAL000320			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Furosemide			S	Oral	40 Mg, Qd		Validus
	Ramipril			S	Oral	5 Mg, Qd		Not Reported
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	10 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Amlodipine			S	Oral	5 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	200 Mg, Unk		Not Reported
	Clopidogrel Bisulfate			S	Oral	75 Mg, Qd		Not Reported
	Gabapentin			S	Oral	1200 Mg, Unk		Not Reported
	Alprazolam			S	Oral	0.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653739	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1930431US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Dependence; Dyspnoea; Expired	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	

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Product Administered; Malaise; Nervousness; Overdose; Poor Quality Sleep	Escitalopram Oxalate - Bp Xarelto	S C	Oral Unknown	Allergan Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653799	EXPEDITED (15-DAY)		LT	FI-ALLERGAN-1930429US			Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcoholic Pancreatitis	Escitalopram Oxalate - Bp			S	Unknown	Strength: 5mg		Allergan	
	Melatonin			S	Unknown	Strength: 3mg		Not Reported	
	Burana			S	Unknown	As Needed		Not Reported	
	Ketipinor			S	Oral	Strenght 25 Mg, Q12h		Not Reported	
	Ketipinor			S				Not Reported	
	Pandol			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653808	EXPEDITED (15-DAY)		HO	NO-MYLANLABS-2019M1071545			Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duodenal Stenosis; Foetal Exposure During Pregnancy	Furadantin			S	Transplacental	50 Milligram, Q8h		Mylan	
	Mirtazapin Orion			S	Transplacental	15 Mg At Night If Necessary.		Mylan	
	Seroquel			S	Transplacental	100 Milligram, Qd		Mylan	
	Truxal /00012101/			S	Transplacental	2 Dosage Forms At Night. Strength Of Dosage Forms Not Known.		Mylan	
	Ciprallex /01588501/			S	Transplacental	5 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653860	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1931021US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Atrioventricular Block; Bradycardia; Electrocardiogram Qt Prolonged; Syncope	Escitalopram Oxalate - Bp	S	Oral	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653877	EXPEDITED (15-DAY)		OT	HR-JNJFOC-20190738493			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Loss Of Consciousness	Rispolept			S	Oral			Not Reported	
	Rivotril			S	Oral			Not Reported	
	Kvetiapin Pharms			S	Unknown			Not Reported	
	Serpentil /01588502/			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16838762	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error;	Lexapro			S	Oral			Not Reported	
Product Dispensing Error;	Humalog			S				Not Reported	
Product Dispensing Error									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	8026713	EXPEDITED (15-DAY)		DE, HO, OT	PL-PFIZER INC-2011153072		69 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antiphospholipid Antibodies; Deep Vein Thrombosis; Pulmonary Embolism	Mirtazapine			S		30 Mg, Unk		Not Reported	
	Mirtazapine			S		45 Mg, Unk		Not Reported	
	Paroxetine			S		20 Mg, Unk		Unknown	
	Reboxetine			S		4 Mg, Unk		Pfizer	
	Sertraline Hcl			S		100 Mg, Unk		Pfizer	
	Venlafaxine Hcl			S		225 Mg, Unk		Pfizer	

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Escitalopram	S	20 Mg, Unk	Not Reported
Quetiapine	S	100 Mg, Unk	Not Reported
Quetiapine	S	300 Mg, Unk	Not Reported
Olanzapine	S	5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16456030	EXPEDITED (15-DAY)		HO, LT, OT	JP-LUPIN PHARMACEUTICALS INC.-2019-03748		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Interaction; Drug Interaction;	Escitalopram Tablets			S	Oral	20 Milligram, Qd		Lupin	
Rhabdomyolysis;	Clomipramine			S	Oral	50 Milligram, Qd (Tablet)		Lupin	
Serotonin Syndrome	Flunitrazepam			S	Unknown	2 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16470246	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX- 2019AP016722		35 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram			S	Oral	Unk, Qd		Apotex	
	Escitalopram			S				Apotex	
	Escitalopram			S				Apotex	
	Clonazepam			S	Oral	0.5 Mg, Tid		Apotex	
	Clonazepam			S				Apotex	
	Clonazepam			S				Apotex	
	Zopiclone			S	Oral	7.5 Mg, Bid		Not Reported	
	Zopiclone			S				Not Reported	
	Zopiclone			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16577233	EXPEDITED (15-DAY)		HO	DE-TORRENT- 00014623		19 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Headache; Insomnia; Product Prescribing Error; Seizure; Syncope	Escitalopram Loratadin	S S	20 Mg, 1-0-0-0 10 Mg	Unknown Unknown					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655496	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039243		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Zopiclone			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Oxazepam			S	Oral			Not Reported	
	Mirtazapine			S				Not Reported	
	Amlodipine			S	Oral			Zydus Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655564	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-04749			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Mania	Escitalopram			S	Unknown	5 Milligram		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655907	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1086022		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported	
	Escitalopram			S	Oral	15 Mg		Ivax	
	Mirtazapine			S		30 Mg		Teva	
	Amlodipine			S	Oral	5 Mg		Teva	
	Seresta 10 Mg, Comprime			S	Oral	5 Mg		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655932	EXPEDITED (15-DAY)		CA, OT	US-ACCORD-149568			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16656683	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019323138		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day		Pfizer	
	Zopiclone			S	Oral	0.5 Df, Unk		Not Reported	
	Escitalopram			S	Oral	15 Mg, 1x/Day		Not Reported	
	Seresta			S	Oral	5 Mg, 1x/Day		Not Reported	
	Mirtazapine			S		30 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16657858	EXPEDITED (15-DAY)		HO	PHHY2019FR176164		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Diltiazem			S	Oral	90 Mg, Qd		Novartis	
	Escitalopram			S	Oral	5 Mg, Qd		Not Reported	
	Ramipril			S	Oral	10 Mg, Qd		Not Reported	
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported	
	Humalog			S	Subcutaneous	2 Iu, Unk		Not Reported	
	Umuline			S	Subcutaneous	16 Ui Le Matin Et 3 Ui Le Soir		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16658258	EXPEDITED (15-DAY)		OT	US-PRINSTON PHARMACEUTICAL INC.-2019PRN00720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease; Colectomy; Crohn'S Disease; Depressed Mood; Malaise; Renal Cancer	Escitalopram Apriso			S C		Unk		Prinston Pharmaceutical Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16658270	EXPEDITED (15-DAY)		OT	IE-MYLANLABS- 2019M1071512			Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Product Substitution Issue	Escitalopram			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16658725	EXPEDITED (15-DAY)		HO	IT-ALLERGAN- 1931013US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error; Tremor; Vomiting	Escitalopram Oxalate - Bp			S	Oral	1 Df, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	8111543	EXPEDITED (15-DAY)		DE, OT	PHHY2011PL76023		69 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Embolism Venous;	Paroxetine Sertraline Venlafaxine Mirtazapine			S S S S	Unknown Unknown Unknown Unknown	20 Mg, Qd 100 Mg, Qd 225 Mg, Qd 30 Mg, Qd		Not Reported Not Reported Not Reported Not Reported	

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Pulmonary Embolism	Mirtazapine	S	Unknown	45 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
	Quetiapine	S	Unknown	100 Mg, Qd	Novartis
	Quetiapine	S	Unknown	300 Mg, Qd	Novartis
	Olanzapine	S	Unknown	5 Mg, Qd	Not Reported
	Reboxetine	S	Unknown	4 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16062343	EXPEDITED (15-DAY)		DE	BE-TEVA-2019-BE-1021544		38 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use	Escitalopram			S	Unknown			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16600767	NON-EXPEDITED			US-CELGENEUS-USA-20190704170		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Gastric Disorder; Vomiting	Otezla			S	Oral	60 Milligram		Celgene	
	Lexapro			S	Unknown			Not Reported	
	Lexapro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16617592	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018511		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased;	Escitalopram			S	Oral	1 Df, Qd		Apotex	
	Pantoprazole			S	Oral	1 Df, Qd		Apotex	
	Celebrex			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	

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Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	1 Df, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16627898	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1068187			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Escitalopram			S		Morning		Not Reported
	Azathioprine			S		With Or Just After Food		Not Reported
	Azathioprine			S		Morning, Lunch And Tea Time (With Or Just After Food/Meal)		Not Reported
	Mirtazapine			S		Night		Not Reported
	Olanzapine			S		5 Milligram, Qd		Not Reported
	Folic Acid			S		Morning		Not Reported
	Dihydrocodeine Mylan			S		Two To Be Taken Four Times A Day If Required.		Mylan
	Dihydrocodeine Mylan			S		Four Times Daily. With Or Just After Food/Meal		Mylan
	Ferrous Fumarate			S		Morning And Night		Mylan
	Ferrous Fumarate			S		Morning And Night		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16627977	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALLERGAN-1929651US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Off Label Use; Seizure; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 100 Tablets		Allergan
	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

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	Mirtazapine	C	Oral	3 Mg, Qd				Not Reported	
	Mirtazapine	C	Oral	6 Mg, Qd				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16629670	EXPEDITED (15-DAY)		DE, OT	PL- ELI_LILLY_AND_COMP ANY-PL201907011955		69 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antiphospholipid	Olanzapine			S	Unknown	5 Mg, Daily		Eli Lilly And Co	
Antibodies;	Reboxetine			S	Unknown	4 Mg, Daily		Not Reported	
Antiphospholipid	Quetiapine			S	Unknown	100 Mg, Daily		Not Reported	
Antibodies Positive; Deep	Quetiapine			S	Unknown	300 Mg, Daily		Not Reported	
Vein Thrombosis;	Escitalopram			S	Unknown	20 Mg, Daily		Not Reported	
Embolism Venous;	Escitalopram			S	Unknown	5 Mg, Daily		Not Reported	
Embolism Venous;	Venlafaxine			S	Unknown	225 Mg, Daily		Not Reported	
Pulmonary Embolism	Paroxetine			S	Unknown	20 Mg, Daily		Not Reported	
	Sertraline			S	Unknown	100 Mg, Daily		Not Reported	
	Mirtazapine			S	Unknown	30 Mg, Daily		Not Reported	
	Mirtazapine			S	Unknown	45 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16659394	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-044308			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form		Not Reported	
	Escitalopram			S	Oral	15 Milligram, Once A Day		Aurobindo	
	Mirtazapine			S	Unknown	30 Milligram, Once A Day		Aurobindo	
	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Seresta			S	Oral	5 Milligram, Once A Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16659493	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019022305			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Milligram, Qd, 0. - 40.2. Gestational Week (First Trimester)		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16660040	EXPEDITED (15-DAY)		DE, HO, OT	PL-AUROBINDO-AUR- APL-2011-03696			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Pulmonary Embolism	Paroxetine			S	Unknown	20 Milligram, Daily		Aurobindo	
	Sertraline			S	Unknown	100 Milligram, Daily		Aurobindo	
	Mirtazapine			S	Unknown	30 Milligram, Daily		Not Reported	
	Mirtazapine			S	Unknown	45 Milligram, Daily		Not Reported	
	Venlafaxine			S	Unknown	225 Milligram, Daily		Not Reported	
	Reboxetine			S	Unknown	4 Milligram, Daily		Not Reported	
	Escitalopram			S	Unknown	20 Milligram, Daily		Not Reported	
	Quetiapine			S	Unknown	100 Milligram, Daily		Not Reported	
	Quetiapine			S	Unknown	300 Milligram, Daily		Not Reported	
	Olanzapine			S	Unknown	5 Milligram, Daily		Not Reported	
	Olanzapine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16660356	EXPEDITED (15-DAY)		DE, OT	PL-AUROBINDO-AUR- APL-2011-03601			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Embolism Venous;	Olanzapine			S	Unknown	Maximum Daily Dose Of		Aurobindo	

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Pulmonary Embolism

Paroxetine	S	Unknown	5mg	Aurobindo
Escitalopram	S	Unknown	Maximum Daily Dose Of 20mg	Aurobindo
Quetiapine	S	Unknown	Maximum Daily Dose Of 100mg	Aurobindo
Quetiapine	S	Unknown	300 Milligram	Aurobindo
Sertraline	S	Unknown	Maximum Daily Dose Of 100mg	Aurobindo
Venlafaxine	S	Unknown	Maximum Daily Dose Of 225mg	Aurobindo
Mirtazapine	S	Unknown	45 Mg,Unk,	Not Reported
Mirtazapine	S	Unknown	Maximum Daily Dose Of 30mg	Not Reported
Reboxetina	S	Unknown	Maximum Daily Dose Of 4mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16664430	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1931006US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram Oxalate - Bp			S	Transplacental	20 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16664431	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1931011US			Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Drug Reaction; Bruxism; Restless Legs Syndrome	Escitalopram Oxalate - Bp			S	Oral	15 Milligram Daily		Allergan

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2019	16665120	EXPEDITED (15-DAY)		HO	FR-ACCORD-149930		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral			Not Reported	
	Ramipril			S	Oral			Accord	
	Bromazepam			S	Oral			Not Reported	
	Diltiazem			S	Oral			Not Reported	
	Humalog			S	Subcutaneous			Not Reported	
	Umuline			S	Subcutaneous	16 lu In The Morning And 3 lu In The Evening		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2019	16665212	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022361			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S	Unknown	Unk		Macleods	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	15244173	NON-EXPEDITED			US-PFIZER INC- 2018315144		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Fentanyl Citrate			S		Unk		Unknown	
	Gabapentin			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	
	Boniva			S		Unk		Not Reported	

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Lisinopril	S	Unk	Not Reported
Fosamax	S	Unk	Not Reported
Carbamazepine	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16198661	EXPEDITED (15-DAY)		DS, OT	ES-MYLANLABS-2019M1034739		45 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Libido	Sertraline			S	Oral	50 Milligram, Qd		Not Reported	
	Sertraline			S	Oral	100 Milligram, Qd		Not Reported	
	Escitalopram			S		10 Mg, 1x/Day		Not Reported	
	Enalapril			C		20 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16412184	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1924235US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Breast Feeding; Neonatal Respiratory Depression; Pregnancy	Escitalopram Oxalate - Bp			S	Transmammary	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16559711	NON-EXPEDITED			US-PFIZER INC-2019291589		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity; Rash Macular; Reaction To Excipient; Urticaria	Sertraline Hcl			S		25 Mg, 1x/Day		Pfizer	
	Metoprolol Succinate			S		50 Mg, 1x/Day		Not Reported	
	Benazepril Hydrochloride			S	Oral	20 Mg, 1x/Day		Not Reported	
	Escitalopram			S		5 Mg, 1x/Day (10mg 1/2		Not Reported	

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Escitalopram	S		Pill At Bed)	Not Reported
Hydralazine	S	Oral	5 Mg, 1x/Day	Not Reported
			12.5 Mg, 2x/Day (25mg 1/2 By Mouth)	
Silicon Dioxide, Colloidal	S		Unk	Not Reported
Sodium Starch Glycolate Type A Potato	S		Unk	Not Reported
Premarin	C		Unk	Not Reported
Synthroid	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16634813	EXPEDITED (15-DAY)		DE, OT	PL-ASTRAZENECA- 2019SF05029		69 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antiphospholipid Antibodies; Death; Deep Vein Thrombosis; Embolism Venous; Pulmonary Embolism	Quetiapine			S	Unknown			Zeneca
	Quetiapine			S	Unknown			Zeneca
	Reboxetine			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Paroxetine			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16667886	EXPEDITED (15-DAY)		OT	CH-JNJFOC- 20190743390		42 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphasia; Cognitive Disorder; Confusional	Tramadol/Apap			S	Unknown			Not Reported

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State; Drug Interaction; Drug Interaction	Escitalopram	S	Oral		Not Reported
	Escitalopram	S	Oral		Not Reported
	Topiramate	S	Oral		Not Reported
	Trazodone	S	Oral		Not Reported
	Cannabidiol	S	Oral		Not Reported
	Olanzapine	S	Unknown		Not Reported
	Desloratadine	C	Oral	5 Mg, Unk	Not Reported
	Tizanidine	C	Oral	4 Mg, 1/Day	Not Reported
	Ibuprofen	C	Oral	Unk	Not Reported
	Dienogest	C	Oral	2 Mg, 1/Day	Not Reported
	Calcitriol	C	Oral	Unk	Not Reported
	Euthyrox	C	Unknown	175 Mcg, 1/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16669129	DIRECT					32 YR	Transgender	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Product Substitution Issue	Escitalopram 10 Mg Tablet			S	Oral	Quantity:1 Tablet(S);	1 WEEK	Torrent	
	Tylenol			C				Not Reported	
	Claritin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16669247	EXPEDITED (15-DAY)		HO	CA-ALLERGAN-1931934US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Incorrect Dose Administered; Off Label Use; Suicidal Ideation	Escitalopram Oxalate - Bp			S		20 Mg		Allergan	
	Escitalopram Oxalate - Bp			S		15 Mg		Allergan	
	Escitalopram Oxalate - Bp			S		Unk		Allergan	
	Effexor Xr			S	Unknown	37.5 Mg		Not Reported	
	Effexor Xr			S	Unknown	75 Mg		Not Reported	

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	Venlafaxine Hydrochloride		S	Unknown				Not Reported	
	Quetiapine		C					Not Reported	
	Seroquel		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16669957	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2019M1072611		39 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Insomnia; Psychomotor Hyperactivity	Escitalopram			S	Oral	20 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	15979662	NON-EXPEDITED			US-PFIZER INC-2019064474		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ceftriaxone Sodium			S		Unk			Unknown
	Ciprofloxacin			S		Unk			Unknown
	Ibuprofen			S		Unk			Pfizer
	Aspirin [Acetylsalicylic Acid]			S		Unk			Not Reported
	Bactrim			S		Unk			Not Reported
	Duloxetine Hcl			S		Unk			Not Reported
	Escitalopram Oxalate			S		Unk			Not Reported
	Prednisone			S		Unk			Not Reported
	Tramadol			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16671810	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-045981			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S	Unknown	Unk			Aurobindo

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06-Aug-2019	16671915	EXPEDITED (15-DAY)		OT	HR-ROCHE-2366339			Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Loss Of Consciousness	Rivotril			S	Oral			Not Reported	
	Kvetiapin Pharms			S	Unknown			Not Reported	
	Risperidon			S	Oral			Not Reported	
	Serpentil [Escitalopram Oxalate]			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16672775	EXPEDITED (15-DAY)		HO	IE-MYLANLABS-2019M1072971		55 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Moclobemide			S		Unk		Not Reported	
	Agomelatine			S		Unk		Not Reported	
	Duloxetine			S		Unk		Not Reported	
	Sertraline			S		Unk		Not Reported	
	Fluoxetine			S		Unk		Not Reported	
	Mirtazapine			S	Oral	Unk		Not Reported	
	Escitalopram			S		Unk		Not Reported	
	Quetiapine			S		Unk		Not Reported	
	Olanzapine			S		Unk		Not Reported	
	Fluvoxamine			S		Unk		Not Reported	
	Venlafaxine			S		Unk		Not Reported	
	Amitriptyline Hydrochloride			S		Unk		Mylan	
	Phenelzine Sulfate			S		Unk		Mylan	
	Sodium Valproate			S		Unk		Mylan	
	Lithium			S		Unk		Mylan	
	Trimipramine			S		Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16672852	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1072733		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hypochloraemia; Hyponatraemia; Nausea	Escitalopram			S		Unk		Not Reported	
	Coaprovel			S	Oral			Mylan	
	Urbason /00049601/			C				Mylan	
	Paracetamol			C		Unk		Mylan	
	Alprazolam			C		Unk		Mylan	
	Eutirox			C				Mylan	
	Pantoprazole Sodium Sesquihydrate			C		Unk		Mylan	
	Alendronic Acid Sodium			C	Oral	70 Milligram		Mylan	
	Colecalciferol			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16672871	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2009S1002345		53 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Pulmonary Embolism; Sedation; Weight Increased	Olanzapine			S	Unknown	5 Mg,Qd		Not Reported	
	Escitalopram			S	Unknown	10 Mg/Day		Not Reported	
	Alprazolam			S	Unknown	1 Mg/Day		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16673562	EXPEDITED (15-DAY)		HO	US-APOTEX-2019AP019728		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Drug Ineffective; Headache; Hot Flush	Trazodone			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Citalopram			S	Unknown	Unk		Apotex	

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	Sertraline	S	Unknown	Unk		Apotex
	Fluoxetine	S	Unknown	Unk		Apotex
	Lurasidone	S	Unknown	Unk		Not Reported

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06-Aug-2019	16674176	EXPEDITED (15-DAY)		DS, OT	CA-ALLERGAN-1931944US			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Asthenia; Back Pain; Chest Pain; Chills; Confusional State; Decreased Appetite; Depression; Fatigue; Insomnia; Irritability; Libido Decreased; Memory Impairment; Somnolence; Suicidal Ideation; Thirst	Escitalopram Oxalate - Bp			S	Oral	97		Allergan
	Atorvastatin Calcium			C	Unknown	97		Not Reported
	Morphine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16674177	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1931942US			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mastitis	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	8123119	EXPEDITED (15-DAY)		DE, OT	PL-RANBAXY-2011RR-47274		69 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Embolism Venous	Paroxetine			S	Unknown	20 Mg/Day		Sun
	Sertraline			S	Unknown	100 Mg/Day		Sun
	Venlafaxine			S	Unknown	225 Mg/Day		Sun
	Mirtazapine			S	Unknown	30 Mg/Day		Sun
	Mirtazapine			S	Unknown	45 Mg/Day		Sun

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Quetiapine	S	Unknown	100 Mg/Day	Sun
Quetiapine	S	Unknown	300 Mg/Day	Sun
Reboxetine	S	Unknown	4 Mg/Day	Not Reported
Escitalopram	S	Unknown	20 Mg/Day	Not Reported
Olanzapine	S	Unknown	5 Mg/Day	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16591013	EXPEDITED (15-DAY)	HO, OT		US-PFIZER INC-2019300678		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Neutropenia; Platelet Count Decreased; Tinnitus	Ibrance			S		125 (Unknown Unit), Cyclic		Pfizer
	Ibrance			S		100 Mg, Cyclic		Pfizer
	Ibrance			S		75 Mg, Cyclic (X21 Days)		Pfizer
	Lexapro			S		20 Mg, Unk		Not Reported
	Lexapro			S		10 Mg, Daily		Not Reported
	Zofran [Ondansetron]			C		4 Mg, As Needed		Not Reported
	Ativan			C		Unk, As Needed (0.5 To 1 Mg)		Not Reported
	Ativan			C				Not Reported
	Tylenol [Paracetamol]			C		500 Mg, As Needed		Not Reported
	Tizanidine			C		Unk, As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16675860	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2019-04726		72 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea	Escitalopram			S	Unknown	10 Milligram, Qd		Lupin
	Escitalopram			S	Unknown	5 Milligram, Qd		Lupin

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16676931	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-216664		84 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall	Zopiclone			S	Oral	0.5 Dosage Form Unk		Not Reported	
	Escitalopram			S	Oral	15 Milligram, Daily		Not Reported	
	Mirtazapine			S	Unknown	30 Milligram, Daily		Sun	
	Amlodipine			S	Oral	5 Milligram, Daily		Sun	
	Seresta 10 Mg, Comprime			S	Oral	5 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16676968	EXPEDITED (15-DAY)		OT	GB-TORRENT- 00021455		61 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677230	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-052440			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Aurobindo	
	Esomeprazole			S	Oral	20 Milligram, Daily		Aurobindo	
	Furosemide			S	Oral	40 Milligram, Daily		Aurobindo	
	Simvastatin			S	Oral	20 Milligram, Daily		Aurobindo	
	Spironolactone			S	Oral	25 Milligram, Daily		Aurobindo	
	Seresta			S	Oral	2 Dosage Form, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677363	NON-EXPEDITED		OT	US-JNJFOC-20190743964			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Cystitis Interstitial; Headache; Off Label Use; Pharyngeal Swelling; Product Use Issue; Swollen Tongue	Elmiron			S	Oral			Not Reported	
	Elmiron			S	Oral			Not Reported	
	Elmiron			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677577	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019336372		22 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16678453	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMP ANY-FR201907015331		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Humalog Lispro			S	Subcutaneous	2 International Unit, Unknown		Eli Lilly And Co	
	Umuline			S	Subcutaneous	16 International Unit, In The Morning		Not Reported	
	Umuline			S	Subcutaneous	3 International Unit, In The Evening		Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Diltiazem			S	Oral			Not Reported	
	Ramipril			S	Oral			Not Reported	

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Bromazepam			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16678831	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-022136		90 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Fibrosis	Venlafaxine			S	Unknown			Not Reported	
	Duloxetine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16679357	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1073222		1 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Retrognathia	Escitalopram			S	Transplacental	15 [Mg/D]		Not Reported	
	L-Thyroxin /00068002/			C	Transplacental	50 [Mg/D]		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16680250	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1931951US			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Decreased	Escitalopram Oxalate - Bp			S		20 Mg, Unk		Allergan	
	Mirtazapine			C				Not Reported	
	Diazepam			C				Not Reported	
	Ramipril			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Apixaban			C				Not Reported	
	Tamsulosin			C				Not Reported	
	Torasemide			C				Not Reported	
	Metformine			C				Not Reported	
	Baldorat			C				Not Reported	
	Levodopa			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16680255	EXPEDITED (15-DAY)		OT	HR-ALLERGAN-1931707US			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Suicide Attempt	Escitalopram Oxalate - Bp			S	Oral	Overdose: 120mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16680313	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1931722US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16680314	EXPEDITED (15-DAY)		HO	AT-ALLERGAN-1932039US			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Airway Burns; Burning Sensation; Paraesthesia; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16682814	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Yawning	Celexa Lexapro			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16681019	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Confusional State; Delirium; Drug Hypersensitivity; Dyspepsia; Fatigue; Mental Status Changes; Nausea; Pruritus; Vomiting	Escitalopram			S	Unknown	Unk		Lupin
	Fluoxetine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Duloxetine			S	Unknown	Unk		Lupin
	Oxycodone			S	Unknown	Unk		Novel Labs
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16681314	EXPEDITED (15-DAY)		HO	FR-ACCORD-150541		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Escitalopram			S	Oral			Not Reported
	Levothyrox			S	Oral	50 Micrograms, Scored Tablet		Not Reported
	Coumadine			S	Oral	5 Mg, Scored Tablet		Not Reported
	Ezetrol			S	Oral	10 Mg Tablet		Not Reported
	Clotiazepam			C	Oral			Not Reported
	Alfuzosine			C	Oral			Not Reported
	Cordarone			C		200 Mg, Scored Tablet		Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported
	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium Pulmicort			C	Oral			Not Reported
				C	Respiratory (inhalation)	200 Microg / Dose, Suspension For Inhalation In A Pressurized Bottle		Not Reported

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Coaprovel	C	Oral	300 Mg / 12.5 Mg Tablets	Not Reported
Fucidine	C	Cutaneous	2 Percent, Ointment	Not Reported
Janumet	C	Oral	50 Mg / 1000 Mg Film-Coated Tablets	Not Reported
Tadenan	C	Oral	50 Mg Soft Capsule	Not Reported
Mono Tildiem	C	Oral	300 Mg, Prolonged Release Capsule	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16681336	EXPEDITED (15-DAY)	CA		US-HETERO-HET2019US01076			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unk		Hetero

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16681425	EXPEDITED (15-DAY)	HO		FR-AUROBINDO-AUR-APL-2019-046468			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Bromazepam			S	Oral	3 Milligram, Once A Day		Not Reported
	Diltiazem			S	Oral	90 Milligram, Once A Day		Not Reported
	Escitalopram			S	Oral	5 Milligram, Once A Day		Aurobindo
	Ramipril			S	Oral	10 Milligram, Once A Day		Aurobindo
	Umluline			S	Subcutaneous	16 Iu In The Morning And 3 Iu In The Evening		Not Reported
	Humalog			S	Subcutaneous	2 International Unit		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16682731	NON-EXPEDITED			US-PFIZER INC-2019338961		57 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue	Gabapentin			S		300 Mg, 3x/Day		Pfizer	
	Pantoprazole			S	Oral	20 Mg, Daily		Pfizer	
	Dexamethasone			S	Oral	4 Mg, 2x/Day		Not Reported	
	Escitalopram			S	Oral	20 Mg, Daily (10 Mg, 2 Tablets Daily By Mouth)		Not Reported	
	Tegretol			S	Oral	200 Mg, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684680	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1932262US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia; Panic Disorder; Salivary Hypersecretion; Vomiting	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Abilify			S	Unknown			Not Reported	
	Abilify			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684715	EXPEDITED (15-DAY)		LT	FR-ALLERGAN-1839199US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Confusional State; Fall	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Unk		Allergan	
	Tercian			S	Oral	Unk		Not Reported	
	Ciflox			S	Unknown	Unk		Not Reported	
	Trivastal			S	Oral	50 Mg, Unk		Not Reported	
	Lyrica			S	Oral	75 Mg, Unk		Not Reported	
	Baclofene			S	Unknown	2 Df, Unk		Not Reported	
	Takadol			S	Oral	1.5 Df, Unk		Not Reported	
	Temesta (Lorazepam)			S	Oral	1 Df, Unk		Not Reported	

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Levothyrox	C	Oral	1 Df, Unk	Not Reported
Tahor	C	Oral	1 Df, Unk	Not Reported
Furosemide	C	Oral	20 Mg, Unk	Not Reported
Daflon	C	Oral	2 Df, Unk	Not Reported
Paralyoc	C	Oral	Unk	Not Reported
Previscan	C	Oral	Unk	Not Reported
Cordarone	C	Oral	0.5 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684735	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1073757		50 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Tongue Biting	Escitalopram			S		20 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684952	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1074249		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Clozapine			S	Oral	500 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported	
	Inexium			S	Oral	1500 Milligram, Qd		Mylan	
	Xanax			S	Oral	0.75 Milligram, Qd		Mylan	
	Ditropan			S	Oral	5 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684955	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1932542US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Headache; Hot Flush	Escitalopram Oxalate - Bp			S	Unknown			Allergan	

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Citalopram Hydrobromide - Bp	S	Unknown	Allergan
Fluoxetine Hcl Unk	S	Unknown	Allergan
Trazodone	S	Unknown	Not Reported
Lurasidone	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16685066	EXPEDITED (15-DAY)	HO		FR-009507513-1908FRA002570		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Ezetrol			S	Oral	1 Dosage Form, Qd		Merck
	Levothyrox			S	Oral	1 Dosage Form, Qd		Not Reported
	Coumadine			S	Oral	1 Dosage Form, Qd		Not Reported
	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Clotiazepam			C	Oral	5 Milligram, Qd		Not Reported
	Alfuzosin Hydrochloride			C	Oral	10 Milligram, Qd		Not Reported
	Cordarone			C		1 Dosage Form, Qd		Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)	2 Dosage Form, Qd		Not Reported
	Esomeprazole			C	Oral	40 Milligram, Qd		Not Reported
	Pulmicort			C	Respiratory (inhalation)	4 Dosage Form, Qd; Formulation: Suspension For Inhalation		Not Reported
	Coaprovel			C	Oral	1 Dosage Form, Qd		Not Reported
	Fucidine (Fusidate Sodium)			C	Cutaneous	1 Dosage Form, Qd		Not Reported
	Janumet			C	Oral	2 Dosage Form, Qd		Not Reported
	Tadenan			C	Oral	2 Dosage Form, Qd		Not Reported
	Mono-Tildiem			C	Oral	1 Dosage Form, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	15285226	EXPEDITED (15-DAY)		LT	FR-BAYER-2018-146724		86 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Confusional State; Fall	Ciflox			S	Unknown	Unk		Bayer	
	Seroplex			S	Oral	1 Df, Unk		Not Reported	
	Tercian			S	Oral	Unk		Not Reported	
	Trivastal [Piribedil]			S	Oral	1 Df, Unk		Not Reported	
	Lyrica			S	Oral	1 Df, Unk		Not Reported	
	Baclofen			S	Unknown	2 Df, Unk		Not Reported	
	Takadol			S	Oral	1.5 Df, Unk		Not Reported	
	Temesta (Lorazepam)			S	Oral	1 Df, Unk		Not Reported	
	Levothyrox			C	Oral	1 Df, Unk		Not Reported	
	Tahor			C	Oral	1 Df, Unk		Not Reported	
	Furosemide			C	Oral	20 Mg, Unk		Not Reported	
	Paralyoc			C	Oral	Unk		Not Reported	
	Previscan [Fluindione]			C	Oral	Unk		Not Reported	
	Cordarone			C	Oral	0.5 Df, Unk		Not Reported	
	Daflon [Diosmin;Hesperidin]			C	Oral	2 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16278163	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019184504		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Fluctuation; Cardiac Disorder; Palpitations	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Lexapro			S		1 Pill		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Aspirin 81			C		81 Mg, Unk		Not Reported	
	Biotin			C		1 Mg, Unk		Not Reported	

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Caltrate [Calcium Carbonate; Colecalciferol]	C	Unk (Calcium Carbonate 250mg+ Colecalciferol 4iu)	Not Reported
Prilosec [Omeprazole]	C	20 Mg, Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unk (2500 Mc)	Not Reported
Meloxicam	C	Unk (7.5)	Not Reported
Folic Acid	C	1 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16685409	EXPEDITED (15-DAY)		HO	FR-SA-2019SA219039		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Ramipril			S	Oral	10 Mg, Qd		Sanofi
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported
	Bromazepam			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			S	Oral	90 Mg, Unk		Sanofi
	Insulin Lispro			S	Subcutaneous	2 Iu, Unk		Sanofi
	Umuline			S	Subcutaneous	16 Ui Le Matin Et 3 Ui Le Soir		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16686059	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/19/0112897		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Fluoxetine Delayed-Release Capsules			S				Not Reported
	Venlafaxine Hydrochloride			S				Not Reported
	Escitalopram			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16686345	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1090117		61 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Skin Reaction; Vaginal Haemorrhage	Escitalopram			S				Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16686453	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1089456			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis	Amitriptyline			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Ivax	
	Metoprolol /00376903/			S	Unknown	Unk		Actavis	
	Ibuprofen			S	Unknown	Unk		Actavis	
	Prednisolone			S	Unknown	25 Mg, Unk		Actavis	
	Salbutamol			S	Unknown	Unk		Barr	
	Prednisolon /00016201/			S	Unknown	Unk		Actavis	
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported	
	Metoprolol Mylan /00376902/			S	Unknown	Unk		Not Reported	
	Golimumab			S	Unknown	Unk		Not Reported	
	Implanon			S	Unknown	Unk		Not Reported	
	Escitalopram Mylan			S	Unknown	Unk		Not Reported	
	Escitalopram Hexal			S	Unknown	Unk		Not Reported	
	Metoprolol Hexal			S	Unknown	Unk		Not Reported	
	Metoprolol Stada			S	Unknown	Unk		Not Reported	
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported	
	Pantozol /01263204/			S	Unknown	Unk		Not Reported	
	Ibuprofen Stada			S	Unknown	Unk		Not Reported	
	Salbutamol Stada			S	Unknown	Unk		Not Reported	
	Methotrexate Mylan			S	Unknown	Unk		Not Reported	
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported	

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	Prednisolon Stada	S	Unknown	Unk				Not Reported	
	Escitalopram Stada	S	Unknown	Unk				Not Reported	
	Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	C						Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16687752	NON-EXPEDITED			US-PFIZER INC-2019342333		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nightmare; Off Label Use; Product Use In Unapproved Indication	Sertraline Hcl			S	Oral	25 Mg, 3x/Day		Pfizer	
	Lexapro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16688939	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2019M1072714			Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Sedation; Weight Increased	Olanzapine			S	Unknown	20 Milligram, Qd		Not Reported	
	Escitalopram			S	Unknown	10 Milligram		Not Reported	
	Lamotrigine			S	Unknown	25 Milligram		Not Reported	
	Trazodone			S	Unknown	150 Milligram		Mylan	
	Oxazepam			S	Unknown	15 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16689904	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1074225		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Headache; Hot Flush	Escitalopram			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Fluoxetine			S	Oral			Not Reported	

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Sertraline	S	Unknown	Not Reported
Alprazolam	S	Oral	Not Reported
Lurasidone	S	Unknown	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	14510860	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2018TUS002973		34 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Drug Reaction; Crohn'S Disease; Fatigue; Headache; Hyperhidrosis; Hypoaesthesia; Insomnia; Loss Of Consciousness; Malaise; Male Orgasmic Disorder; Off Label Use; Rectal Haemorrhage	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram, Q4weeks		Takeda
	Ciprallex /01588501/			S	Unknown	Unk		Not Reported
	Allopurinol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	15296536	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2018328674		86 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Confusional State; Fall	Lyrica			S	Oral	1 Df, Unk		Pfizer
	Seroplex			S	Oral	1 Df, Unk		Not Reported
	Tercian /00759302/			S	Oral	Unk		Not Reported
	Ciflox /00697202/			S	Unknown	Unk		Not Reported
	Trivastal /00397201/			S	Oral	1 Df, Unk		Not Reported
	Baclofen			S	Unknown	2 Df, Unk		Not Reported
	Takadol			S	Oral	1.5 Df, Unk		Not Reported
	Temesta /00273201/			S	Oral	1 Df, Unk		Not Reported
	Levothyrox			C	Oral	1 Df, Unk		Not Reported

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Tahor	C	Oral	1 Df, Unk	Not Reported
Furosemide	C	Oral	20 Mg, Unk	Not Reported
Daflon /01026201/	C	Oral	2 Df, Unk	Not Reported
Paralyoc	C	Oral	Unk	Not Reported
Previscan /00789001/	C	Oral	Unk (According To Inr)	Not Reported
Cordarone	C	Oral	0.5 Df, Unk (5 Days A Week)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	15508194	EXPEDITED (15-DAY)		DE, HO, OT	BE-ALLERGAN-1849439US			Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Dementia; Loss Of Consciousness; Mental Disorder; Psychotic Disorder; Wrong Product Administered	Escitalopram Oxalate - Bp			S	Oral	0.5 Df, Qd		Allergan
	Afebryl			C	Unknown	Unk		Not Reported
	Loortan			C				Not Reported
	Nobiten			C				Not Reported
	Amlor			C				Not Reported
	Venuroton			C				Not Reported
	Cardioasperine			C				Not Reported
	Cholemed			C				Not Reported
	Lormetazepan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	15722239	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018224866			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Voltaren (Diclofenac Sodium)			S	Topical	Unk Unk, Qd		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Glaxosmithkline
	Escitalopram			S	Oral	20 Mg, Qd		Glaxosmithkline
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Naproxen			S	Unknown	1000 Mg, Qd		Not Reported
	Naprelan			S	Unknown	1000 Mg, Qd		Not Reported

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Cimzia	S	Subcutaneous	Unk	Not Reported
Tylenol	S	Topical	Unk Unk, Prn	Not Reported
Diclofenac (Diclofenac Sodium)	C	Unknown	Unk	Glaxosmithkline
Inflectra	C	Intravenous (not otherwise specified)	700 Mg, Every 6 Weeks	Not Reported
Inflectra	C	Intravenous (not otherwise specified)	600 Mg,/ Q 0, 2, 6 Weeks, Then Every 8 Weeks	Not Reported
Inflectra	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	15736924	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1857959US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alcohol Increased; Impulsive Behaviour	Escitalopram Oxalate - Bp			S	Oral	15 Mg, Qd		Allergan
	Xanax			C	Unknown	Unk		Not Reported
	Kenzen			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16558342	EXPEDITED (15-DAY)		HO	PHHY2019IT158363		41 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradyphrenia; Diplopia; Malaise; Nausea; Vomiting	Tolep			S	Oral	Unk		Novartis
	Cipraxel			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16592140	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2019M1066498			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Herbal Interaction; Serotonin Syndrome	Sertraline			S		Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported

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	Escitalopram	S	Unknown	Unk		Mylan
	Ginseng /01384001/	S	Unknown	Unk		Mylan
	Echinacea Purpurea	S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691130	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-052159			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Escitalopram			S	Oral	Unk		Aurobindo	
	Baclofene			S	Oral	200 Milligram Total		Not Reported	
	Antalnox			S	Oral	3300 Milligram Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691535	EXPEDITED (15-DAY)		HO	FR-ACCORD-150716		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral			Not Reported	
	Furosemide			S	Oral			Accord	
	Simvastatin			S	Oral			Accord	
	Spironolactone			S	Oral			Accord	
	Esomeprazole/Esomeprazole			S	Oral			Not Reported	
	Magnesium/Esomeprazole								
	Sodium Seresta			S	Oral	Strength: 10 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691919	EXPEDITED (15-DAY)		DE	FR-ACCORD-150957		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Clozapine			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	

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Inexium	S	Oral		Not Reported
Ditropan	S	Oral	Scored Tablet	Not Reported
Xanax	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691948	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1086618		7 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Attention Deficit/Hyperactivity Disorder; Foetal Exposure During Pregnancy	Escitalopram			S	Transplacental	20 Milligram/Day		Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691975	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04942		64 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Escitalopram			S	Unknown	10 Milligram, Unk		Lupin	
	Mirtazapine			S	Unknown	30 Milligram, Unk		Not Reported	
	Bromazepam			S	Unknown	1.5 Milligram, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16691976	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04929		65 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Escitalopram			S	Unknown	20 Milligram, Unk		Lupin	
	Bupropion			S	Unknown	300 Milligram, Unk		Lupin	
	Ziprasidone			S	Unknown	Unk		Lupin	
	Mirtazapine			S	Unknown	30 Milligram, Unk		Not Reported	
	Trazodone			S	Unknown	100 Milligram, Unk		Not Reported	

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Thyroxine			S		Unknown		50 Microgram, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Aug-2019	16691979	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04943		35 YR	Female	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Depression	Escitalopram			S	Unknown	20 Milligram, Unk		Lupin		
	Paroxetine			S	Unknown	100 Milligram, Unk		Lupin		
	Quetiapine Fumarate			S	Unknown	300 Milligram, Unk		Lupin		
	Olanzapine			S	Unknown	05 Milligram, Unk		Not Reported		
	Pregabalin			S	Unknown	300 Milligram		Not Reported		
	Amitriptyline			S	Unknown	100 Milligram, Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Aug-2019	16692211	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04946		70 YR	Male	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Depression	Escitalopram			S	Unknown	20 Milligram, Unk (Dose Increased)		Lupin		
	Pregabalin			S	Unknown	150 Milligram, Unk (Dose Increased)		Not Reported		
	Trazodone			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Aug-2019	16692212	EXPEDITED (15-DAY)		HO	AT-LUPIN PHARMACEUTICALS INC.-2019-04947		68 YR	Female	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Depression	Escitalopram			S	Unknown	15 Milligram, Unk		Lupin		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16692482	EXPEDITED (15-DAY)		HO	PHHY2019FR181862		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Furosemide			S	Oral	40 Mg, Qd		Novartis	
	Simvastatine			S	Oral	20 Mg, Qd		Not Reported	
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported	
	Spiroinolactone			S	Oral	25 Mg, Qd		Not Reported	
	Seresta			S	Oral	2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16692550	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019340500		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poisoning; Somnolence	Xanax			S	Oral	20 Tablets		Pfizer	
	Risperdal			S	Oral	4 Mg, Unk		Not Reported	
	Zyprexa			S	Intramuscular	1 Vial (10 Mg)		Not Reported	
	Escitalopram			S	Unknown	15 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16693760	EXPEDITED (15-DAY)		DE	FR-ASTRAZENECA-2019SF12983		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Inexium			S	Oral			Astrazeneca	
	Escitalopram			S	Oral			Not Reported	
	Ditropan			S	Oral			Not Reported	
	Xanax			S	Oral			Not Reported	
	Clozapine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16694079	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR141115		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Voltaren Emulgel			S		1 Every 1 Week		Glaxosmithkline	
	Escitalopram			S		1 Tablet, Qd		Glaxosmithkline	
	Cosentyx			S	Subcutaneous	150 Mg, Once Every Week		Not Reported	
	Methotrexate			S		Unk		Not Reported	
	Povidone-Iodine			S		Unk		Not Reported	
	Vitamin D3			S		Unk		Not Reported	
	Enbrel			C		Unk		Not Reported	
	Humira			C		Unk		Not Reported	
	Remicade			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16694577	EXPEDITED (15-DAY)		HO	FR-009507513-1908FRA002837		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Simvastatin			S	Oral	20 Milligram, Qd		Merck	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Furosemide			S	Oral	40 Milligram, Qd		Not Reported	
	Seresta			S	Oral	2 Dosage Form, Qd		Not Reported	
	Esomeprazole			S	Oral	20 Milligram, Qd		Not Reported	
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16694684	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2019M1074710			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Discomfort; Blood Potassium Increased; Cough; Electrocardiogram Qt Prolonged; Gastrooesophageal Reflux Disease; Lethargy; Malaise; Product Dispensing Error; Somnolence	Escitalopram Fluoxetine	S C	Oral	40 Milligram, Qd 20 Milligram	Not Reported Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16485428	NON-EXPEDITED			US-JNJFOC-20190619402		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Asthenia; Blood Pressure Increased; Depression; Dizziness; Heart Rate Increased; Nausea; Pain; Palpitations; Panic Disorder; Vision Blurred	Ibrutinib			S	Oral	420 Mg, Qd		Not Reported
	Escitalopram			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16587744	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1928929US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradypnoea; Cyanosis; Foetal Exposure During Pregnancy; Hypotonia Neonatal	Escitalopram Oxalate - Bp			S	Transplacental	10 Mg, Qd		Allergan
	Tercian			S	Transplacental	45 Mg		Not Reported
	Seresta			S	Transplacental	150 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16686614	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1088015		72 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Confusional State; Decreased Appetite; Disorientation; Dry Mouth; Dyspnoea; Fatigue; Headache; Hypertension; Micturition Urgency; Nausea; Pallor; Palpitations; Pyrexia; Somnolence; Vertigo; Vomiting; Weight Decreased	Escitalopram Teva 10 Mg Noctamide	S C	Oral	10 Milligram Daily;	Ivax Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695137	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039563		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral			Cadila
	Ramipril			S	Oral			Zydus Pharm
	Bromazepam			S	Oral			Not Reported
	Umuline			S	Subcutaneous	16 lu At Am And 3 lu At Pm		Not Reported
	Diltiazem/Diltiazem Hydrochloride/Diltiazem Malate			S	Oral			Not Reported
	Humalog			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695266	EXPEDITED (15-DAY)		OT	IT-ACCORD-151145		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse	Escitalopram			S	Oral			Not Reported
	En			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695751	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SF11372		81 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Esomeprazole			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Spironolactone			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Simvastatin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695875	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/19/0112970		67 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Not Reported
	Quetiapine			S		400 Mg, 0-0-1-0		Not Reported
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Microgram, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16696174	EXPEDITED (15-DAY)		HO	DE-ACCORD-151211		67 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphonia; Vomiting	Quetiapine			S		400 Mg, 0-0-1-0		Not Reported
	Escitalopram			S		20 Mg, 0-0-1-0		Not Reported
	Pipamperone			S		40 Mg, 0-0-1-0		Not Reported
	Levothyroxine/Levothyroxine Sodium			C		112 Microg, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699117	EXPEDITED (15-DAY)		OT	PHHY2019CA188460		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Voltaren Emulgel	S	Unknown	1 Df, Qw (1 Every 1 Week)	Not Reported
Arthralgia; Lip Ulceration;	Cosentyx	S	Subcutaneous	150 Mg, Qw (Once Every Week)	Novartis
Lower Respiratory Tract Infection Viral; Malaise;	Escitalopram	S	Unknown	1 Df, Qd	Not Reported
Mouth Ulceration;	Methotrexate	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness;	Povidone-Iodine	S	Unknown	Unk	Not Reported
Nasopharyngitis; Nausea;	Vitamin D3	S	Unknown	Unk	Not Reported
Pain; Swollen Tongue;	Enbrel	C	Unknown	Unk	Not Reported
Tonsillar Ulcer; Tonsillitis;	Humira	C	Unknown	Unk	Not Reported
Vomiting	Remicade	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699331	EXPEDITED (15-DAY)	HO		PHHY2019DE182303		56 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palpitations	Metoprolol			S	Unknown	47.5 Mg, Bid (1-0-1-0)		Not Reported
	Ramipril+Amlodipine			S	Unknown	1 Df, Qd		Not Reported
	Ramipril			S	Unknown	1 Df, Qd		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Teriflunomide			C	Unknown	14 Mg, Qd (1-0-0-0)		Not Reported
	Atorvastatin			C	Unknown	40 Mg, Qd (0-0-1-0)		Not Reported
	Dabigatran			C	Unknown	150 Mg, Bid (1-0-1)		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699534	EXPEDITED (15-DAY)	HO, LT		FR-ALLERGAN-1932101US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma	Escitalopram Oxalate - Bp			S	Oral			Allergan

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	Baclofene		S	Oral	200 Mg			Not Reported	
	Antalnox		S	Oral	3300 Mg			Not Reported	
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13-Aug-2019	16699614	EXPEDITED (15-DAY)		OT	IT-ALLERGAN-1932552US			Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poisoning; Somnolence	Escitalopram Oxalate - Bp			S	Unknown	15 MI		Allergan	
	Xanax			S	Oral	20 Tablets		Not Reported	
	Risperdal			S	Oral	4 Mg		Not Reported	
	Zyprexa			S	Intramuscular	1 Vial		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699652	EXPEDITED (15-DAY)		CA, OT	US-ALLERGAN-1932768US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram Oxalate Unk			S	Transplacental	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699823	EXPEDITED (15-DAY)		HO	PHHY2019DE184930		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Mg, Qd		Not Reported	
	Quetiapine			S	Unknown	400 Mg, Qd		Novartis	
	Pipamperone			S	Unknown	40 Mg, Qd		Not Reported	
	Levothyroxine Sodium			C	Unknown	112 Ug, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16702170	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Escitalopram			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	15305579	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-182217		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hyperthermia; Malaise; Nausea; Night Sweats; Pruritus; Serotonin Syndrome; Tremor	Tramadol			S	Oral	Inconnue ()		Sun	
	Seroplex 15 Mg, Comprime			S	Oral	Inconnue ()		Not Reported	
	Pellicule Secable Paracetamol			C	Oral	Inconnue ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	15724405	EXPEDITED (15-DAY)		HO	IE-BAUSCH-BL-2018- 034714		55 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Venlafaxine Hydrochloride			S	Unknown			Not Reported	
	Moclobemide			S	Unknown			Not Reported	
	Lithium			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Sertraline Hydrochloride			S	Unknown			Not Reported	
	Amitriptyline Hydrochloride			S	Unknown			Not Reported	
	Quetiapine Fumarate			S	Unknown			Not Reported	
	Duloxetine Hydrochloride			S	Unknown			Not Reported	
	Sodium Valproate			S	Unknown			Not Reported	

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Olanzapine	S	Unknown	Not Reported
Mirtazapine	S	Oral	Not Reported
Agomelatine	S	Unknown	Not Reported
Trimipramine	S	Unknown	Not Reported
Fluvoxamine Maleate	S	Unknown	Not Reported
Phenelzine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16700738	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-217490			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis	Metoprolol			S	Unknown	Unk		Sun
	Ibuprofen			S	Unknown	Unk		Ranbaxy
	Escitalopram			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Methotrexate Mylan			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	25 Milligram, Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Metoprolol Mylan			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported

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Prednisolon	S	Unknown	Unk	Not Reported
Escitalopram Hexal	S	Unknown	Unk	Not Reported
Prednisolon Stada	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Escitalopram Stada	S	Unknown	Unk	Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Ellipta [Fluticasone Furoate/Vilanterol Trifenatate]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701334	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-052182			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Body Temperature Increased; Diarrhoea; Drug Interaction; Hyperhidrosis; Influenza Like Illness; Nasopharyngitis; Pain; Serotonin Syndrome	Mirtazapine Tablet			S	Oral	15.0 Milligram, Daily		Aurobindo
	Ciprallex			S	Oral	5.0 Milligram, Daily		Not Reported
	Ciprallex			S	Oral	20 Milligram, Daily		Not Reported
	Ciprallex			S	Oral	10.0 Milligram, Daily		Not Reported
	Fluconazole			S	Oral	400.0 Milligram, Daily		Not Reported
	Fluconazole			S				Not Reported
	Zyvoxam			S	Oral	600 Milligram, Two Times A Day		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Dimenhydrinate			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Ondansetron			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701739	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-052391			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Infusion Related Reaction; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Mirtazapine Tablet			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Cipralex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	14 Milligram, Every Week		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abilify			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Milligram		Not Reported
	Fluoxetine			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Oxycontin			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Sertraline Hydrochloride			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701750	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-052957			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Subdural Haematoma	Escitalopram	S	Oral	20 Milligram, Once A Day	Aurobindo
	Ezetrol	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Levothyrox	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Coumadine	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Clotiazepam	C	Oral	5 Milligram, Once A Day	Not Reported
	Alfuzosin	C	Oral	10 Milligram, Once A Day	Not Reported
	Cordarone	C	Unknown	1 Dosage Form, Once A Day	Not Reported
	Spiriva Respimat	C	Respiratory (inhalation)	2 Dosage Form, Once A Day	Not Reported
	Esomeprazole	C	Oral	40 Milligram, Once A Day	Not Reported
	Pulmicort	C	Respiratory (inhalation)	4 Dosage Form, Once A Day	Not Reported
	Coaprovel	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Janumet	C	Oral	2 Dosage Form, Once A Day	Not Reported
	Mono Tiazem Lp	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Tadenan	C	Oral	2 Dosage Form, Once A Day	Not Reported
	Fucidine	C	Cutaneous	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701796	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1932717US		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan	
	Ezetrol			S	Oral	1 Df, Unknown		Not Reported	

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Levothyrox	S	Oral	1 Df, Unknown	Not Reported
Coumadine	S	Oral	1 Df, Unknown	Not Reported
Clotiazepam	C	Oral		Not Reported
Alfuzosine	C	Oral		Not Reported
Cordarone	C	Unknown		Not Reported
Spiriva Respimat	C	Respiratory (inhalation)		Not Reported
Esomeprazole	C	Oral		Not Reported
Pulmicort	C	Respiratory (inhalation)		Not Reported
Coaprovel	C	Oral		Not Reported
Fucidine	C	Cutaneous	1 Df	Not Reported
Janumet	C	Oral		Not Reported
Tadenan	C	Oral		Not Reported
Mono Tildiem	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701944	EXPEDITED (15-DAY)	DE		FR-PFIZER INC-2019348520		41 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Xanax			S	Oral	0.75 Mg, 1x/Day		Pfizer
	Inexium [Esomeprazole Sodium]			S	Oral	1500 Mg, 1x/Day		Not Reported
	Ditropan			S	Oral	5 Mg, 1x/Day		Not Reported
	Escitalopram			S	Oral	20 Mg, 1x/Day		Not Reported
	Clozapine			S	Oral	500 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16702863	EXPEDITED (15-DAY)		HO, OT	CZ-TEVA-648211ISR		53 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Deep Vein Thrombosis; Pulmonary Embolism; Sedation; Weight Increased	Olanzapine Escitalopram Alprazolam	S S S	Oral Unknown	5 Milligram Daily; 10 Milligram Daily; 1 Milligram Daily;	Teva Ivax Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16703039	EXPEDITED (15-DAY)		HO	DE-ASTRAZENECA- 2019SF13715		67 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphonia; Vomiting	Quetiapine			S	Oral	400 Mg, 0-0-1-0		Zeneca
	Escitalopram			S	Unknown	20 Mg, 0-0-1-0 Non Az Product		Not Reported
	Pipamperone			S	Unknown	40 Mg, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C		112 Ȧ½G, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16703054	EXPEDITED (15-DAY)		OT	CZ-TEVA-648359ISR		71 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Sedation; Weight Increased	Olanzapine			S	Oral	20 Milligram Daily; Antipsychotic Treatment		Teva
	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax
	Trazodone			S	Unknown	150 Milligram Daily;		Not Reported
	Oxazepam			S	Unknown	15 Milligram Daily;		Not Reported
	Lamotrigine			S		25 Milligram Daily;		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16704039	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1075070		85 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Drug Interaction	Escitalopram			S	Oral	5 Milligram, Qd		Not Reported

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Previscan /00789001/

S

Oral

15 Milligram, Qd

Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16704172	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1091201		86 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall	Escitalopram			S	Oral			Ivax
	Diltiazem (Chlorhydrate De)			S	Oral			Teva
	Ramipril			S	Oral			Actavis
	Bromazepam			S	Oral			Not Reported
	Umuline			S	Subcutaneous	16 lu In The Morning And 3 lu In The Evening		Not Reported
	Humalog			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16704591	EXPEDITED (15-DAY)		OT	IT-ELI_LILLY_AND_COMP ANY-IT201907016853		54 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Poisoning; Somnolence	Zyprexa Im 10mg			S	Intramuscular	10 Mg, Unknown		Eli Lilly And Co
	Xanax			S	Oral	0.25 Mg, Other (20 Tablets)		Not Reported
	Risperdal			S	Oral	4 Mg, Unknown		Not Reported
	Escitalopram			S	Unknown	15 MI, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15709435	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018503440		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Amlodipine Besilate			S	Unknown	2.5 Mg, 1x/Day		Pfizer
Balance Disorder;	Amlodipine Besilate			S	Unknown	2.5 Mg, 2x/Day		Pfizer
Bradycardia; Dizziness;								

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Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Codeine	S	Unknown	30 Mg, 2x/Day	Not Reported
	Codeine	S	Unknown	30 Mg, 3x/Day	Not Reported
	Furosemide	S	Unknown	20 Mg, 1x/Day	Unknown
	Furosemide	S	Unknown	40 Mg, 1x/Day	Unknown
	Oxazepam	S	Unknown	10 Mg, 2x/Day	Pfizer
	Cipraxel [Escitalopram]	S	Unknown	10 Mg, 1x/Day	Not Reported
	Cipraxel [Escitalopram]	S			Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.4 Mg, 2x/Day	Not Reported
	Glyceryl Trinitrate	S	Unknown	0.4 Mg, 1x/Day	Not Reported
	Metoprolol	S	Unknown	25 Mg, 1x/Day	Not Reported
	Metoprolol	S	Unknown	50 Mg, 1x/Day	Not Reported
	Ramipril	S	Unknown	5 Mg, 1x/Day	Not Reported
	Zopiclone	S	Unknown	2.5 Mg, 1x/Day	Not Reported
	Zopiclone	S	Unknown	5 Mg, 1x/Day	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Clopidogrel	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Polyethylene Glycol	C		Unk	Not Reported
	Rabeprazole	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16670232	EXPEDITED (15-DAY)		OT	LT-BAUSCH-BL-2019-021837		40 YR	Female	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Treatment Noncompliance	Lorazepam			S	Unknown			Not Reported	
	Venlafaxine			S	Unknown			Not Reported	
	Dexamethasone			S	Intravenous (not			Not Reported	

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				otherwise specified)					
	Dexamethasone	S							Not Reported
	Olanzapine	S	Unknown	Up To 15 Mg/Day					Not Reported
	Olanzapine	S	Unknown						Not Reported
	Olanzapine	S	Unknown						Not Reported
	Escitalopram	S	Unknown						Not Reported
	Sertraline	S	Unknown						Not Reported
	Quetiapine	S	Unknown						Not Reported
	Carbamazepine	S	Unknown	Up To 600 Mg/Day					Not Reported
	Carbamazepine	S	Unknown						Not Reported
	Carbamazepine	S	Unknown	After A Month Of Treatment					Not Reported
	Zuclopenthixol	S	Unknown						Not Reported
	Biseptol	S	Unknown						Not Reported
	Clemastine	S	Intramuscular						Not Reported
	Clemastine	S							Not Reported
	Bromazepam	S	Unknown						Not Reported
	Bromazepam	S	Unknown	3 Mg As Needed					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16707207	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019346811			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis	Premarin			S	Oral	0.625 Mg, 1x/Day		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported
	Marijuana			S	Unknown	Unk, 1x/Day		Not Reported
	Pentasa			S	Unknown	Unk		Not Reported
	Propranolol Hydrochloride			S	Oral	40 Mg, 2x/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16707383	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1933029US			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Labelled Drug-Disease Interaction Medication Error; Metrorrhagia; Product Use In Unapproved Indication	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Dinagest			S	Oral	1 Mg, Q12h		Not Reported	
	Dinagest			S	Oral	1 Mg, Bid		Not Reported	
	Bayaspirin			S	Oral	100 Mg, Qd		Not Reported	
	Lamictal			C	Oral	150 Mg, Q12h		Not Reported	
	E Keppra			C	Oral	500 Mg, Q12h		Not Reported	
	Leuprorelin			C		1.88 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16707658	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-023106		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Diltiazem Hydrochloride			S	Oral			Not Reported	
	Ramipril			S	Oral			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Bromazepam			S	Oral			Not Reported	
	Bromazepam			S	Unknown	Dose Reduced		Not Reported	
	Humalog			S	Subcutaneous			Not Reported	
	Humalog			S	Subcutaneous	Dose Increased		Not Reported	
	Umuline			S	Subcutaneous	16 lu In The Morning And 3 lu In The Evening		Not Reported	
	Umuline			S	Subcutaneous	Dose Increased		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16707978	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2019348636		56 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Glomerular Filtration Rate Decreased; Palpitations	Ramipril			S		5 Mg, Qd, 0-0-1-0		Pfizer
	Escitalopram Oxalate			S		5 Mg, Qd, 1-0-0-0		Not Reported
	Metoprolol			S		47.5 Mg, Bid, 1-0-1-0		Not Reported
	Amlodipine/Ramipril			S		5/5 Mg, 1-0-0-0		Not Reported
	Magnesium			C		1-0-0-0		Not Reported
	Teriflunomide			C		14 Mg, Qd, 1-0-0-0		Not Reported
	Atorvastatin			C		40 Mg, Qd, 0-0-1-0		Not Reported
	Dabigatran			C		150 Mg, Bid, 1-0-1-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	15808936	EXPEDITED (15-DAY)		HO	PHHY2019IT004170		30 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram Oxalate			S	Oral	20 Mg, Total		Not Reported
	Quetiapine			S	Oral	25 Mg, Total		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16595899	EXPEDITED (15-DAY)		HO	ES-ZYDUS-038525		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypomagnesaemia	Enalapril/Hydrochlorothiazide			S				Not Reported
	Escitalopram			S				Cadila
	Omeprazole			S				Not Reported
	Trazodone/Trazodone Hydrochloride			S		()		Not Reported
	Metformin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16599649	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1929132US			Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradyphrenia; Diplopia; Malaise; Nausea; Product Use In Unapproved Indication; Vomiting	Escitalopram Oxalate - Bp			S		Overdose: Unknown Dose		Allergan	
	Tolep			S	Oral	Overdose: Unknown Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16672466	EXPEDITED (15-DAY)		CA, OT	US-TORRENT-00009053			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Septal Defect; Foetal Exposure During Pregnancy; Persistent Left Superior Vena Cava; Ventricular Septal Defect	Escitalopram			S	Transplacental	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16692147	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1074409		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Urinary Retention	Escitalopram			S	Oral	1/2-0-0		Not Reported	
	Gabapentin			S	Oral	1-1-1. 1ª Semana 0-0-1 , 2ª Semana 0-1-1, 3ª Semana 1-1-1 Y Seguir Hasta Nueva Revisión		Mylan	
	Zytram Bid			S	Oral	1-0-1. 1ª Semana 0-0-1 , 2ª Semana 1-0-1 Y Seguir Hasta Revisión		Mylan	
	Nebivolol			C	Oral	Unk		Mylan	
	Atorvastatina /01326101/			C	Oral	Unk		Mylan	
	Acetylsalicylic Acid			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708420	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01109			Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708430	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01131			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708439	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01134			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708482	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01135			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708520	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01133			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Maternal Exposure During Pregnancy; Postpartum Haemorrhage		Escitalopram	S	Unknown	Unk				Hetero
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708528	EXPEDITED (15-DAY)		OT	IT-HETERO-HET2019IT01132			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Postpartum Haemorrhage	Escitalopram			S	Unknown	Unk		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16708903	NON-EXPEDITED			PHEH2019US033733		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis	
	Lexapro			S	Unknown			Not Reported	
	Zoloft			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16709004	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP020000		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Ineffective; Fatigue; Irritability	Fluoxetine			S	Unknown	Unk		Apotex	
	Paroxetine			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16709221	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039724		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Fall	Escitalopram	S	Oral	Cadila
	Simvastatin	S	Oral	Zydus Pharm
	Esomeprazole/Esomeprazole	S	Oral	Not Reported
	Magnesium/Esomeprazole			
	Sodium			
	Furosemide	S	Oral	Not Reported
	Spironolactone	S	Oral	Zydus Pharm
	Seresta	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16709229	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039693		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Ezetrol			S	Oral			Not Reported
	Levothyrox			S	Oral			Not Reported
	Coumadine			S	Oral			Not Reported
	Escitalopram			S	Oral			Zydus Pharm
	Clotiazepam			C	Oral			Not Reported
	Alfuzosin			C	Oral			Not Reported
	Cordarone			C				Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort			C	Respiratory (inhalation)			Not Reported
	Coaprovel			C	Oral			Not Reported
	Fucidine			C	Cutaneous			Not Reported
	Janumet			C	Oral			Not Reported
	Tadenan			C	Oral			Not Reported
	Diltiazem			C	Oral			Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16709518	EXPEDITED (15-DAY)		HO, LT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2019022598			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Intentional Overdose	Escitalopram Oxalate			S	Oral	560 Milligram, Qd		Macleods	
	Armopl - Armolipid Plus 20			S	Oral	6 Gram, Qd		Not Reported	
	Magnesium			S	Oral	18 Gram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710350	NON-EXPEDITED			US-PFIZER INC- 2019349799		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Effexor Xr			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Prozac			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710610	EXPEDITED (15-DAY)		HO	DE-TORRENT- 00015196		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Unknown	
	Pipamperon			S		40 Mg, 0-0-1-0		Unknown	
	Levothyroxine Sodium			C		112 G, 1-0-0-0		Unknown	
	Quetiapin			S		400 Mg, 0-0-1-0		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710899	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019344557		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Fall	Spironolactone	S	Oral	25 Mg, 1x/Day	Pfizer
	Esomeprazole Magnesium	S	Oral	20 Mg, 1x/Day	Unknown
	Escitalopram	S	Oral	10 Mg, 1x/Day	Not Reported
	Furosemide	S	Oral	40 Mg, 1x/Day	Not Reported
	Seresta	S	Oral	2 Df, 1x/Day	Not Reported
	Simvastatine	S	Oral	20 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16711054	EXPEDITED (15-DAY)		HO	FR-PROVELL PHARMACEUTICALS- 2073250		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Euthyrox			S	Oral			Provell Pharmaceuticals Not Reported
	Ezetrol			S	Oral			Not Reported
	Coumadine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Clotiazepam			C				Not Reported
	Alfuzosine			C	Oral			Not Reported
	Cordarone			C				Not Reported
	Spiriva			C				Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort			C				Not Reported
	Coaprovel			C	Oral			Not Reported
	Fucidine			C	Cutaneous			Not Reported
	Janumet			C	Oral			Not Reported
	Tadenan			C	Oral			Not Reported
	Mono Tildiem			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16711137	EXPEDITED (15-DAY)		OT	IT-ALLERGAN- 1933560US			Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Abuse;	Escitalopram Oxalate - Bp	S	Oral	Overdose 1200 Mg	Allergan
Electrocardiogram Qt	En	S	Oral	Overdose : 20 MI	Not Reported
Prolonged; General					
Physical Health					
Deterioration; Intentional					
Overdose					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16712671	EXPEDITED (15-DAY)		HO	PHHY2019AT188072		35 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety;	Escitalopram			S	Unknown	20 Mg, Unk		Not Reported
Depressed Mood;	Quetiapine			S	Unknown	300 Mg, Unk		Novartis
Depression; Drug	Pregabalin			S	Unknown	300 Mg, Unk		Not Reported
Resistance; Merycism								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	15230890	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR- APL-2018-033340			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder;	Escitalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
Depression; Dizziness;	Brintellix			S	Unknown	10 Milligram, Once A Day		Not Reported
Fear-Related Avoidance	Tianeptine			C	Unknown	10 Milligram, Daily		Not Reported
Of Activities; Mental								
Impairment; Overdose;								
Therapeutic Product Effect								
Incomplete								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16558145	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-137849		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left;	Escitalopram			S				Not Reported
Dyspnoea Exertional;	Trazodone/Trazodone			S				Not Reported
Electrocardiogram Qt	Hydrochloride							
Prolonged; Extrasystoles;	Enalapril			S				Not Reported

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Hypocalcaemia; Hypomagnesaemia	Maleate/Hydrochlorothiazide Omeprazole Metformin	S C	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16712803	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR- APL-2019-053186			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Clozapine			S	Oral	500 Milligram, Once A Day		Aurobindo
	Inexium			S	Oral	1500 Milligram, Once A Day		Not Reported
	Ditropan			S	Oral	5 Milligram, Once A Day		Not Reported
	Xanax			S	Oral	0.75 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16712981	EXPEDITED (15-DAY)		HO	DE-HETERO- HET2019DE01138		56 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palpitations	Escitalopram			S	Unknown	5 Mg, A.M. (1-0-0-0)		Hetero
	Amlodipine W/Ramipril			S	Unknown	5/5 Mg, 1-0-0-0		Not Reported
	Ramipril			S	Unknown	5 Mg (0-0-1-0)		Not Reported
	Metoprolol			S	Unknown	47.5 Mg (1-0-1-0)		Not Reported
	Teriflunomide			C	Unknown	14 Mg, A.M. (1-0-0-0)		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported
	Atorvastatin			C	Unknown	40 Mg (0-0-1-0)		Not Reported
	Dabigatran			C	Unknown	150 Mg, 1-0-1-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16713018	EXPEDITED (15-DAY)		OT	GB-ACCORD-151409		74 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral			Not Reported
	Bedranol			C				Not Reported
	Atorvastatin			C				Not Reported
	Diazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16713032	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2019-053569			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palpitations	Ramipril			S	Unknown	5 Milligram, 0-0-1-0		Aurobindo
	Escitalopram			S	Unknown	5 Milligram, 1-0-0-0		Aurobindo
	Amlodipine;Ramipril			S	Unknown	5 5 Mg, 1-0-0-0		Not Reported
	Metoprolol			S	Unknown	47.5 Milligram, 1-0-1-0		Not Reported
	Magnesium			C	Unknown	Nk Mg, 1-0-0-0, Brausetabletten		Not Reported
	Teriflunomida			C	Unknown	14 Milligram, 1-0-0-0		Not Reported
	Atorvastatin			C	Unknown	40 Milligram, 0-0-1-0		Not Reported
	Dabigatran			C	Unknown	150 Milligram, 1-0-1-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16267767	EXPEDITED (15-DAY)			US- ELI_LILLY_AND_COMP ANY-US201905000023			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Abnormal; Drug Hypersensitivity; Palpitations	Cymbalta			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Lexapro			S	Unknown	Unk Unk, Unknown		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Biotin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Caltrate [Calcium Carbonate;Colecalciferol]			C				Not Reported
	Prilosec [Omeprazole]			C				Not Reported

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Magnesium]		
Vitamin B12 [Cobamamide]	C	Not Reported
Meloxicam	C	Not Reported
Prilosec [Omeprazole]	C	Not Reported
Folic Acid	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16678341	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019331502		22 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Serotonin Syndrome	Linezolid			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16682491	EXPEDITED (15-DAY)		OT	LT-PFIZER INC-2019334268		40 YR	Female	LTU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Self-Injury; Mood Altered; Treatment Noncompliance	Venlafaxine Hcl			S		150 Mg, Daily		Pfizer
	Olanzapine			S		5 Mg, Daily		Not Reported
	Olanzapine			S		10 Mg, Daily		Not Reported
	Escitalopram			S		10 Mg, Daily		Not Reported
	Lorazepam			S		1 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16685456	EXPEDITED (15-DAY)		OT	DE-HETERO-HET2019DE01055		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram			S	Unknown	Unk		Hetero
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Pantozol /01263204/			S	Unknown	Unk		Not Reported
	Amitriptylin			S	Unknown	Unk		Not Reported

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Metoprolol Hexal	S	Unknown	Unk	Not Reported
Escitalopram Stada	S	Unknown	Unk	Not Reported
Escitalopram Hexal	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Metoprolol Stada	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk (Ibuprofen Hexal)	Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Salbutamol Stada	S	Unknown	Unk	Not Reported
Escitalopram Mylan	S	Unknown	Unk	Not Reported
Prednisolon Stada	S	Unknown	Unk	Not Reported
Implanon	S	Unknown	Unk	Not Reported
Metoprolol /00376903/	S	Unknown	Unk	Not Reported
Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
Prednisolon /00016201/	S	Unknown	Unk	Not Reported
Methotrexate Mylan	S	Unknown	Unk, Qw	Not Reported
Ibuprofen	S	Unknown	Ibuprofen Hormosan	Not Reported
Prednisolone	S	Unknown	2.5 Milligram	Not Reported
Salbutamol	S	Unknown	Unk	Not Reported
Ellipta [Fluticasone	C			Not Reported
Furoate\Vilanterol Trifenatate]				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16696336	EXPEDITED (15-DAY)		DS, HO, LT	FI-JNJFOC-20190809768		75 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Imbruvica			S	Oral			Not Reported	
	Primaspan			S	Oral	Once		Not Reported	
	Cipralex /01588501/			S	Unknown			Not Reported	
	Madopar			C	Unknown			Not Reported	

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Florinef			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16714527	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2019-05194		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Qd (0-0-1-0)		Lupin	
	Quetiapine Fumarate			S	Unknown	400 Milligram, Qd (0-0-1-0)		Lupin	
	Pipamperon			S	Unknown	40 Milligram, Qd (0-0-1-0)		Not Reported	
	Levothyroxine Sodium			C	Unknown	112 Microgram, Qd (1-0-0-0)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16714765	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022604			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral	5 Milligram		Macleods	
	Bedranol			C	Unknown	10 Milligram		Not Reported	
	Diazepam			C	Unknown	2 Milligram		Not Reported	
	Atorvastatin			C	Unknown	10 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16714863	EXPEDITED (15-DAY)		HO	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019022559			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Qd(0-0-1-0)		Macleods	
	Quetiapine 400 Mg			S	Unknown	400 Milligram, Qd (0-0-1-		Macleods	

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Pipamperone	S	Unknown	0) 40 Milligram, Qd (0-0-1-0)	Not Reported
Levothyroxine Sodium	C	Unknown	112 Microgram, Qd (1-0-0-0)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16714900	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1076580		38 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Sertraline			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Lithium			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16715463	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR142097		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Voltaren Emulgel			S		Unk		Glaxosmithkline
Arthralgia; Lip Ulceration;	Voltaren Emulgel			S		Unk, Z		Glaxosmithkline
Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration;	Cosentyx			S	Subcutaneous	150.0 Ug, Unk (1 Every 1 Week)		Not Reported
Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx			S	Subcutaneous	150.0 Ug, Unk (1 Every 1 Month)		Not Reported
	Cosentyx			S		Unk		Not Reported
	Escitalopram			S		1 Df, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported
	Povidone-Iodine			S		Unk		Not Reported
	Vitamin D3			S		Unk		Not Reported
	Remicade			C		Unk		Not Reported

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	Enbrel		C			Unk		Not Reported	
	Humira		C			Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16716089	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2019M1076778		27 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Intentional Overdose; Suicide Attempt	Leponex			S	Oral	1250 Milligram		Mylan	
	Byol Cor			S	Oral	75 Milligram		Mylan	
	Elicea			S	Oral	280 Milligram		Mylan	
	Zoloft			S	Oral	2800 Milligram		Mylan	
	Siofor			S	Oral	120 Gram		Mylan	
	Lacipil			S	Oral	112 Gram		Mylan	
	Xanax			S	Oral	30 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717029	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1092930		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma	Escitalopram			S	Oral			Ivax	
	Antalnox 550 Mg, Comprimé Pelliculé Sécable			S	Oral	3300 Milligram For Every 1 Total		Not Reported	
	Baclofene			S	Oral	200 Milligram For Every 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717259	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-1933430US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anger; Anxiety; Arthropod	Escitalopram Oxalate - Bp			S	Unknown			Allergan	

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Bite; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cerebrovascular Accident; Contusion; Cough; Crying; Depressed Mood; Depression; Diarrhoea; Emotional Distress; Erythema; Fall; Fatigue; Feeling Jittery; Gait Disturbance; Head Banging; Headache; Hypoacusis; Inappropriate Schedule Of Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture	Amlodipine Ergocalciferol Calcium Carbonate Hydromorphone Pantoprazole Sandostatin Sandostatin Sandostatin Acetaminophen Gabapentin Perindopril Prednisone Resotran Olanzapine	S S S S S S S S C C C C C C	Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Intramuscular Unknown Unknown Unknown Unknown Unknown Unknown	1 Df, Bid 30 Mg, Q Month 20 Mg, Q Month 28	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717295	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1933505US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	

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Confusional State;
Dizziness; Flushing; Heart
Rate Increased; Loss Of
Consciousness; Nausea

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717343	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2019M1077407		15 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Derealisation; Drug Ineffective; Nausea	Escitalopram			S	Unknown			Not Reported	
	Fluvoxamine			S	Unknown			Not Reported	
	Imipramine			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Venlafaxine			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Clonazepam			S				Not Reported	
	Lorazepam			S	Unknown			Not Reported	
	Lorazepam			S				Not Reported	
	Prazosin			S	Unknown			Not Reported	
	Aripiprazole			S	Unknown			Not Reported	
	Ziprasidone			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Ketamine			S	Other	Received Six Infusions Of Ketamine 0.5 Mg/Kg Per Infusion For A Span Of 3 Weeks, Beginning With T...		Not Reported	
	Chlorpromazine			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717461	EXPEDITED (15-DAY)		OT	HR-TAKEDA- 2019TUS048595			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Mydriasis; Somnolence; Suicide Attempt	Brintellix	S	Oral	10 Milligram	Takeda
	Elicea /01588502/	S	Oral	100 Milligram	Not Reported
	Velafax	S	Oral	1500 Milligram	Not Reported
	Tramadol	S	Oral	Unk	Not Reported
	Olandix	S	Oral	2.5 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717849	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN-1933606US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Disturbance In Attention; Inappropriate Antidiuretic Hormone Secretion; Pneumonia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan
	Amaluet			C	Oral	1 Df, Qd		Not Reported
	Zolpidem Tartrate			C	Oral			Not Reported
	Belsomra			C	Oral	15 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16560184	EXPEDITED (15-DAY)		HO, OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2019022056			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Extrasystoles; Hypocalcaemia; Hypomagnesaemia	Escitalopram Oxalate			S	Unknown	Unk		Macleods
	Omeprazole			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Tablet, Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16691987	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019344074		86 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Ramipril			S	Oral	10 Mg, Qd		Pfizer	
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported	
	Bromazepam			S	Oral	3 Mg, Qd		Not Reported	
	Bromazepam			S	Unknown	Unk		Not Reported	
	Diltiazem Hydrochloride			S	Oral	90 Mg, Unk		Not Reported	
	Humalog			S	Subcutaneous	2 lu, Unk		Not Reported	
	Umuline			S	Subcutaneous	16 lu In The Morning And 3 lu In The Evening		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16718891	EXPEDITED (15-DAY)		OT	DE-HETERO- HET2019DE01154		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Mg, Qd, 0-0-1-0		Not Reported	
	Pipamperon			S	Unknown	40 Mg, Qd, 0-0-1-0		Not Reported	
	Quetiapin			S	Unknown	400 Mg, Qd, 0-0-1-0		Not Reported	
	Levothyroxine Sodium			C	Unknown	112 Ug 1-0-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16718921	EXPEDITED (15-DAY)		DE	FR-ZYDUS-039769		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Escitalopram			S	Oral			Cadila	
	Inexium			S	Oral			Not Reported	
	Ditropan			S	Oral	Scored Tablet		Not Reported	
	Xanax			S	Oral	Scored Tablet		Not Reported	
	Clozapine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16718936	EXPEDITED (15-DAY)		HO, LT	ES-ZYDUS-039841		32 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Intentional Overdose	Escitalopram			S	Oral			Cadila	
	Magnesium Lactate			S	Oral	In Total		Not Reported	
	Armopl/Armolid Plus 20			S	Oral	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16719127	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-054877			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral	20 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Aldactone			S	Oral	12.5 Milligram, Once A Day		Not Reported	
	Fungizone			S	Unknown	Unk		Not Reported	
	Lovenox			S	Subcutaneous	Unk		Not Reported	
	Lasilix			S	Oral	40 Milligram, Once A Day		Not Reported	
	Diffu K			S	Oral	1800 Milligram, Once A Day		Not Reported	
	Renutryl			C	Unknown	Unk		Not Reported	
	Lysanxia			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16719322	NON-EXPEDITED			US-TAKEDA- 2019TJP018935		87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Prevacid			S	Unknown	Unk		Takeda	
	Metformin			S	Unknown	Unk		Not Reported	

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Lexapro	S	Unknown	Unk	Not Reported
Prozac	S	Unknown	Unk	Not Reported
Carbidopa Monohydrate W/Levodopa	S	Unknown	Unk	Not Reported

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20-Aug-2019	16719664	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS- 2019GMK042712			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od		Glenmark
	Benzotropine Mesylate			S	Transplacental	1.5 Mg, Od		Not Reported
	Rabeprazole			S	Transplacental	Unk		Not Reported
	Escitalopram			S	Transplacental	20 Mg, Od		Not Reported
	Quetiapine			S	Transplacental	300 Mg, Bid (1 Every 12 Hours)		Not Reported
	Zopiclone			S	Transplacental	Unk		Not Reported
	Methadose Dye-Free, Sugar- Free, Unflavored			S	Transplacental	70 Mg, Od		Not Reported
	Nortriptyline			S	Transplacental	20 Mg, Od		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16720488	EXPEDITED (15-DAY)		DE	FR-ALLERGAN- 1933490US			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan
	Inexium			S	Oral	1500 Mg		Not Reported
	Ditropan			S	Oral	5 Mg		Not Reported
	Xanax			S	Oral	0.75 Mg		Not Reported
	Clozapine			S	Oral	500 Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16720508	EXPEDITED (15-DAY)		HO	DE-ALLERGAN-1933796US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram Oxalate - Bp			S		20 Mg, 0-0-1-0		Allergan	
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported	
	Quetiapin			S		400 Mg, 0-0-1-0		Not Reported	
	Levothyroxine Sodium			C		112 Mg, 1-0-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16721616	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2019M1076507		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Malaise; Pain	Alprazolam Mylan 0,25 Mg			S	Oral	1 Dosage Form, Qd		Mylan	
	Rivastigmine Mylan Pharma 9,5 Mg/24 Heures, Dispositif Transdermique			S	Transdermal	1 Dosage Form, Qd		Mylan	
	Paracetamol, Tramadol Mylan			S	Oral	Unk		Mylan	
	Escitalopram Mylan Generiques 10 Mg, Comprimé Pelliculé Sécable			S	Oral	1 Dosage Form, Qd,1 Cp Matin		Mylan	
	Levodopa/Carbidopa Teva			S	Oral	1 Dosage Form, Qd,1 Cp Au Coucher		Mylan	
	Modopar			S	Oral	4 Dosage Form, Qd, 2cp À 16h Et 2cp Le Soir		Mylan	
	Clozapine Merck			S	Oral	1 Dosage Form, Qd,1 Cp Le Soir		Mylan	
	Acupan			S		4 Dosage Form, Qd		Mylan	
	Doliprane			S	Oral	Unk		Mylan	
	Sinemet			S	Oral	2 Dosage Form, Qd,1cp Matin Et 1cp Midi		Mylan	
	Dutasteride Sandoz			S	Oral	1 Dosage Form, Qd		Mylan	

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Oxynormoro	S	Oral	4 Dosage Form, Qd,Si Douleur	Mylan
Monocrixo	S	Oral	Unk	Mylan

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20-Aug-2019	16721708	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1093265		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haematoma	Escitalopram			S	Oral			Ivax
	Ezetrol 10 Mg, Comprimé			S	Oral			Not Reported
	Levothyrox 50 Microgrammes, Comprimé Sécable			S	Oral			Not Reported
	Coumadine 5 Mg, Comprimé Sécable			S	Oral			Not Reported
	Clotiazepam			C	Oral			Not Reported
	Alfuzosine (Chlorhydrate D')			C	Oral			Not Reported
	Cordarone 200 Mg, Comprimé Sécable			C				Not Reported
	Spiriva Respimat			C	Respiratory (inhalation)			Not Reported
	Esomeprazole			C	Oral			Not Reported
	Pulmicort 200 Ug/Dose, Suspension Pour Inhalation En Flacon Pressurisé			C	Respiratory (inhalation)			Not Reported
	Coaprovel 300 Mg/12,5 Mg, Comprimé			C	Oral			Not Reported
	Fucidine 2 Pour Cent, Pommade			C	Cutaneous			Not Reported
	Janumet 50 Mg/1000 Mg, Comprimé Pelliculé			C	Oral			Not Reported
	Tadenan 50 Mg, Capsule Molle			C	Oral			Not Reported
	Mono Tildiem Lp 300 Mg, Gélule À Libération Prolongée			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16721745	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-MYLANLABS-2019M1077239		49 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of	Mylan-Escitalopram			S	Oral	Unk		Mylan
Consciousness; Anuria;	Amlodipine			S	Oral	Unk		Mylan
Blindness; Blindness	Amlodipine			S	Oral	150 Milligram		Mylan
Cortical; Cardiogenic	Epinephrine			S	Unknown	30 Microgram		Mylan
Shock; Cerebral Infarction;	Escitalopram			S	Unknown	60 Milligram, Qd		Mylan
Circulatory Collapse;	Escitalopram			S	Oral	Unk		Mylan
Colour Blindness;	Glucose			S	Unknown	Unk		Mylan
Condition Aggravated; Csf	Norepinephrine Bitartrate			S	Intravenous (not otherwise specified)	30 Microgram		Mylan
Pressure Increased;	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Mylan
Cytotoxic Oedema;	Potassium Chloride			S	Oral	Unk		Mylan
Depressed Level Of	Risperidone			S	Unknown	6 Milligram, Qd		Mylan
Consciousness;	Risperidone			S	Oral	6 Milligram		Mylan
Electrocardiogram P Wave	Vasopressin			S	Unknown	Unk		Mylan
Abnormal;	Activated Charcoal			C		Unk		Mylan
Electrocardiogram St	Calcium Gluconate			C		Unk		Mylan
Segment Depression;	Dextrose			C		Unk		Mylan
Electrocardiogram T Wave	Epinephrine			C		Unk		Mylan
Amplitude Decreased;	Escitalopram			C		Unk		Mylan
Electrocardiogram T Wave	Glucagon			C		Unk		Mylan
Inversion;	Insulin			C		Unk		Mylan
Electrocardiogram U	Norepinephrine			C		Unk		Mylan
Wave Present; Embolism;	Potassium Chloride			C		Unk		Mylan
Embolism Arterial;	Risperidone			C		Unk		Mylan
Hyperdynamic Left	Vasopressin			C		Unk		Mylan
Ventricle; Hypoglycaemia;								
Hypokalaemia;								
Hypotension;								
Hypothermia; Intentional								
Overdose; Ischaemia;								
Optic Atrophy; Optic Nerve								
Injury; Overdose;								
Pulmonary Oedema;								
Renal Tubular Necrosis;								
Retinal Ischaemia;								
Reversible Cerebral								
Vasoconstriction								
Syndrome; Shock;								
Tachycardia; Toxicity To								
Various Agents; Visual								
Impairment								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16722010	EXPEDITED (15-DAY)		OT	PHHY2019CA194095		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Cosentyx			S	Subcutaneous	150 Ug, Qw (1 Every 1 Week)		Novartis
	Cosentyx			S	Subcutaneous	150 Ug, Qmo (1 Every 1 Month)		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Voltaren Emulgel			S	Unknown	Unk		Not Reported
	Voltaren Emulgel			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Povidone-Iodine			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	14461442	EXPEDITED (15-DAY)		OT	BE-TEVA-2018-BE-851750		41 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Maternal Exposure During Pregnancy	Xyzall Tablet			S	Unknown	5 Mg, Once Daily (Qd)		Teva
	Ventolin			S	Unknown	100 ?G, Unk		Not Reported
	Xanthium (Theophylline)			S	Unknown	200 Mg, Once Daily Qd		Not Reported
	Avamys Nasal Spray			S	Unknown	2 Unk, Bid		Not Reported
	Mepolizumab Powder For Solution For Injection			S	Subcutaneous	100 Mg, Unk		Not Reported
	Vilanterol Trifenatate Inhalation Powder			S		1 Daily; Unk, Unk, Qd		Not Reported

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Seretide	S	Unknown	Unk	Not Reported
Fluticasone Furoate Inhalation Powder	S		Unk, Once Daily (Qd)	Not Reported
Flixotide	S	Unknown	500 Milligram Daily; 250 ?G, 2x/Day (Bid)	Not Reported
Pantomed (Pantoprazole)	S	Unknown	20 Milligram Daily; 20 Mg, Once Daily (Qd)	Not Reported
D-Cure	S	Unknown	25 Kiu, Unk	Not Reported
Sipralaxa Tablet	S	Unknown	10 Mg, Z, Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	14760635	EXPEDITED (15-DAY)		HO, LT	CZ-ROCHE-2102288			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea;	Clonazepam			S	Oral			Not Reported
Electrocardiogram Qt Prolonged;	Melperone			S	Oral			Not Reported
Electrocardiogram Qt Shortened; Epilepsy;	Venlafaxine			S	Oral			Not Reported
Gastrointestinal Hypermotility; Loss Of Consciousness;	Olanzapine			S	Oral			Not Reported
Poisoning; Toxicity To Various Agents	Levomepromazine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Metoclopramide			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15830438	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE04570		30 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Interval Abnormal; Sopor;	Quetiapine			S	Oral	25.0mg Once/Single Administration		Zeneca
Speech Disorder; Substance Abuse	Escitalopram Oxalate			S	Oral	20.0mg Once/Single Administration		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16078756	EXPEDITED (15-DAY)		CA, HO	CA-GLENMARK PHARMACEUTICALS- 2019GMK040190			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Gabapentin			S	Transplacental	1800 Mg, Od (1 Every 1 Day)		Glenmark	
	Gabapentin			S	Transplacental	Unk		Glenmark	
	Benztropine Mesylate			S	Transplacental	1.5 Mg, Od (1 Every 1 Day)		Not Reported	
	Benztropine Mesylate			S	Transplacental	Unk		Not Reported	
	Escitalopram			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported	
	Escitalopram			S	Transplacental	Unk		Not Reported	
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	70 Mg, Od (1 Every 1 Day)		Not Reported	
	Methadose Dye-Free, Sugar-Free, Unflavored			S	Transplacental	Unk		Not Reported	
	Nortriptyline			S	Transplacental	20 Mg, Od (1 Every 1 Day)		Not Reported	
	Nortriptyline			S	Transplacental	Unk		Not Reported	
	Quetiapine			S	Transplacental	300 Mg, Bid (1 Every 12 Hours)		Not Reported	
	Quetiapine			S	Transplacental	Unk		Not Reported	
	Rabeprazole			S	Transplacental	Unk		Not Reported	
	Zopiclone			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16259829	EXPEDITED (15-DAY)		HO, OT	CA-USPHARMA LIMITED-2019-CA- 000026		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Dislocation; Device Malfunction; Drug Ineffective	Nitro-Dur			S	Unknown			Uspharma	
	Dexilant			S	Unknown	Delayed Release Capsule		Not Reported	

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Diltiazem	S	Unknown	Not Reported
Emo Cort	S	Topical	Not Reported
Escitalopram	S	Unknown	Not Reported
Jamp Asa	S	Unknown	Not Reported
Metonia	S	Unknown	Not Reported
Mylan Nitro	S	Oral	Not Reported
Nasonex	S	Nasal	Not Reported
Ratio-Zopiclone	S	Unknown	Not Reported
Rosuvastatin Calcium	S	Unknown	Not Reported
Amlodipine Besilate	S	Unknown	Not Reported
Synthroid	S	Unknown	Not Reported
Bisoprolol	S	Unknown	Not Reported
Triatec [Ramipril]	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Tamsulosin	S	Unknown	Not Reported
Trazodone	S	Unknown	Not Reported
Brilinta	S	Unknown	Not Reported
Ciclopirox Olamine	S	Unknown	Not Reported
Clonazepam	S	Unknown	Not Reported
Delatestryl	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16723290	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-182445		86 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Confusional State; Fall	Baclofen			S	Unknown	2 Dosage Form, Unk		Sun
	Seroplex			S	Oral	1 Dosage Form, Unk		Not Reported
	Tercian			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciflox	S	Unknown	Inconnue	Not Reported
Trivastal	S	Oral	Unk	Not Reported
Lyrica	S	Oral	1 Dosage Form, Unk	Not Reported
Takadol	S	Oral	1 Df, Unk	Not Reported
Temesta (Lorazepam)	S	Oral	1 Dosage Form, Unk	Not Reported
Levothyrox	C	Oral	1 Dosage Form	Not Reported
Tahor	C	Oral	1 Dosage Form	Not Reported
Furosemide	C	Oral	20 Mg, Unk	Not Reported
Daflon	C	Oral	2 Dosage Form, Unk	Not Reported
Paralyoc	C	Oral	Inconnue ()	Not Reported
Previscan	C	Oral	Selon Inr ()	Not Reported
Cordarone	C	Oral	0.5 Dosage Form, 5 Jours Par Semaine	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16723381	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2019-054444			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphonia; Vomiting	Escitalopram			S	Unknown	20 Milligram, Once A Day, 0-0-1-0		Aurobindo
	Quetiapine			S	Unknown	400 Milligram, Once A Day, 0-0-1-0		Aurobindo
	Pipamperone			S	Unknown	40 Milligram, Once A Day, 0-0-1-0		Not Reported
	Levothyroxine Sodium			C	Unknown	112 Microgram, Once A Day, 1-0-0-0		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16724184	EXPEDITED (15-DAY)		OT	GB-TORRENT- 00021626		74 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Fibromyalgia; Musculoskeletal Chest Pain	Bedranol Atorvastatin Escitalopram Diazepam	C C S C	Oral	Unknown Unknown Unknown Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16724547	EXPEDITED (15-DAY)		OT	US-VANDA PHARMACEUTICALS, INC-2019TASUS003285			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Hetlioz			S		20 Mg, Qd		Vanda Pharmaceuticals	
	Wellbutrin			S				Not Reported	
	Lexapro			S				Not Reported	
	Zantac			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16725436	EXPEDITED (15-DAY)		OT	GB-ALLERGAN- 1934200US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Bedranol			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Diazepam			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16725438	EXPEDITED (15-DAY)		HO	DE-MYLANLABS- 2019M1077994			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Muscle Disorder; Rhabdomyolysis	Escitalopram			S	Unknown	20 Milligram		Not Reported	
	Lavitan A Z Mais			C	Unknown	Unk		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16725464	NON-EXPEDITED			US-TEVA-2019-US-1093852			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Headache; Hyperhidrosis	Escitalopram Tablets			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726035	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1934402US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Jaundice; Nausea; Pruritus	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Theralene			S	Oral	20 Mg, Qd		Not Reported	
	Largactil			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726241	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1094670		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10mg		Ivax	
	Furosemide			S	Oral	40mg		Not Reported	
	Simvastatine			S	Oral	20mg		Ivax	
	Esomeprazole			S	Oral	20mg		Teva	
	Spiroonolactone			S	Oral	25mg		Actavis	
	Seresta 10 Mg, Comprimé			S	Oral	2 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726368	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR149267			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Arteriosclerosis Coronary	Salbutamol Sulphate	S	Unk Unk, Qd(3-4 Times)	Glaxosmithkline
Artery; Asthma; Blood	Advair	S	Unk	Glaxosmithkline
Count Abnormal;	Avelox	S	Unk	Glaxosmithkline
Condition Aggravated;	Doxazosin	S	4 Mg, Unk	Glaxosmithkline
Conjunctivitis Allergic;	Dutasteride	S	0.5 Mg, Unk	Glaxosmithkline
Dust Allergy; Hypoxia;	Rosuvastatin	C	20 Mg, Unk	Glaxosmithkline
Mite Allergy; Mycotic	Levofloxacin	S	500 Mg, Unk	Glaxosmithkline
Allergy; Productive Cough;	Vitamin D	S	Unk	Glaxosmithkline
Pulmonary Embolism;	Escitalopram	S	10 Mg, Unk	Glaxosmithkline
Spirometry Abnormal;	Budesonide	S	Unk	Glaxosmithkline
Therapeutic Product Effect	Tiazac	S	120 Mg, Unk	Glaxosmithkline
Incomplete; Wheezing	Amoxi Clav	S	Unk(875)	Not Reported
	Spiriva	S	Unk	Not Reported
	Omnaris	S	Unk	Not Reported
	Eliquis	S	Unk	Not Reported
	Prednisone	S	15 Mg, Qd	Not Reported
	Prednisone	S	10 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726629	EXPEDITED (15-DAY)		LT, OT	ES- GLAXOSMITHKLINE- ES2019GSK148139		44 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acquired Gene Mutation;	Escitalopram Oxalate			S		Unk		Glaxosmithkline
Arrhythmia; Cardio-	Salbutamol			S		Unk		Glaxosmithkline
Respiratory Arrest;	Olanzapine			S		Unk		Not Reported
Cardiotoxicity; Long Qt								
Syndrome; Torsade De								
Pointes								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726824	EXPEDITED (15-DAY)		OT	FR-ALLERGAN- 1934405US			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Drug Interaction; Supraventricular Extrasystoles	Escitalopram Oxalate - Bp			S	Oral	5 Mg, Qd		Allergan	
	Exelon			S	Transdermal	9.5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726893	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2019VAL000430			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Furosemide			S	Oral	40 Mg, Qd		Validus	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Oxazepam			S	Oral	2 Df, Qd		Not Reported	
	Oxazepam			S	Unknown	Unk		Not Reported	
	Simvastatin			S	Oral	20 Mg, Qd		Not Reported	
	Esomeprazole			S	Oral	20 Mg, Qd		Not Reported	
	Spironolactone			S	Oral	25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	12978391	NON-EXPEDITED			US-PFIZER INC-2016542784		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Zosyn			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk		Unknown	
	Voltaren			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Evista			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	13408354	NON-EXPEDITED			US-JNJFOC-20161010489		8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Emotional Distress; Gynaecomastia; Off Label Use; Product Use In Unapproved Indication; Weight Increased	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperdal			S	Oral			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Adderall			S	Unknown			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Depakote			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15534068	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1078404			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hypertensive Cardiomyopathy; Hypokalaemia; Hypomagnesaemia; Pyrexia; Syncope; Ventricular Tachycardia	Bendamustine Hydrochloride			S	Intravenous (not otherwise specified)	149 Milligram		Not Reported	
	Escitalopram			S	Unknown	Unk, Unknown		Not Reported	
	Omeprazole			S	Oral	Unk		Not Reported	
	Obinutuzumab			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Mylan	
	Obinutuzumab			S				Mylan	
	Sulfamethoxazole And Trimethoprim			S		Unk		Mylan	
	Atorvastatin			C	Unknown	Unk Unk, Unknown		Mylan	
	Valsartan			C	Unknown	Unk Unk, Unknown		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16080839	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-013657			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drug Ineffective; Feeling Abnormal; Muscular Weakness; Suicidal Ideation	Escitalopram Tablets			S	Oral	Unk Unk, Once A Day		Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Escitalopram Tablets			S				Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Zopiclone			S	Oral	7.5 Milligram, Two Times A Day		Not Reported
	Zopiclone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16438399	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-033491			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage	Escitalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Ibuprofen			S	Oral	400 Milligram,As Required		Not Reported
	Diclofenac Potassium			S	Oral	50 Milligram, Two Times A Day		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16476904	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035629			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort; Arthralgia; Lip Ulceration; Lower Respiratory Tract Infection Viral; Malaise; Mouth Ulceration; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; No Adverse Event; Pain; Swollen Tongue; Tonsillar Ulcer; Tonsillitis; Vomiting	Escitalopram Tablets Cosentyx Cosentyx Cosentyx Voltaren Methotrexate Vitamin D3 Cholecalciferol Enbrel Humira Remicade	S S S S S S S S C C C	Unknown Subcutaneous Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Subcutaneous Intravenous (not otherwise specified)	Unk Unk, Daily 150 Milligram, Unk Unk 150 Milligram Unk Unk Unk Unk Unk Unk Unk	Aurobindo Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16476908	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-035634			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Interstitial Lung Disease	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Venlafaxine Xr Extended Release Capsule			S	Unknown	37.5 Milligram, Once A Day		Aurobindo	
	Venlafaxine			S	Unknown	37.5 Milligram, Daily		Aurobindo	
	Duloxetine Dr			S	Unknown	15.0 Milligram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16727255	EXPEDITED (15-DAY)		HO	US-SA-2019SA221933		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Drug Ineffective; Dystonia; Muscle Contractions Involuntary; Tardive Dyskinesia; Tenderness	Escitalopram Oxalate			S		10 Mg		Not Reported	
	Escitalopram Oxalate			S		20 Unk		Not Reported	
	Lorazepam			S	Intravenous (not	Unk		Not Reported	

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				otherwise specified)					
	Lorazepam		S	Oral	Lorazepam1 Mg 3 Times Per Day As Needed				Not Reported
	Diphenhydramine	Y	S		50 Mg, Tid				Sanofi
	Propranolol Hydrochloride		S		20 Mg				Not Reported
	Trihexyphenidyl Hydrochloride		S						Not Reported
	Diazepam		S						Not Reported
	Benzotropine [Benzatropine]		S						Not Reported
	Estrogen		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16727582	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR- APL-2019-054112			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Drug Ineffective; Dyspnoea; Gastrooesophageal Reflux Disease; Lung Disorder; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Rhinorrhoea; Sputum Discoloured; Weight Increased; Wheezing	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Atrovent			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	Unk		Not Reported
	Cipraxel			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Olodaterol + Tiotropium			S	Unknown	Unk		Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Solu-Medrol			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Theophylline			S	Unknown	Unk		Not Reported
	Uniphyll			S	Unknown	Unk		Not Reported

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	Zantac		S	Unknown	Unk			Not Reported	
	Zithromax		S	Unknown	Unk			Not Reported	
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22-Aug-2019	16727676	EXPEDITED (15-DAY)		HO	IT-ACCORD-115805		30 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16728150	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-218325		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported	
	Esomeprazole			S	Oral	20 Milligram, Daily		Sun	
	Simvastatin			S	Oral	20 Milligram, Daily		Sun	
	Furosemide			S	Oral	40 Milligram, Daily		Not Reported	
	Seresta 10 Mg, Comprime			S	Oral	2 Dosage Form, Daily		Not Reported	
	Spironolactone			S	Oral	25 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16729150	EXPEDITED (15-DAY)		OT	US-TORRENT- 00009110		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Fluoxetine			S				Unknown	
	Escitalopram			S				Unknown	
	Levonorgestrel			C	Intra-uterine	Unknown		Unknown	

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22-Aug-2019	16729216	EXPEDITED (15-DAY)		HO	US-ASTELLAS-2019US027490		96 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Fatigue; Feeling Abnormal; Hypersomnia; Weight Increased	Enzalutamide			S	Oral	Unk, Once Daily		Astellas	
	Lexapro /01588501/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16729939	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1078024		37 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Hyperhidrosis; Loss Of Consciousness; Tachycardia; Tremor	Escitalopram Mylan			S	Oral	10 Microgram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16731314	EXPEDITED (15-DAY)		DE	FR-TEVA-2019-FR-1094729		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Escitalopram			S	Oral			Ivax	
	Clozapine			S	Oral			Ivax	
	Inexium			S	Oral			Not Reported	
	Ditropan 5 Mg, Comprime			S	Oral			Not Reported	
	Secable								
	Xanax 0,25 Mg, Comprime			S	Oral			Not Reported	
	Secable								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16731412	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1078255		26 YR	Male	NLD

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Micturition Urgency; Urinary Hesitation; Urinary Retention	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16732004	EXPEDITED (15-DAY)		OT	SE-ALLERGAN-1934210US			Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Discomfort; Drug Interaction; Palpitations; Tremor	Escitalopram Oxalate - Bp			S		10 Mg		Allergan	
	Phenylephrine Hydrochloride			S		Strength 2.5%, One Drop Per Eye		Not Reported	
	Selokenzoc			C	Unknown	50 Mg, Qd		Not Reported	
	Trombyl			C	Unknown	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16732008	EXPEDITED (15-DAY)		DE, HO	FR-ALLERGAN-1934427US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Dehydration; General Physical Health Deterioration; Hyperkalaemia	Escitalopram Oxalate - Bp			S	Oral			Allergan	
	Aldactone			S	Oral			Not Reported	
	Fungizone			S	Unknown			Not Reported	
	Lovenox			S	Subcutaneous			Not Reported	
	Lasilix			S	Oral			Not Reported	
	Esomeprazole			S	Oral			Not Reported	
	Diffu K			S	Oral			Not Reported	
	Lysanxia			C	Unknown			Not Reported	
	Renutryl			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	13434099	EXPEDITED (15-DAY)		DS, HO, OT	US-SA-2017SA061824		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Ankle Fracture;	Teriflunomide			S	Oral	14 Mg, Qd		Sanofi
Cystitis; Diarrhoea; Drug	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Hypersensitivity; Eye	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Swelling; Fall; Fall;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Fatigue; Gait Disturbance;	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
Head Discomfort; Head	Escitalopram Oxalate			S		10 Mg		Not Reported
Titubation; Hospitalisation;	Tizanidine Hydrochloride			S	Unknown	2 Mg,Unk		Not Reported
Injury; Kidney Infection;	Ampyra			S	Unknown	10 Mg,Bid		Not Reported
Memory Impairment;	Ampyra			S	Unknown	10 Mg,Bid		Not Reported
Mood Swings; Muscle	Tecfidera			C	Unknown	1 Df,Bid		Not Reported
Spasms; Musculoskeletal	Aciclovir			C	Unknown	1 Df,Tid		Not Reported
Pain; Pain In Extremity;	Atorvastatin			C	Unknown	1 Df,Hs		Not Reported
Paraesthesia; Product	Cyanocobalamin			C	Unknown	1000 Mg,Qd		Not Reported
Dose Omission; Pruritus;	Baclofen			C	Unknown	10 Mg,Unk		Not Reported
Rash; Rash; Unevaluable	Fish Oil			C	Unknown	1200 Mg,Unk		Not Reported
Event; Urinary Retention;	Fish Oil			C		360 Mg, Bid		Not Reported
Urinary Tract Infection;	Gabapentin			C	Unknown	600 Mg,Tid		Not Reported
Walking Aid User	Gabapentin			C	Unknown	300 Mg,Unk		Not Reported
	Levothyroxine			C	Unknown	25 Ug,Qd		Not Reported
	Magnesium			C	Unknown	400 Mg,Qd		Not Reported
	Magnesium			C	Unknown	250 Mg,Unk		Not Reported
	Montelukast			C	Unknown	10 Mg,Qd		Not Reported
	Ropinirole			C	Unknown	1 Mg,Tid		Not Reported
	Sertraline			C	Unknown	50 Mg,Prn		Not Reported
	Sertraline			C	Unknown	25 Mg,Unk		Not Reported
	Venlafaxine			C	Unknown	75 Mg,Bid		Not Reported

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Venlafaxine	C	Unknown	25 Mg,Unk	Not Reported
Venlafaxine	C	Unknown	150 Mg,Unk	Not Reported
Vesicare	C	Unknown	10 Mg,Prn	Not Reported
Vitamin D2	C	Unknown	50000 Df,Qw	Not Reported
Hydrocodone	C	Unknown	Unk Unk,Prn	Not Reported
Levofloxacin	C	Unknown	Unk Unk,Unk	Not Reported
Methylphenidate Hydrochloride	C	Unknown	10 Mg,Unk	Not Reported
Nitrofurantoin	C	Unknown	10 Mg,Unk	Not Reported
Vitamin D3	C	Unknown	2000 Iu,Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16125335	EXPEDITED (15-DAY)		OT	PHHY2019DE063579		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	2.5 Mg, Unk		Novartis
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram Hexal			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Prednisolon Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported

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Metoprolol Stada	S	Unknown	Unk	Not Reported
Metoprolol Mylan	S	Unknown	Unk	Not Reported
Salbutamol Stada	S	Unknown	Unk	Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Qw	Not Reported
Fluticasone;Vilanterol	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16404344	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2019-031647			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Left; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Extrasystoles; Hypocalcaemia; Hypomagnesaemia	Escitalopram			S	Unknown	Unk		Aurobindo
	Omeprazole			S	Unknown	Unk		Aurobindo
	Enalapril Tablets			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Enalapril Maleate;Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16609127	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX- 2019AP018502		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Dislocation; Device Malfunction; Drug Ineffective	Apo-Escitalopram			S	Unknown	Unk		Apotex
	Apo-Trazodone			S	Unknown	1 Df, Qd		Apotex
	Apo-Tamsulosin Cr			S	Unknown	1 Df, Qd		Not Reported
	Amlodipine			S	Unknown	1.5 Df, Qd		Apotex
	Diltiazem			S	Unknown	1 Df, Qd		Apotex
	Escitalopram			S	Unknown	1 Df, Unk		Apotex
	Clonazepam			S	Unknown	1 Df, Tid		Apotex

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Rosuvastatin	S	Unknown	1 Df, Qd	Apotex
Ciclopirox	S	Unknown	Unk	Apotex
Brilinta	S	Unknown	1 Df, Bid	Not Reported
Delatestryl	S	Unknown	0.5 Ml, Q.O.Wk.	Not Reported
Dexilant	S	Unknown	1 Df, Qd	Not Reported
Emo Cort	S	Topical	Unk, Qd	Not Reported
Jamp Asa	S	Unknown	1 Df, Qd	Not Reported
Metonia	S	Unknown	1 Df, Tid	Not Reported
Nasonex	S	Other	Unk, Qd,(Intra-Nasal)	Not Reported
Nitro-Dur	S	Unknown	1 Df, Qd	Not Reported
Ratio-Zopiclone	S	Unknown	1 Df, Unk	Not Reported
Synthroid	S	Unknown	1 Df, Qd	Not Reported
Triatec /00116401/	S	Unknown	1 Df, Qid	Not Reported
Tevabisoprol	S	Unknown	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16635309	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-044186			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Gastrointestinal Disorder; Off Label Use; Somnolence	Zolpidem			S	Unknown	Unk		Aurobindo
	Zolpidem			S				Aurobindo
	Zolpidem			S				Aurobindo
	Quetiapine			S	Unknown	Unk		Aurobindo
	Mirtazapine			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Sertraline			S	Unknown	Unk		Aurobindo
	Fluoxetine			S	Unknown	Unk		Aurobindo
	Trazodone			S	Unknown	Unk(Low Dose)		Not Reported
	Trazodone			S				Not Reported
Agomelatine			C	Unknown	Unk		Not Reported	

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	Diazepam	C	Unknown	Unk		Not Reported
	Perampanel	C	Unknown	Unk		Not Reported
	Lormetazepam	C	Unknown	Unk		Not Reported
	Zolpidem	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733350	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-055246			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral	5 Milligram		Aurobindo
	Bedranol			C	Unknown	10 Milligram		Not Reported
	Atorvastatin			C	Unknown	10 Milligram		Not Reported
	Diazepam			C	Unknown	2 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733401	NON-EXPEDITED			US-DRREDDYS- USA/USA/19/0113307		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Weight Increased	Fluoxetine Tablets			S				Not Reported
	Escitalopram			S				Not Reported
	Levonorgestrel			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733678	EXPEDITED (15-DAY)		DE, HO	FR-ASTRAZENECA- 2019SF18391		90 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral			Astrazeneca
	Escitalopram			S	Oral			Not Reported
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported

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Lasilix	S	Oral	Not Reported
Diffu K, Gelule	S	Oral	Not Reported
Lysanxia	C		Not Reported
Renutryl 500, Emulsion Buvable En Boite	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733971	EXPEDITED (15-DAY)		DE, HO	FR-ACCORD-152690		90 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dehydration; Hyperkalaemia	Escitalopram			S	Oral			Not Reported
	Esomeprazole/Esomeprazole			S	Oral			Not Reported
	Magnesium/Esomeprazole							
	Sodium							
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Diffu K			S	Oral			Not Reported
	Lysanxia			C				Not Reported
	Renutryl			C		Drinkable Emulsion In Box		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16734032	NON-EXPEDITED			US-ALLERGAN-1853417US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use	Celexa			S	Unknown	Unk		Allergan
	Celexa			S				Allergan
	Escitalopram			S	Unknown	Unk		Not Reported
	Escitalopram			S				Not Reported
	Sertraline			C		Unk		Not Reported
	Sertraline			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16734067	NON-EXPEDITED			US-ALLERGAN-1905273US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Feeling Abnormal; Hypoaesthesia	Celexa			S	Unknown	Unk		Allergan	
	Lexapro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16735395	EXPEDITED (15-DAY)		OT	HR-PFIZER INC-2019358434		27 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Intentional Overdose; Suicide Attempt	Zoloft			S	Oral	2800 Mg, Unk		Pfizer	
	Xanax			S	Oral	30 Mg, Unk		Pfizer	
	Elicea			S	Oral	280 Mg, Unk		Not Reported	
	Leponex			S	Oral	1250 Mg, Unk		Not Reported	
	Siofor			S	Oral	120 G, Unk		Not Reported	
	Lacipil			S	Oral	112 G, Unk		Not Reported	
	Byol Cor			S	Oral	75 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16736761	EXPEDITED (15-DAY)		HO, OT	CA-009507513-1908CAN008061		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Dislocation; Device Malfunction; Drug Ineffective	Nitroglycerin			S	Unknown	1 Dosage Form X 1 Per 1 Days		Merck	
	Nasonex			S	Nasal	X 1 Per 1 Days		Merck	
	Amlodipine Besylate			S	Unknown	1.5 Dosage Form X 1 Per 1 Days		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Tamsulosin Hydrochloride			S	Unknown	1 Dosage Form X 1 Per 1		Not Reported	

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Trazodone Hydrochloride	S	Unknown	Days 1 Dosage Form X 1 Per 1 Days	Not Reported
Brilinta	S	Unknown	1 Dosage Form X 2 Per 1 Days	Not Reported
Ciclopirox Olamine	S	Unknown		Not Reported
Clonazepam	S	Unknown	1 Dosage Form X 3 Per 1 Days	Not Reported
Delatestryl	S	Unknown	0.5 MI X 1 Per 2 Weeks	Not Reported
Dexilant	S	Unknown	Delayed Release Capsule, 1 Dosage Form X 1 Per 1	Not Reported
Diltiazem	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Emo-Cort	S	Topical	X 1 Per 1 Days	Not Reported
Escitalopram	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Aspirin	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Metonia	S	Unknown	1 Dosage Form X 3 Per 1 Days	Not Reported
Mylan Nitro	S	Oral	Unk,	Not Reported
Mylan Nitro	S	Oral	Metered-Dose Aerosol	Not Reported
Zopiclone	S	Unknown	1 Dosage Form	Not Reported
Rosuvastatin Calcium	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Synthroid	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Bisoprolol	S	Unknown	1 Dosage Form X 1 Per 1 Days	Not Reported
Triatec (Ramipril)	S	Unknown	1 Dosage Form X 4 Per 1 Days	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16736769	EXPEDITED (15-DAY)		DE, HO	CH-ALLERGAN-1934571US			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease; Respiratory Failure	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qam (2-0-0-0)		Allergan	
	Dexilant			S	Oral	60 Mg		Not Reported	
	Atorvastatin Pfizer			S	Unknown	40 Mg, Qpm (0-0-1-0)		Not Reported	
	Beloc Zok			S	Oral	50 Mg, Qam (1-0-0-0)		Not Reported	
	Aspirin Cardio			C	Oral			Not Reported	
	Pregabalin Pfizer			C	Oral			Not Reported	
	Toviaz			C	Oral			Not Reported	
	Mirtazapin			C		15 Mg		Not Reported	
	Temesta			C		2.5 Mg		Not Reported	
	Brilique			C		90 Mg		Not Reported	
	Mst Continus			C		1 Df		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16737644	EXPEDITED (15-DAY)		HO	US-PRINSTON PHARMACEUTICAL INC.-2019PRN00765		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Tardive Dyskinesia; Torticollis	Escitalopram			S	Unknown	10 Mg		Prinston Pharmaceutical	
	Estrogen Oral Contraceptive			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2019	13752508	EXPEDITED (15-DAY)		HO, OT	SE-TEVA-784948ISR			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Persistent	Escitalopram			S	Transplacental			Ivax	

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Foetal Circulation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	13155136	NON-EXPEDITED			US-PFIZER INC-2017034216		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Drug Hypersensitivity; Off Label Use; Product Use In Unapproved Indication	Neurontin			S		Unk		Pfizer
	Neurontin			S				Pfizer
	Escitalopram Oxalate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16651331	NON-EXPEDITED			US-TAKEDA-2019TJP017299			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Prevacid			S	Unknown	Unk		Takeda
	Edarbi			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported
	Azactam			S	Unknown	Unk		Not Reported
	Butrans			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Scopolamine Aminoxide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16682369	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019335906		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Myoclonus; Serotonin Syndrome	Ondansetron			S		40 Mg, Unk (He Was Using Ondansetron Up To 5 Times A Day)		Pfizer
	Ondansetron			S		Unk (He Reduced His		Pfizer

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	Escitalopram	S	Ondansetron To 3 Times A Day)	Not Reported
	Escitalopram	S	5 Mg, Unk	Not Reported
	Escitalopram	S	15 Mg, Unk (Escitalopram Was Titrated Gradually To 15 Mg Within 4 Months)	Not Reported
	Escitalopram	S	10 Mg, Unk (Reduction Of Escitalopram To 10 Mg)	Not Reported
	Escitalopram	S	15 Mg, Unk (Three Months Later, His Escitalopram Was Increased Again To 15 Mg)	Not Reported
	Stribild	S	Unk	Not Reported
	Alprazolam	C	0.5 Mg, 4x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16739063	EXPEDITED (15-DAY)		HO	US-APOTEX-2019AP020771		16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Galactorrhoea	Escitalopram			S	Oral	10 Mg, Qd		Apotex
	Risperidone			S	Oral	Unk		Apotex
	Duloxetine			S	Oral	20 Mg, Qd		Apotex
	Duloxetine			S	Oral	40 Mg, Qd		Apotex
	Duloxetine			S	Oral	20 Mg, Qd		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16739686	EXPEDITED (15-DAY)		OT	US-TORRENT-00009115		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased;	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Unknown
Myoclonus; Serotonin Syndrome	Escitalopram			S		Titrated Gradually To 15		Unknown

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Alprazolam Stribild		C S		Mg Within 4 Months. Unknown		Unknown Unknown			
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26-Aug-2019	16741177	EXPEDITED (15-DAY)		OT	HR-JNJFOC-20190828778			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral	Unk		Not Reported	
	Elicea			S	Oral	100 Mg, Unk		Not Reported	
	Velafax			S	Oral	1500 Unk, Unk		Not Reported	
	Brintellix			S	Oral	10 Mg, Unk		Not Reported	
	Olandix			S	Oral	Adr Adequately Labelled: Somnolencexadr Not Adequately Labelled: Mydriasis		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16741604	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1934765US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Coeliac Disease; Decreased Appetite; Nausea; Vomiting	Escitalopram Oxalate - Bp			S	Unknown	97		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16741880	EXPEDITED (15-DAY)		OT	PHHY2019DE196338		65 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Hypertension; Muscle Spasms; Tremor	Tegretal			S	Unknown	Unk		Novartis	
	Tegretal			S	Unknown	400 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram	S	Unknown	10 Mg, Unk	Not Reported
Escitalopram	S	Unknown	5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16742215	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019AMR152779			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation Neonatal; Drug Withdrawal Syndrome	Nicotine			S	Transplacental	Unk		Glaxosmithkline
Neonatal; Facial Asymmetry; Foetal Exposure During Pregnancy; Hyperbilirubinaemia	Calcium			S	Transplacental	Unk		Glaxosmithkline
Neonatal; Hypoglycaemia	Cholecalciferol			S	Transplacental	Unk		Glaxosmithkline
Neonatal; Jaundice	Folic Acid			S	Transplacental	Unk		Glaxosmithkline
Neonatal; Knee Deformity; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress Syndrome; Selective Eating Disorder; Talipes; Weight Decrease Neonatal	Cipralex Tablet			S	Transplacental	Unk		Not Reported
	Suboxone			S	Transplacental	Unk		Not Reported
	Subutex			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	12645979	NON-EXPEDITED			US-PFIZER INC- 2016246041			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Butamben-Tetracaine-Benzocaine			S		Unk		Not Reported
	Cetacaine			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

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Prozac	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Reglan	S	Unk	Not Reported
Zofran	S	Unk	Not Reported
Percocet	S	Unk	Not Reported
Tylenol	S	Unk	Not Reported
Tetanus Toxoid	S	Unk	Not Reported
Amylase/Lipase/Protease	S	Unk	Not Reported
Creon 10	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Hctz	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Paroxetine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16170479	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1915122US			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Golimumab			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported

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Pantozol	S	Unknown	Unk	Not Reported
Metoprolol Stada	S	Unknown	Unk	Not Reported
Fluticasone; Vilanterol	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported
Escitalopram Stada	S	Unknown	Unk	Not Reported
Prednisolon Stada	S	Unknown	Unk	Not Reported
Metoprolol Mylan	S	Unknown	Unk	Not Reported
Escitalopram Hexal	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	2.5 Mg	Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Q Week	Not Reported
Salbutamol	S	Unknown	Unk	Not Reported
Metoprolol Hexal	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16227792	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2019-011478		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Bausch And Lomb
	Ibuprofen			S	Unknown			Not Reported
	Methotrexate Mylan			S	Unknown			Not Reported
	Implanon			S	Unknown			Not Reported
	Metoprolol Mylan			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Escitalopram Stada			S	Unknown			Not Reported
	Escitalopram Hexal			S	Unknown			Not Reported
	Metoprolol Stada			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram Mylan	S	Unknown	Not Reported
Prednisolon Jenapharm	S	Unknown	Not Reported
Ibuprofen Hormosan	S	Unknown	Not Reported
Metoprolol	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Metoprolol Hexal	S	Unknown	Not Reported
Pantozol	S	Unknown	Not Reported
Ibuprofen Stada	S	Unknown	Not Reported
Prednisolon Stada	S	Unknown	Not Reported
Salbutamol Stada	S	Unknown	Not Reported
Ibuhexal	S	Unknown	Not Reported
Fluticasone; Vilanterol	C	Unknown	Not Reported
6 Months Before Diagnosis			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16568514	EXPEDITED (15-DAY)		OT	PHHY2019BR160623		33 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fear; Malaise; Skin Lesion; Systemic Lupus Erythematosus	Cosentyx			S	Subcutaneous	Unk Unk, Qmo		Novartis
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Prednisona			S	Oral	40 Mg, Qd (Approximatly 5 Years Ago)		Not Reported
	Rivotril			S	Oral	0.5 Mg, Unk		Not Reported
	Leflunomida			C	Oral	20 Mg, Qd (End Of Jun After Apperence Of The Lesions)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16686954	EXPEDITED (15-DAY)		HO	US-ACCORD-150888		16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blood Prolactin Increased; Galactorrhoea		Escitalopram		S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16743178	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2019-002183			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram			S	Oral	20 Milligram, In Total		Aurobindo	
	Quetiapine			S	Oral	25 Milligram, In Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16744868	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS- 2019GMK042785		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	40 Mg, Unk (Up To 5 Times A Day, Ingestion)		Glenmark	
	Escitalopram			S	Unknown	15 Mg, Unk (Titrated Gradually To 15 Mg Within 4 Months)		Not Reported	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
	Stribild			S	Unknown	Unk		Not Reported	
	Alprazolam			C	Unknown	0.5 Mg, Qid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745112	EXPEDITED (15-DAY)		OT	FR- GLAXOSMITHKLINE- FR2019154395		39 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse	Doliprane			S	Unknown	Unspecified		Glaxosmithkline	
	Ventoline			S	Unknown	Unspecified		Glaxosmithkline	
	Seroplex			S	Unknown	Unspecified		Glaxosmithkline	

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Lexomil	S	Unknown	Unspecified	Glaxosmithkline
Tramadol Hydrochloride	S	Oral	1-0-1	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16746066	EXPEDITED (15-DAY)	HO		IT-MYLANLABS-2019M1079435		58 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depressed Level Of Consciousness; Drug Abuse; Hypokinesia; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	1 Dosage Form, Total		Not Reported
	Quetiapine Fumarate			S	Oral	1 Dosage Form, Total		Mylan
	Clonazepam			C		Unk		Mylan
	Lorazepam			C		Unk		Mylan
	Depakin Chrono /00228502/			C		1500 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16747179	EXPEDITED (15-DAY)	OT		PHHY2019US194620		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	40 Mg, Up To 5 Times A Day		Novartis
	Ondansetron			S	Oral	40 Mg, Tid		Novartis
	Escitalopram			S	Unknown	5 Mg, Titrated Gradually To 15 Mg Within 4 Months		Not Reported
	Escitalopram			S	Unknown	10 Mg, Unk		Not Reported
	Escitalopram			S	Unknown	15 Mg, Unk		Not Reported
	Stribild			S	Unknown	Elvitegravir 150 Mg, Cobicistat 150 Mg, Emtricitabine 200 Mg, And Tenofovir Disoproxil Fumarate 300		Not Reported
	Alprazolam			C	Unknown	0.5 Mg, Qid		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16747696	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1096563		67 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Vomiting	Escitalopram			S		20 Mg, 0-0-1-0		Ivax	
	Quetiapin			S		40 Mg, 0-0-1-0		Teva	
	Pipamperon			S		40 Mg, 0-0-1-0		Not Reported	
	Levothyroxine Sodium			C		112 Microgram, 1-0-0-0		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16748617	EXPEDITED (15-DAY)		LT, OT	BE-RANBAXY-2014RR-90201		65 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Long Qt Syndrome	Escitalopram			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Astrazeneca	
	Sotalol			S	Unknown			Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16749021	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR-1097242			Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Mydriasis; Somnolence; Suicide Attempt	Olandix			S	Oral			Teva	
	Tramadol			S	Oral			Teva	
	Velafax			S	Oral			Teva	
	Elicea			S	Oral			Not Reported	
	Brintellix			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16749596	EXPEDITED (15-DAY)		OT	US-ACCORD-151416		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S		Up To 5 Times A Day		Accord	
	Escitalopram			S				Not Reported	
	Alprazolam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16749635	EXPEDITED (15-DAY)		HO	US-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00321		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Tardive Dyskinesia; Torticollis	Escitalopram			S	Unknown	10 Mg		Jubilant	
	Escitalopram			S	Unknown	20 Mg		Jubilant	
	Estrogen Oral Contraceptive			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16750920	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1080683		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Escitalopram			S	Oral	1 Dosage Form		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16752093	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1097360		74 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fibromyalgia; Musculoskeletal Chest Pain	Escitalopram			S	Oral			Ivax	
	Bedranol			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Diazepam			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	15832915	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-997687		30 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal; Sopor; Speech Disorder; Substance Abuse	Escitalopram Oxalate			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16683748	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1073230		44 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Escitalopram			S	Oral	5 Milligram		Not Reported	
	Escitalopram			S	Oral	5 Milligram		Not Reported	
	Escitalopram			S	Oral	10 Milligram		Not Reported	
	Olanzapin			C	Oral	15 Milligram, Qd (Daily Dose: 15 Mg Milligram(S) Every Days)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16732564	NON-EXPEDITED		OT	US-DRREDDYS-USA/USA/19/0113551		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Not Reported	
	Escitalopram			S		Titrated Gradually To 15 Mg Within 4 Months.		Not Reported	
	Escitalopram			S				Not Reported	
	Stribild			S				Not Reported	
	Alprazolam			C				Not Reported	

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29-Aug-2019	16752881	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2019-05483		44 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardio- Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Unknown	Unk		Lupin	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16753086	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US06017			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Escitalopram			S	Unknown	5 Milligram		Invagen	
	Escitalopram			S	Unknown	15 Milligram, (Titrated Gradually To 15 Mg Within 4 Months)		Invagen	
	Ondansetron			S	Oral	40 Milligram, Up To 5 Times A Day, Ingestion		Not Reported	
	Stribild			S	Unknown	Unk		Not Reported	
	Alprazolam			C	Unknown	0.5 Milligram, Qid (Every 6 Hours)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16753163	NON-EXPEDITED			US-009507513- 1908USA000225		40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Weight Increased	Remeron			S	Oral	45 Milligram, Unk		Merck	
	Escitalopram			S		20 Milligram, Unk		Not Reported	

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29-Aug-2019	16753469	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1099066		38 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Drug Ineffective	Venlafaxine			S	Unknown	225 Milligram Daily;		Teva	
	Sertraline			S	Unknown	100 Milligram Daily;		Not Reported	
	Mirtazapine			S	Unknown	30 Milligram Daily;		Teva	
	Escitalopram			S	Unknown			Ivax	
	Lithium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16754223	EXPEDITED (15-DAY)		OT	ES-MACLEODS PHARMACEUTICALS US LTD- MAC2019022737			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardio- Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram Oxalate			S	Unknown	Unk		Macleods	
	Olanzapine			S	Unknown	Unk		Macleods	
	Salbutamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16756099	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2019M1081062		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Movement Disorder; Loss Of Consciousness	Escitalopram			S		15 Mg, Unk		Not Reported	
	Prior /01421801/			S		40 Mg, Om		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16756348	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2019-ES-1098054		32 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Intentional Overdose	Escitalopram (2858a)			S	Oral	560 Milligram		Ivax	
	Magnesio [Magnesium]			S	Oral	18 Gram		Not Reported	
	Armopl - Armolipid Plus 20 Comp (Diet)			S	Oral	6 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16756626	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC- 2019364693		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Dehydration; Hyperkalaemia	Aldactone			S	Oral	12.5 Mg, 1x/Day		Pfizer	
	Esomeprazole Magnesium			S	Oral	20 Mg, 1x/Day		Unknown	
	Fungizone			S		Unk		Not Reported	
	Lovenox			S	Subcutaneous	Unk		Not Reported	
	Lasilix			S	Oral	40 Mg, 1x/Day		Not Reported	
	Escitalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
	Diffu K			S	Oral	1800 Mg, 1x/Day		Not Reported	
	Lysanxia			C		Unk		Not Reported	
	Renutryl			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16180279	EXPEDITED (15-DAY)		OT	DE-JNJFOC- 20190404775		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Simponi			S	Subcutaneous			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Pantozol			S	Unknown			Not Reported	
	Implanon			S	Unknown			Not Reported	

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Ibuprofen	S	Unknown		Not Reported
Metoprolol Tartrate	S	Unknown		Not Reported
Salbutamol Sulfate	S	Unknown		Not Reported
Escitalopram Oxalate	S	Unknown		Not Reported
Prednisolon Jenapharm	S	Unknown		Not Reported
Metoprolol Hexal	S	Unknown		Not Reported
Amitriptylin	S	Unknown		Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Ow	Not Reported
Metoprolol Succinate	S			Not Reported
Amitriptyline	S	Unknown		Not Reported
Prednisolone	S	Unknown		Not Reported
Prednisolone	S	Unknown		Not Reported
Fluticasone;Vilanterol	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Prednisolon /00016201/	S	Unknown		Not Reported
Salbutamol	S	Unknown		Not Reported
Escitalopram Hexal	S	Unknown		Not Reported
Metoprolol /00376903/	S	Unknown		Not Reported
Escitalopram Stada	S	Unknown		Not Reported
Metoprolol Mylan /00376902/	S	Unknown		Not Reported
Salbutamol Stada	S	Unknown		Not Reported
Salbutamol Stada	S	Unknown		Not Reported
Escitalopram Mylan	S	Unknown		Not Reported
Metoprolol Stada	S	Unknown		Not Reported
Prednisolon Stada	S	Unknown		Not Reported
Ibuhexal /00109201/	S	Unknown		Not Reported
Prednisolon Jenapharm	S	Unknown		Not Reported
Fluticasone	C	Unknown		Not Reported

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30-Aug-2019	16567173	EXPEDITED (15-DAY)		OT	JP-ALLERGAN-1928431US			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Anxiety Disorder;	Ursodeoxycholic Acid - Bp			S	Oral	Unk		Allergan
Autonomic Nervous System Imbalance;	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd For 5-6 Years		Allergan
Decreased Activity;	Depas (Etizolam)			S	Oral	Unk		Not Reported
Depression; Dizziness;	Depas (Etizolam)			S	Oral	Unk		Not Reported
Dysgeusia; Dyspepsia;	Brotizolam			S	Oral	Unk, Qhs		Not Reported
Feeling Abnormal;	Goodmin			S	Oral	Unk		Not Reported
Insomnia; Malaise; Mania;	Tegretol			S	Oral	800 Mg, Qd		Not Reported
Nausea; Nausea;	Tegretol			S	Oral	400 Mg, Qd		Not Reported
Neuralgia; Off Label Use;	Tegretol			S	Oral	200 Mg In The Evening And 400 Mg At Bedtime		Not Reported
Palpitations; Somnolence;								
Somnolence; Therapeutic Product Effect Incomplete								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16607790	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-214382		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea Exertional;	Enalapril			S	Unknown	() , Unk		Ranbaxy
Electrocardiogram Qt Prolonged; Extrasystoles;	Escitalopram			S	Unknown	() , Unk		Not Reported
Hypomagnesaemia	Omeprazole			S	Unknown	() , Unk		Astrazeneca
	Trazodone			S	Unknown	() , Unk		Not Reported
	Metformin			C	Unknown	() , Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16757923	EXPEDITED (15-DAY)		DE, HO	FR-SA-2019SA231378		90 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Kidney Injury; Dehydration; Hyperkalaemia	Lovenox	S	Subcutaneous	Unk Unk, Unk	Sanofi
	Lasilix	S	Oral	40 Mg, Qd	Sanofi
	Esomeprazole	S	Oral	20 Mg, Qd	Not Reported
	Spironolactone	S	Oral	12.5 Mg, Qd	Not Reported
	Escitalopram Oxalate	S	Oral	10 Mg, Qd	Not Reported
	Potassium Chloride	S	Oral	1800 Mg, Qd	Not Reported
	Fungizone	S	Unknown	Unk Unk, Unk	Not Reported
	Lysanxia	C	Unknown	Unk Unk, Unk	Not Reported
	Renutryl	C	Unknown	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16758473	EXPEDITED (15-DAY)		OT	ES-ACCORD-152839		44 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardio- Respiratory Arrest; Drug Level Increased; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S				Not Reported
	Olanzapine			S				Not Reported
	Salbutamol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16759279	EXPEDITED (15-DAY)		OT	BR-TORRENT- 00005083			Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Decreased; Decreased Appetite; Dyspnoea; Insomnia; Pallor; Product Administration Error; Product Prescribing Error; Somnolence	Escitalopram			S	Oral	Qne Tablet Daily		Torrent
	Menelat			S		Half Tablet Daily		Torrent

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30-Aug-2019	16759511	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1100632		65 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Language Disorder; Muscle Twitching; Tremor	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	5 Milligram Daily;		Ivax	
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	10 Milligram Daily;		Ivax	
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	7.5 Milligram Daily;		Ivax	
	Escitalopram Abz 5 Mg Filmtabletten			S	Oral	5 Milligram Daily;		Ivax	
	Tegretal			C		Intake For One Year		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16759807	NON-EXPEDITED			US-TEVA-2019-US-1101540			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16761525	EXPEDITED (15-DAY)		HO, LT	PHHY2019US202613		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Dyspnoea; Overdose; Pulseless Electrical Activity; Unresponsive To Stimuli	Quetiapine			S	Oral	3000 Mg, Unk		Novartis	
	Clonazepam			S	Oral	5 Mg, Unk		Not Reported	
	Bisoprolol			S	Oral	25 Mg, Unk		Not Reported	
	Escitalopram			S	Oral	250 Mg, Unk		Not Reported	
	Venlafaxin			S	Oral	1000 Mg, Unk		Not Reported	
	Flecainide			S	Oral	2500 Mg, Unk		Not Reported	

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30-Aug-2019	16762045	EXPEDITED (15-DAY)		HO	CA-VIIV HEALTHCARE LIMITED-CA2019GSK155978			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Lung Disorder	Triumeq			S		Unk		Viiv	
	Cipralex			S		Unk		Not Reported	
	Ecasa			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2019	16762281	EXPEDITED (15-DAY)		DE, HO	FR-ZYDUS-040119		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Dehydration; Hyperkalaemia	Spironolactone			S	Oral			Not Reported	
	Amphotericin B			S	Unknown			Not Reported	
	Lovenox			S	Subcutaneous			Not Reported	
	Lasilix			S	Oral			Not Reported	
	Esomeprazole/Esomeprazole			S	Oral			Not Reported	
	Magnesium/Esomeprazole								
	Sodium Escitalopram			S	Oral			Cadila	
	Diffu K			S	Oral			Not Reported	
	Lysanxia			C				Not Reported	
	Renutryl			C		Drinkable Emulsion In Box		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2019	16762440	EXPEDITED (15-DAY)		HO	US-HETERO-HET2019US01169		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Prolactin Increased; Galactorrhoea	Escitalopram			S	Unknown	10 Milligrams		Hetero	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2019	16762485	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-057670			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000 Milligram, In Totoal		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, In Total		Aurobindo	
	Propranolol			S	Oral	4000 Milligram, In Totoal		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	15458413	EXPEDITED (15-DAY)		DE, HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-185951		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Amiodarone			S	Oral	Inconnue ()		Taro	
	Lansoprazole			S	Oral	15 Mg, Daily		Sun	
	Escitalopram			S	Oral	10 Mg, Daily		Not Reported	
	Lactulose			S	Oral	2 Df, Daily		Not Reported	
	Atorvastatine			S	Oral	10 Mg, Daily		Sun	
	Repaglinide			S	Oral	2 Mg, Daily		Sun	
	Trimebutine			S	Oral	300 Mg, Daily		Not Reported	
	Bisoc 1,25 Mg, Comprime Pellicule			S	Oral	In Total		Not Reported	
	Fungizone 10 Pour Cent, Suspension Buvable			S	Buccal	3 Df, Daily		Not Reported	
	Prograf			S	Oral	3 Mg, Qd		Not Reported	
	Driptane 5 Mg, Comprime Secable			S	Oral	3 Df, Daily, 15 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	16763210	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-		26 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

19-467

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased; Myoclonus; Serotonin Syndrome	Ondansetron			S	Oral	Up To 5 Times A Day, Ingestion		Westward
	Escitalopram			S	Unknown	Titrated Gradually From 5 To 15 Mg Within 4 Months.		Hikma
	Escitalopram			S	Unknown			Hikma
	Cobicistat			S	Unknown	()		Not Reported
	Alprazolam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	16764258	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2019-FR-1099761		90 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral			Teva
	Escitalopram			S	Oral			Ivax
	Aldactone			S	Oral			Not Reported
	Fungizone			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Lasilix			S	Oral			Not Reported
	Diffu K, Gélule			S	Oral			Not Reported
	Lysanxia			C				Not Reported
	Renutryl 500, Émulsion Buvable En Boite			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	16764432	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1935388US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardiac Disorder; Fatigue; Feeling Abnormal; Hypersomnia; Weight Increased	Lexapro	S	Unknown			Allergan
	Xtandi	S	Oral	Unk, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16570141	EXPEDITED (15-DAY)		HO	FR-ACCORD-138345		81 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Off Label Use; Pleural Effusion; Somnolence; Traumatic Haemothorax	Clozapine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16639432	EXPEDITED (15-DAY)		DE, LT, OT	PL-ALLERGAN- 1930434US			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Pulmonary Embolism	Escitalopram Oxalate Unk			S	Unknown	20 Mg, Qd		Allergan
	Reboxetine			S	Unknown	4 Mg, Qd		Not Reported
	Quetiapine			S	Unknown	100 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	5 Mg, Qd		Not Reported
	Venlafaxine			S	Unknown	25 Mg, Qd		Not Reported
	Paroxetine			S	Unknown	20 Mg, Qd		Not Reported
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	30 Mg, Qd		Not Reported
	Mirtazapine			S	Unknown	45 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16751451	EXPEDITED (15-DAY)		OT	ES- ELI_LILLY_AND_COMP ANY-ES201908009715		44 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased;	Olanzapine	S	Unknown	Unk, Unknown	Not Reported
Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram	S	Unknown	Unk Unk, Unknown	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16764967	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-055865			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardio-Respiratory Arrest; Drug Level Increased;	Escitalopram			S	Unknown	Unk		Aurobindo
Electrocardiogram Qt Prolonged; Torsade De Pointes	Olanzapine			S	Unknown	Unk		Aurobindo
	Salbutamol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16765420	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-055873			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased;	Ondansetron			S	Oral	40 Milligram, Up To 5 Times A Day, Ingestion		Aurobindo
Myoclonus; Serotonin Syndrome	Escitalopram			S	Unknown	15 Milligram, Titrated Gradually To 15 Mg Within 4 Months.		Aurobindo
	Escitalopram			S	Unknown	5 Milligram		Aurobindo
	Stribild			S	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	0.5 Milligram, Four Times/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16765815	EXPEDITED (15-DAY)		DE, HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		90 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019RR-219559

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dehydration; Hyperkalaemia	Esomeprazole			S	Oral	20 Milligram, Daily		Sun
	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Aldactone			S	Oral	12.5 Milligram, Daily		Not Reported
	Fungizone			S	Unknown	Unk		Not Reported
	Diffu K, Gelule			S	Oral	1800 Milligram, Daily		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Lasilix			S	Oral	40 Milligram, Daily		Not Reported
	Lysanxia			C	Unknown	Unk		Not Reported
	Renutryl 500, Emulsion Buvable En Boite			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16765965	EXPEDITED (15-DAY)		HO, LT	FR-ACCORD-153474		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Poisoning Deliberate; Sinus Bradycardia; Somnolence	Escitalopram			S	Oral			Not Reported
	Quetiapine			S	Oral			Not Reported
	Propranolol/Propranolol Hydrochloride/Propranolol			S	Oral			Accord
	Phenobarbital							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16766308	NON-EXPEDITED			US-NEOPHARMA INC-000190			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Amoxicillin			S				Not Reported
	Neurontin			S	Oral	Take 1 Capsule 300 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Total By Mouth Nightly

Escitalopram	S	Not Reported
Fluoxetine	S	Not Reported
Cephalexin	S	Not Reported
Duloxetine/Duloxetine	S	Not Reported
Hydrochloride		
Erythromycin Base	S	Not Reported
Oxycodone	S	Not Reported
Phenylephrine	S	Not Reported
Guaifenesin	S	Not Reported
Sulfamethoxazole	S	Not Reported
Trimethoprim	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16769650	EXPEDITED (15-DAY)		HO	PHHY2019SE201683		18 YR	Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Intentional Self-Injury	Escitalopram			S	Oral	140 Mg, Unk		Not Reported
	Desloratadine			S	Oral	60 Mg, Unk		Novartis
	Lergigan (Promethazine Hydrochloride)			S	Oral	200 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16723366	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2019-053382			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Prolactin Increased; Galactorrhoea	Duloxetine			S	Unknown	20 Milligram, Daily		Aurobindo
	Duloxetine			S	Unknown	40 Milligram, Daily, After 5 Days		Aurobindo
	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16770280	EXPEDITED (15-DAY)		OT	ES-ALKEM LABORATORIES LIMITED-ES-ALKEM- 2019-07667		44 YR	Female	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Olanzapine			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16770496	NON-EXPEDITED		HO	ZA-LUPIN PHARMACEUTICALS INC.-2018-06634			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Chest Pain	Amlodipine			S	Oral	10 Mg, Unk		Lupin
	Indapamide Mylan			S	Oral	2.5 Mg, Unk		Not Reported
	Ecotrin			S	Oral	81 Mg, Unk		Not Reported
	Zolnoxs			S	Oral	10 Mg, Unk		Not Reported
	Lexamil			S	Oral	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16770628	EXPEDITED (15-DAY)		OT	PHHY2019FR204273			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Incorrect Dose Administered	Escitalopram Sandoz			S	Unknown	10 Mg, Bid		Not Reported
	Tramadol			S	Unknown	100 Mg, Bid		Not Reported
	Tramadol			S	Unknown	500 Mg, Qid (If It Was Needed)		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Depakine Chrono			C	Unknown	1.5 Mg, Bid		Not Reported
	Urbanyl			C	Unknown	2 Df (20 Units Not Specified), Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16771183	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA- 2019SF24765		31 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000.0mg Once/Single Administration		Zeneca	
	Propranolol			S	Oral	4000.0mg Once/Single Administration		Not Reported	
	Escitalopram			S	Oral	10.0mg Once/Single Administration		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16772253	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019373295		28 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Decreased Interest; Loss Of Personal Independence In Daily Activities	Xanax			S	Oral	2 Df, 1x/Day		Pfizer	
	Tercian [Cyamemazine Tartrate]			S	Oral	2 Df, 1x/Day		Not Reported	
	Parkinane Lp			S	Oral	2 Df, 1x/Day		Not Reported	
	Risperdal			S	Oral	Unk		Not Reported	
	Seroplex			S	Oral	1 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16772764	EXPEDITED (15-DAY)		DE, HO	CH-ALLERGAN- 1935238US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia; Febrile Neutropenia	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Wellvone			S	Oral	1500 Mg		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg; In Total		Not Reported	
	Diflucan			S	Unknown	400 Mg/D		Not Reported	
	Benerva			S	Unknown			Not Reported	
	Amlodipin-Mepha			S	Unknown	10 Mg		Not Reported	
	Brufen			S	Unknown	400 Mg 2-3/D		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imodium	S	Unknown	2 Mg 2-3/D	Not Reported
Novorapid	S	Unknown		Not Reported
Levemir	S	Unknown	Unk	Not Reported
Bactrim Ds	C	Unknown	Unk	Not Reported
Cefepime	C	Unknown		Not Reported
Piperacillin And Tazobactam	C	Unknown		Not Reported
Dafalgan	C	Unknown	1 G, Tid	Not Reported
Esomep	C	Unknown	20 Mg	Not Reported
Fragmin	C	Unknown		Not Reported
Aspirin Cardio	C	Unknown	100 Mg	Not Reported
Beloc Zok	C	Unknown	25 Mg, Qd	Not Reported
Beloc Zok	C	Unknown	50 Mg, Qd	Not Reported
Diovan	C	Unknown	80 Mg, Qd	Not Reported
Diovan	C	Unknown	160 Unk	Not Reported
Atorvastatin Pfizer	C	Unknown	40 Mg, Qd	Not Reported
Spiricort	C	Unknown	50 Mg, Qd	Not Reported
Mestinon	C	Unknown	60 Mg 6x/D	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16772775	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1935646US			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations; Tachycardia Paroxysmal	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Amlodipine			C	Unknown	In The Evening		Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Candesartan			C	Unknown	In The Morning		Not Reported	
	Xarelto			C	Unknown	In The Morning		Not Reported	
	Trazodone			C	Unknown	In The Evening		Not Reported	
	Trazodone			C	Unknown	In The Evening		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	8242547	EXPEDITED (15-DAY)		DE, HO, OT	DK-MYLANLABS-2011S1022479			Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Mirtazapine			S	Oral	30 Mg,Qd		Not Reported
Cardiac Hypertrophy;	Mirtazapine			S				Not Reported
Confusional State;	Zeldox /01487003/			S	Oral	40 Mg,Bid		Mylan
Constipation; Depressed	Litrex /00033708/			S	Oral	1.5 Df (In The Evening)		Mylan
Level Of Consciousness;	Cipraxel /01588501/			S	Oral	30 Mg, Qd (Daily Dose Of		Mylan
Dyspnoea; Fall; Hepatic						1 Tablet In The Morning		
Cirrhosis; Hepatic Enzyme						And 1.5 Tablet In The		
Increased; Humerus						Evening)		
Fracture; Hyperdynamic	Fragmin			C		Unk		Mylan
Left Ventricle;	Ferro Duretter			C	Unknown	100 Milligram, Qd		Mylan
Hypertension;	Centyl Med Kaliumklorid			C	Unknown	1 Dosage Form, Qd		Mylan
Hyperventilation; Internal	Furix			C		Unk		Mylan
Fixation Of Fracture;	Amlodipine			C		Unk		Mylan
Lactic Acidosis; Lacunar	Alprazolam			C		0.5 Milligram Daily		Mylan
Infarction; Myocardial	Alprazolam			C		0.5 Milligram, Qd		Mylan
Infarction; Neuroleptic								
Malignant Syndrome;								
Organ Failure; Pyrexia;								
Renal Failure;								
Rhabdomyolysis; Urinary								
Tract Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16595645	EXPEDITED (15-DAY)		OT	DE-ACCORD-138972		48 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pancreatitis; Skin Ulcer	Escitalopram			S	Oral	10 Mg, Qd		Not Reported	
	Ledipasvir/Sofosbuvir			S	Oral	90 Mg, Qd		Not Reported	
	Ribavirin			S	Oral	600 Mg, Bid		Not Reported	
	Braunovidon			C				Not Reported	
	Ribavirin			S	Oral	400mg-0-200mg		Not Reported	
	Ribavirin			S	Oral	400 Mg, Bid		Not Reported	

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05-Sep-2019	16639176	EXPEDITED (15-DAY)		DE, HO, OT	CH-PFIZER INC-2019317201		78 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Atorvastatin Pfizer			S		40 Mg, 1x/Day (0-0-1-0)		Pfizer	
	Pregabalin Pfizer			S	Oral	50 Mg, 4x/Day (1-1-1-1)		Pfizer	
	Toviaz			S	Oral	8 Mg, 1x/Day		Pfizer	
	Toviaz			S	Oral	8 Mg, 1x/Day (0-0-1-0)		Pfizer	
	Temesta [Lorazepam]			S	Oral	2.5 Mg, 2x/Day (1-0-0-1)		Pfizer	
	Temesta [Lorazepam]			S	Oral	2.5 Mg, 2x/Day (1-0-0-1, Already For 40 Years In Different Dosage)		Pfizer	
	Beloc Zok			S	Oral	50 Mg, 1x/Day		Not Reported	
	Beloc Zok			S	Oral	50 Mg, 1x/Day (1-0-0-0)		Not Reported	
	Ciprallex [Escitalopram Oxalate]			S	Oral	20 Mg, Daily (2-0-0-0)		Not Reported	
	Dexilant			S	Oral	60 Mg, 1x/Day		Not Reported	
	Pantoprazole Sandoz			S	Oral	40 Mg, 1x/Day (1-0-0-0)		Not Reported	
	Aspirin Cardio			S	Oral	100 Mg, 1x/Day (1-0-0-0)		Not Reported	
	Quetiapin Sandoz			S	Oral	12.5 Mg, 2x/Day		Not Reported	
	Quetiapin Sandoz			S	Oral	12.5 Mg, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16653405	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE176104		22 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Serotonin Syndrome	Linezolid			S	Unknown	Unk		Novartis	
	Escitalopram			S	Unknown	Unk, (Long Term Medication)		Not Reported	

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05-Sep-2019	16774550	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-04010			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug	Duloxetine			S	Unknown	Unk		Lupin	
Hypersensitivity; Fatigue;	Amlodipine Besylate Tablets			S	Unknown	Unk		Lupin	
Irritability; Oedema;	Escitalopram			S	Unknown	Unk		Lupin	
Palpitations; Tinnitus	Gabapentin			S	Unknown	Unk		Lupin	
	Lorazepam			S	Unknown	Unk		Lupin	
	Losartan Potassium			S	Unknown	Unk		Lupin	
	Metoprolol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16778002	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAUSCH-BL-2019-024991		52 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine	Lorazepam			S	Oral			Not Reported	
Phosphokinase Increased;	Lorazepam			S	Oral			Not Reported	
Blood Creatinine	Diazepam			S	Unknown			Not Reported	
Increased; Blood	Altace			S	Unknown			Not Reported	
Potassium Increased;	Diazepam			S	Oral			Not Reported	
Blood Pressure	Diazepam			S	Oral			Not Reported	
Decreased; Bradycardia;	Diazepam			S	Oral			Not Reported	
Coma; Coma Scale	Cipralelex			S	Unknown			Not Reported	
Abnormal; Drug	Cipralelex			S	Oral			Not Reported	
Interaction; Drug Screen	Cipralelex			S	Unknown			Not Reported	
Positive;	Cipralelex			S	Unknown			Not Reported	
Electrocardiogram	Morphine			S	Oral			Not Reported	
Abnormal;	Morphine			S	Unknown			Not Reported	
Electrocardiogram Qt	Morphine			S	Unknown			Not Reported	
Prolonged; Heart Rate	Morphine			S	Unknown			Not Reported	
Decreased;	Morphine			S	Unknown			Not Reported	
Hyperkalaemia;									
Hypotension; Intentional									

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Overdose; Loss Of Consciousness;	Morphine	S	Unknown	Not Reported
Mechanical Ventilation;	Morphine	S	Unknown	Not Reported
Opiates Positive;	Morphine	S	Unknown	Not Reported
Overdose; Oxygen Saturation Decreased;	Morphine	S	Oral	Not Reported
Sinus Tachycardia;	Morphine	S	Oral	Not Reported
Suicide Attempt	Oxycodone	S	Unknown	Not Reported
	Oxycodone	S	Oral	Not Reported
	Oxycodone	S	Oral	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Zopiclone	S	Oral	Not Reported
	Zopiclone	S	Oral	Not Reported
	Oxycodone-Acetaminophen	S	Oral	Not Reported
	Citalopram	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16778098	NON-EXPEDITED			US-TEVA-2019-US-1103807		19 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Orthostatic Hypotension	Escitalopram Tablets			S	Unknown			Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16479768	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1067478			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis; Off Label Use; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Propranolol Hydrochloride			S	Oral	80 Milligram Daily;		Actavis
	Marijuana			S	Oral	1 Dosage Forms Daily;		Not Reported
	Pentasa			S	Unknown			Not Reported

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Premarin S Oral .625 Milligram Daily; Not Reported

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06-Sep-2019	16678876	EXPEDITED (15-DAY)		OT	DE-TOPROL ACQUISITION LLC- 2019-TOP-000790		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Metoprolol Succinate			S	Oral	Unk		Not Reported
	Metoprolol Stada			S		Stada		Not Reported
	Metoprolol Stada			S		Mylan		Not Reported
	Metoprolol Stada			S		Hexal		Not Reported
	Metoprolol Tartrate			S	Oral	Unk		Not Reported
	Escitalopram			S		Unk		Not Reported
	Escitalopram			S		Unk, Hexal		Not Reported
	Escitalopram			S		Unk, Mylan		Not Reported
	Escitalopram			S		Unk, Stada		Not Reported
	Prednisolone			S		25 Mg, Unk		Not Reported
	Prednisolone			S		Unk, Jenapharm		Not Reported
	Prednisolone			S		Unk, Stada		Not Reported
	Salbutamol			S		Unk		Not Reported
	Salbutamol			S		Unk, Stada		Not Reported
	Pantozol /01263204/			S		Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Methotrexate			S		1 Df, Weekly		Not Reported
	Amitriptyline Hydrochloride			S		Unk		Not Reported
	Implanon			S		Unk		Not Reported
	Ibuprofen			S		Stada		Not Reported
Ibuprofen			S		Hexal		Not Reported	
Ibuprofen			S		Hormosan		Not Reported	
Ibuprofen			S		Unk		Not Reported	

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Fluticasone Furoate W/Vilanterol Trifenatate			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16779525	EXPEDITED (15-DAY)		HO	FR-ACCORD-153980		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Toxicity To Various Agents	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16779533	EXPEDITED (15-DAY)		HO	IT-ACCORD-153959		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram Xanax			S S	Oral			Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16779871	EXPEDITED (15-DAY)		OT	DE-KADMON PHARMACEUTICALS, LLC-KAD-201907-01471		48 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Ribavirin			S	Oral	600 Mg (1200 Mg)		Kadmon	
	Ribavirin			S	Oral	800 Mg		Kadmon	
	Ribavirin			S	Oral	400 Mg-0-200 Mg (600 Mg)		Kadmon	
	Ledipasvir W/Sofosbuvir			S	Oral	90mg		Not Reported	
	Escitalopram			S	Oral	10 Mg		Not Reported	
	Braunovidon			C				Not Reported	

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06-Sep-2019	16780410	EXPEDITED (15-DAY)		HO, LT	IL-AMNEAL PHARMACEUTICALS- 2019-AMRX-01804		35 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Overdose; Pulse Absent; Pulseless Electrical Activity; Unresponsive To Stimuli	Escitalopram Oxalate			S	Oral	250 Milligram, Once		Amneal	
	Flecainide Acetate			S	Oral	2500 Milligram, Once		Amneal	
	Quetiapine Fumarate			S	Oral	3000 Milligram, Once		Amneal	
	Venlafaxine Hydrochloride			S	Oral	1000 Milligram, Once		Amneal	
	Bisoprolol			S	Oral	25 Milligram, Once		Not Reported	
	Clonazepam			S	Oral	5 Milligram, Once		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16780521	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2019M1083170		16 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Product Use Issue; Suicidal Ideation; Thinking Abnormal	Escitalopram			S	Unknown	5 Milligram		Not Reported	
	Escitalopram			S	Unknown	15 Milligram		Not Reported	
	Escitalopram			S	Unknown	10 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16782580	EXPEDITED (15-DAY)		HO	SE-009507513- 1909SWE000349		18 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Intentional Self-Injury	Desloratadine			S	Oral	60 Milligram, "Total"		Merck	
	Lergigan (Promethazine Hydrochloride)			S	Oral	200 Milligram, "Total"		Not Reported	
	Escitalopram			S	Oral	140 Milligram, "Total"		Not Reported	

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06-Sep-2019	16782679	NON-EXPEDITED			US-SA-2019SA244397			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Ambien			S		Unk		Sanofi
	Spironolactone			S		Unk		Not Reported
	Amitriptyline Hydrochloride			S		Unk		Not Reported
	Loratadine			S	Unknown	Unk		Not Reported
	Clopidogrel Bisulfate			S	Unknown	Unk		Sanofi
	Escitalopram Oxalate			S	Unknown			Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Morphine Salt Not Specified			S	Unknown	Unk		Not Reported
	Clotrimazole			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Penicillin Nos			S	Unknown	Unk		Not Reported
	Fluticasone			S	Unknown			Not Reported
	Tylox [Oxycodone Hydrochloride;Paracetamol]			S	Unknown			Not Reported
	Mucinex			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2019	16735158	EXPEDITED (15-DAY)		OT	DE-009507513-1904DEU001849		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Implanon			S	Unknown	Unk		Merck
	Golimumab			S	Unknown	Unk		Not Reported
	Albuterol Sulfate			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

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Methotrexate Sodium	S	Unknown	1 Dosage Form, Qw	Not Reported
Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	2.5 Mg, Unk	Not Reported
Pantozol	S	Unknown	Unk	Not Reported
Metoprolol Mylan	S	Unknown	Unk	Not Reported
Metoprolol Succinate	S	Unknown	Unk	Not Reported
Metoprololo Hexal	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Albuterol	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Prednisolon	S	Unknown	Unk	Not Reported
Escitalopram	S	Unknown	Unk	Not Reported
Escitalopram Oxalate	S			Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Amitriptylin	S			Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Ibuprofen Stada	S	Unknown	Unk	Not Reported
Fluticasone Furoate (+) Vilanterol Trifenatate	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16399426	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS- 2019-005100		37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Agitation; Chest	Symdeko			S	Oral	Unk, Bid		Vertex	

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Discomfort; Cough;	Lexapro	S	Unknown		Not Reported
Depressed Mood;	Lexapro	S	Oral	Decreased Dose	Not Reported
Dyspnoea; Fatigue;	Voriconazole	C	Oral	200 Mg, Bid	Not Reported
Respiratory Tract	Azithromycin	C	Oral	500 Mg, Qd	Not Reported
Inflammation; Weight	Cayston	C	Respiratory	75 Mg, Tid	Not Reported
Increased			(inhalation)		
	Insulin	C			Not Reported
	Pulmozyme	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16675534	EXPEDITED (15-DAY)		HO	LT-ALLERGAN-1932121US			Female	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury;	Escitalopram Oxalate Unk			S	Unknown	10 Mg, Qd		Allergan	
Major Depression; Off	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported	
Label Use; Treatment									
Noncompliance									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16739899	EXPEDITED (15-DAY)		HO, LT	US-ASTRAZENECA-2019SF20397		35 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiac Arrest;	Quetiapine			S	Oral	3,000 Mg		Zeneca	
Circulatory Collapse;	Venlafaxine			S	Oral	1,000mg,		Not Reported	
Infection; Intentional	Flecainide			S	Oral	2,500mg		Not Reported	
Overdose; Pulseless	Escitalopram			S	Oral	250mg		Not Reported	
Electrical Activity;	Bisoprolol			S	Oral	25mg		Not Reported	
Thrombocytopenia	Clonazepam			S	Oral	5 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16785110	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2014-00507			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine Tablets			S	Unknown	2.5 Mg,Two Times A Day,		Aurobindo
	Amlodipine Tablets			S	Unknown	2.5 Milligram, Once A Day		Aurobindo
	Ramipril			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Furosemide			S	Unknown	40 Milligram, Once A Day		Not Reported
	Furosemide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Metoprolol Tartrate			S	Unknown	25 Milligram, Once A Day		Not Reported
	Metoprolol Tartrate			S	Unknown	50 Milligram, Once A Day		Not Reported
	Glyceryl Trinitrate			S	Transdermal	Unk		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, Two Times A Day		Not Reported
	Glyceryl Trinitrate			S	Transdermal	0.4 Milligram, 3 Times A Day		Not Reported
	Oxazepam			S	Unknown	20 Milligram, Once A Day		Not Reported
	Zopiclone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Zopiclone			S	Unknown	2.5 Milligram, Once A Day		Not Reported
	Cipraxel			S	Unknown	Unk		Not Reported
	Cipraxel			S	Unknown	10 Milligram, Once A Day		Not Reported
	Codeine			S	Unknown	30 Milligram, Two Times A Day		Not Reported
	Codeine			S	Unknown	30 Milligram, 3 Times A Day		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Clopidogrel			C				Not Reported
	Clopidogrel			C				Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Polyethylene Glycol	C	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16785213	NON-EXPEDITED			US-MYLANLABS-2019M1080868			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Somnolence	Armodafinil			S	Unknown	Unk		Not Reported
	Lexapro			S	Unknown	Daily		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16786287	EXPEDITED (15-DAY)		HO	IL-UNICHEM PHARMACEUTICALS (USA) INC-UCM201908-000		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Infection; Overdose; Pulseless Electrical Activity; Thrombocytopenia	Quetiapine			S	Oral	3000 Mg		Unichem
	Bisoprolol Fumarate			S	Oral	25 Mg		Not Reported
	Flecainide			S	Oral	2500 Mg		Not Reported
	Venlafaxine			S	Oral	1000 Mg		Not Reported
	Escitalopram			S	Oral	250 Mg		Not Reported
	Clonazepam			S	Oral	5 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16786570	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2019M1082851		35 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cardiac Arrest; Fall; Infection; Intentional Overdose; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Quetiapine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Flecainide			S	Oral			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16787717	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC- 2019388979		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Bradycardia; Coma; Coma Scale Abnormal; Drug Interaction; Drug Screen Positive; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hyperkalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased; Sinus Tachycardia;	Altace			S	Unknown	Unk		Pfizer
	Lorazepam			S	Oral	30 Mg, Unk		Pfizer
	Lorazepam			S	Oral	1 Mg, Unk		Pfizer
	Diazepam			S	Unknown	10 Mg, Unk		Pfizer
	Morphine Sulfate			S	Unknown	100 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	2640 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	420 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	9500 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	15 Mg, Unk		Unknown
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Diazepam			S	Oral	1800 Mg, Unk		Not Reported
	Morphine			S	Oral	30 Mg, Qd		Not Reported
	Morphine			S	Oral	30 Mg, Unk		Not Reported
	Citalopram			S	Oral	Unk		Not Reported
	Cipralext [Escitalopram Oxalate]			S	Unknown	10 Mg, Qd		Not Reported
	Cipralext [Escitalopram Oxalate]			S	Oral	140 Mg, Unk		Not Reported
	Cipralext [Escitalopram Oxalate]			S	Unknown	10 Mg, Unk		Not Reported

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Suicide Attempt	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Oxycodone	S	Oral	Unk	Not Reported
	Oxycodone	S	Oral	20 Mg, Unk	Not Reported
	Oxycodone	S		Unk	Not Reported
	Zopiclone	S	Unknown	7.5 Mg, Unk	Not Reported
	Zopiclone	S	Oral	187.5 Mg, Unk	Not Reported
	Zopiclone	S	Oral	15 Mg, Qd	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16197891	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019154782		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen			S	Unknown	Unk		Pfizer
	Pantozol			S	Unknown	Unk		Pfizer
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ibuprofen Stada			S	Unknown	Unk		Not Reported
	Prednisolon Stada			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Implanon			S	Unknown	Unk		Not Reported
	Ibuprofen Hormosan			S		Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Salbutamol Stada			S	Unknown	Unk		Not Reported
	Escitalopram Mylan			S	Unknown	25 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	2.5 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	25 Mg, Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported

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Escitalopram Hexal	S	Unknown	Unk	Not Reported
Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Metoprolol Mylan	S	Unknown	Unk	Not Reported
Ibuhexal [Ibuprofen]	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Prednisolon [Prednisolone]	S	Unknown	25 Milligram	Not Reported
Prednisolon [Prednisolone]	S	Unknown	2.5 Mg, Unk	Not Reported
Methotrexate Mylan	S	Unknown	1 Df, Weekly	Not Reported
Fluticasone Furoate/Vilanterol	S	Unknown	Unk, 6 Months Before Diagnosis	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16573205	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1064989		48 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Overdose; Intentional Product Misuse; Psychomotor Skills Impaired	Escitalopram			S	Oral	100 Milligram, Total		Not Reported
	Quetiapine			S	Oral	500 Milligram, Total		Not Reported
	Lorazepam			S	Oral	250 Milligram, Total		Not Reported
	Trittico			S	Oral	10 Dosage Form, Total		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16600054	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-042524			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Traumatic Haemothorax	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo
	Eliquis			S	Oral	10 Milligram, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16610198	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1929283US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Traumatic Haemothorax	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Eliquis			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16742439	EXPEDITED (15-DAY)		OT	BR-ALLERGAN-1934933US			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Meningioma Benign; Treatment Noncompliance	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S		5 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16788239	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000623		35 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Venlafaxine			S	Oral	Unknown		Alembic	
	Quetiapine Fumarate			S	Oral	Unknown		Alembic	
	Clonazepam			S	Oral	Unknown		Alembic	
	Flecainide			S	Oral	Unknown		Not Reported	
	Bisoprolol			S	Oral	Unknown		Not Reported	
	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789400	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2019-05739		60 YR	Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brugada Syndrome	Escitalopram			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789494	EXPEDITED (15-DAY)		LT	US-ROCHE-2397440		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Infection; Overdose; Thrombocytopenia	Clonazepam			S	Unknown			Not Reported	
	Flecainide			S	Unknown			Not Reported	
	Quetiapine			S	Unknown			Not Reported	
	Venlafaxine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789674	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1082061		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram			S	Oral	18 Dosage Form, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789883	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2019AMN00884		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Feeling Jittery	Escitalopram			S	Unknown	Unk		Amneal	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790072	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1084042		50 YR	Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delusion;	Escitalopram			S		Unk		Not Reported
Eczema; Emotional	Clozaril			S		Unk		Mylan
Distress; Eosinophil Count	Olanzapine			S		Unk		Not Reported
Decreased; Feeling Cold;	Paliperidone			S		Unk		Mylan
Frustration Tolerance	Movicol /01749801/			C				Mylan
Decreased; Haemoglobin	Senna /00142201/			C				Mylan
Decreased; Hallucination,	Lorazepam			C				Mylan
Auditory; Hyperhidrosis;	Calcium Carbonate			C				Mylan
Intentional Self-Injury;	Lurasidone Hydrochloride			C				Mylan
Lymphocyte Count	Zuclopenthixol			C				Mylan
Decreased; Mean Cell	Rosuvastatin Calcium			C				Mylan
Haemoglobin Decreased;	Caltrate /00944201/			C				Mylan
Mental Impairment;	Vitamin B12 /00056201/			C				Mylan
Metamyelocyte Count	Metformin			C				Mylan
Increased; Monocyte	Mirtazapine			C				Mylan
Count Decreased;								
Myelocyte Count								
Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790167	EXPEDITED (15-DAY)		HO, LT, OT	IL-LUPIN PHARMACEUTICALS INC.-2019-05721		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cardiac Arrest;	Quetiapine			S	Oral	3000 Milligram, Single		Lupin
Cardiotoxicity; Circulatory	Escitalopram			S	Oral	250 Milligram		Lupin
Collapse; Dyspnoea;	Venlafaxine			S	Oral	1000 Milligram, Single		Not Reported
Infection; Intentional	Bisoprolol			S	Oral	25 Milligram, Single		Not Reported
Overdose; Pulse Absent;	Flecainide			S	Oral	2500 Milligram, Single		Not Reported
Thrombocytopenia;	Clonazepam			S	Oral	5 Milligram, Single		Not Reported
Unresponsive To Stimuli								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790220	EXPEDITED (15-DAY)		OT	PHHY2019AU209334		50 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Amnesia; Delusion;	Clozaril	S	Unknown	Unk	Not Reported
Eczema; Emotional	Escitalopram	S	Unknown	Unk	Not Reported
Distress; Eosinophil Count	Olanzapine	S	Unknown	Unk	Novartis
Decreased; Feeling Cold;	Paliperidone	S	Unknown	Unk	Not Reported
Frustration Tolerance	Movicol	C	Unknown	Unk	Not Reported
Decreased; Haemoglobin	Senna	C	Unknown	Unk	Not Reported
Decreased; Hallucination,	Lorazepam	C	Unknown	Unk	Not Reported
Auditory; Hyperhidrosis;	Calcium Carbonate	C	Unknown	Unk	Not Reported
Intentional Self-Injury;	Lurasidone Hydrochloride	C	Unknown	Unk	Not Reported
Lymphocyte Count	Zuclopenthixol	C	Unknown	Unk	Not Reported
Decreased; Mean Cell	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Haemoglobin Decreased;	Vitamin B 12 Lichtenstein	C	Unknown	Unk	Not Reported
Mental Impairment;	Metformin	C	Unknown	Unk	Not Reported
Metamyelocyte Count	Mirtazapine	C	Unknown	Unk	Not Reported
Increased; Monocyte					
Count Decreased;					
Myelocyte Count					
Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791524	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1084023		15 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperreflexia; Mydriasis; Poisoning Deliberate	Escitalopram			S	Oral	25 Dosage Form, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791592	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1936501US			Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose;	Escitalopram Oxalate - Bp			S	Oral	Overdose: 140mg		Allergan
Intentional Self-Injury	Lergigan [Promethazine Hydrochloride]			S	Oral	200 Mg		Not Reported
	Desloratadine			S	Oral	60 Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791597	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1936500US			Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Anxiety; Condition Aggravated	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791600	EXPEDITED (15-DAY)		HO, LT, OT	FR-ALLERGAN-1936499US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Poisoning Deliberate; Sinus Bradycardia; Somnolence	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan	
	Propranolol			S	Oral	4000 Mg		Not Reported	
	Quetiapine			S	Oral	1000 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16792919	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-022169			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antinuclear Antibody Positive; Drug Ineffective; Drug Interaction; Ligament Sprain; Musculoskeletal Stiffness; Prostatic Specific Antigen; Psoriasis Area Severity Index; Seborrhoeic Keratosis; Skin Hyperpigmentation; Tenosynovitis; Visual Analogue Scale; Weight Decreased	Acitretin			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	10 Milligram, Every Week		Not Reported	
	Escitalopram			S	Unknown	Unk		Aurobindo	
	Apremilast			S	Oral	30 Milligram, Two Times A Day		Not Reported	
	Apremilast			S	Oral	30 Mg, Bid,12 Hour		Not Reported	
	Cyclosporine			S	Unknown	Unk		Not Reported	
	Infliximab			S	Unknown	Unk		Not Reported	
	Infliximab			S				Not Reported	
	Infliximab			S				Not Reported	

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Adalimumab	S	Unknown	Unk	Not Reported
Adalimumab	S			Not Reported
Adalimumab	S			Not Reported
Cardioaspirin	S	Unknown	Unk	Not Reported
Atenolol	S	Unknown	Unk	Not Reported
Propafenone	S	Unknown	Unk	Not Reported
Colecalciferol	S	Unknown	Unk	Not Reported
Aspirin	S	Unknown	Unk	Not Reported
Calcipotriol	S	Topical	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	12569713	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2016US09743			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S	Unknown	10 Mg, Qd		Invagen
	Zolpidem Tartrate			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	13078818	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2016ES159974		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac	Sintrom			S	Oral	1 Mg, Qd		Not Reported
Failure; Extensor Plantar	Bisoprolol			S	Oral	5 Mg, Bid		Novartis
Response; Hyperreflexia;	Furosemide			S	Oral	60 Mg, Qd		Not Reported
Hypoaesthesia;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
Multimorbidity; Muscular								
Weakness; Neuromyelitis								

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Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Alendronate Omeprazole Allopurinol Spironolactone Lisinopril Ipratropium Bromide Iron Sulphate	S S S S S S S	Oral Oral Oral Oral Oral Respiratory (inhalation) Oral	70 Mg, Qw 20 Mg, Qd 100 Mg, Qd 50 Mg, Qd 5 Mg, Qd 2 Inh, Q8h 256.3 Mg, Qd	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	15889566	EXPEDITED (15-DAY)		HO, OT	JP-ALLERGAN- 1904181US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Activation Syndrome; Nausea; Vomiting	Escitalopram Oxalate - Bp Gasmotin Dogmatyl Lendormin			S C C C	Oral Oral Oral Oral	10 Mg, Qd 5 Mg, Qd 100 Mg, Q12h 0.25 Mg, Qd		Allergan Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16143243	EXPEDITED (15-DAY)		HO, OT	FR-WHANIN PHARM. CO., LTD.- 2019M1030186		24 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Akathisia; Anxiety; Cardiac Disorder; Drug Ineffective; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Thinking Abnormal	Clozapine Clozapine Aripiprazole Aripiprazole Aripiprazole Mirtazapine Mirtazapine			S S S S S S S	 Unknown Unknown Unknown	600 Mg, Qd Unk 30 Mg, Qd 10 Mg, Qd Unk 15 Mg, Qd 30 Mg, Qd		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Escitalopram			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16753047	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2019US06045			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clonus; Confusional State; Delirium; Dysdiadochokinesis; Electrocardiogram Qt Prolonged; Intentional Overdose; Mydriasis; Prescription Drug Used Without A Prescription; Toxicity To Various Agents; Treatment Failure; Tremor	Sertraline			S	Oral	3000 Milligram (Toxic Ingestion), In Total		Invagen	
	Sertraline			S	Unknown	Unk (Antidepressant Trial)		Invagen	
	Escitalopram			S	Unknown	20 Milligram, Per Day		Invagen	
	Olanzapine			S	Unknown	Unk		Invagen	
	Fluvoxamine			S	Unknown	Unk		Not Reported	
	Imipramine			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Venlafaxine			S	Unknown	Unk (Last Medication Regimen)		Not Reported	
	Aripiprazole			S	Unknown	Unk		Not Reported	
	Chlorpromazine			S	Unknown	Unk		Not Reported	
	Ziprasidone			S	Unknown	Unk		Not Reported	
	Ziprasidone			S	Unknown	Unk (Last Medication Regimen)		Not Reported	
	Lorazepam			S	Unknown	Unk		Not Reported	
	Clonazepam			S	Unknown	Unk		Not Reported	
	Prazosin			S	Unknown	Unk		Not Reported	
	Prazosin			S	Unknown	Unk (Last Medication Regimen)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16761330	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2019- 024587		44 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cardio-Respiratory Arrest;	Salbutamol	S	Unknown	Bausch And Lomb
Long Qt Syndrome;	Olanzapine	S	Unknown	Not Reported
Torsade De Pointes	Escitalopram	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16793130	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2019-US-1105410		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cardiac Arrest;	Clonazepam			S	Oral			Barr
Infection; Intentional	Quetiapine			S	Oral			Teva
Overdose; Suicide	Venlafaxine			S	Oral			Teva
Attempt;	Escitalopram			S	Oral			Ivax
Thrombocytopenia	Bisoprolol			S	Oral			Teva
	Flecainide			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16793893	EXPEDITED (15-DAY)		OT	PHHY2018FI180473			Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amniotic Cavity Infection;	Gilenya			S	Unknown	Unk		Novartis
Failed Induction Of	Escitalopram			S	Unknown	1 Df, Qd		Not Reported
Labour; Gestational	Losatrix Comp			C	Unknown			Not Reported
Diabetes; Maternal	Edronax			C	Unknown			Not Reported
Exposure During	Brintellix			C	Unknown	1 Df, Qd		Not Reported
Pregnancy	Albetol			C	Unknown	1 Df, (1 To 2)		Not Reported
	Vitamin D			C	Unknown	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794132	EXPEDITED (15-DAY)		OT	GB-ACCORD-154281		40 YR	Female	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration	Escitalopram			S	Respiratory (inhalation)			Not Reported
	Ventolin			C				Not Reported
	Otomize			C				Not Reported
	Duloxetine			C		Night		Not Reported
	Pregabalin			C				Not Reported
	Hydroxocobalamin			C	Intramuscular			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794179	EXPEDITED (15-DAY)		HO	FR-ACCORD-154578		101 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Orthostatic Hypotension	Escitalopram			S	Oral			Not Reported
	Ramipril			S	Oral			Accord
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Colecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794517	EXPEDITED (15-DAY)		DE, HO	ES-ASTRAZENECA- 2019SF27224		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder;	Omeprazol			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Alendronic Acid			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Iron Sulfate			S	Oral			Not Reported

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Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Bisoprolol	S	Oral			Not Reported
	Bromide Ipratropie	S	Respiratory (inhalation)	2 Inh Every 8 Hours	Inhaled	Not Reported
	Sintrom	S	Oral			Not Reported
	Spironolactone	S	Oral			Not Reported
	Allopurinol	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795166	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1085174		19 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Bradypnoea; Respiratory Acidosis; Somnolence; Tachycardia; Toxicity To Various Agents	Tramadol			S	Oral	Unk		Not Reported	
	Paracetamol			S	Oral	12 Gram		Not Reported	
	Diazepam			S	Oral	100 Milligram		Mylan	
	Seroplex			S	Oral	560 Milligram		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795353	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019384952			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abulia; Anxiety; Decreased Interest; Depressed Mood; Feeling Guilty; Headache; Hyperventilation; Initial Insomnia; Mental Impairment; Pallor; Palpitations	Triazolam			S		0.5mg, Daily		Pfizer	
	Mirtazapine			S		45 Mg, Daily		Not Reported	
	Escitalopram			S		20 Mg, Daily		Not Reported	
	Brotizolam			S		0.25 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795999	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2019M1085164		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury; Shock; Somnolence; Toxicity To Various Agents	Lamotrigine	S	Oral	Unk	Not Reported
	Mirtazapine	S	Oral	Unk	Not Reported
	Escitalopram	S	Oral	Unk	Not Reported
	Racecadotril Bgr	S	Oral	Unk	Mylan
	Levothyrox	S	Oral	Unk	Mylan
	Coveram	S	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796130	EXPEDITED (15-DAY)		HO, LT, OT	IL-PRINSTON PHARMACEUTICAL INC.-2019PRN00792		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Overdose; Unresponsive To Stimuli	Clonazepam			S	Oral	5 Mg		Prinston Pharmaceutical
	Escitalopram			S	Oral	250 Mg		Prinston Pharmaceutical
	Venlafaxine			S	Oral	1000 Mg		Prinston Pharmaceutical
	Quetiapine			S	Oral	3000 Mg		Not Reported
	Flecainide			S	Oral	2500 Mg		Not Reported
	Bisoprolol			S	Oral	25 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796567	EXPEDITED (15-DAY)		OT	AU-ALLERGAN- 1936611US			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Cardiac Event; Seizure; Seizure; Seizure; Seizure; Tachycardia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Epilim			C	Unknown			Not Reported
	Trileptal			C	Unknown			Not Reported
	Florinef			C	Unknown			Not Reported
	Keppra			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796648	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1936683US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Overdose; Sinus Bradycardia	Escitalopram Oxalate - Bp			S	Oral	28 Df, Single		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796667	EXPEDITED (15-DAY)		DS	FR-ALLERGAN-1936870US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Product Use In Unapproved Indication; Subdural Haematoma	Escitalopram Oxalate - Bp			S	Oral	20 Mg		Allergan	
	Inegy			S	Unknown			Not Reported	
	Inexium			S	Oral	1 Df		Not Reported	
	Kardegic			S	Oral	1 Df		Not Reported	
	Keppra			C	Unknown			Not Reported	
	Tenormine			C	Unknown			Not Reported	
	Tiapridal			C	Unknown			Not Reported	
	Coaprovel			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796674	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2019-10933			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Off Label Use; Poisoning Deliberate; Product Use Issue; Sinus Bradycardia; Somnolence	Propranolol			S	Oral	4000mg In Total		Pierre Fabre Medicament	
	Quetiapine			S	Oral	1000mg In Total		Not Reported	
	Escitalopram			S	Oral	10mg In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16797083	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR- APL-2019-059126		27 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Diarrhoea; Influenza Like Illness; Malaise; Product Prescribing Error; Serotonin Syndrome	Escitalopram			S	Unknown	Unk		Aurobindo	
	Trazodone			S	Unknown	Unk		Not Reported	
	Tramagit			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	12594481	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR- APL-2016-09711		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Autoimmune Hepatitis; Blood Bilirubin Increased; Hepatic Necrosis; Hepatitis Cholestatic; Hepatomegaly; Hepatosplenomegaly	Escitalopram			S	Unknown	Unk		Aurobindo	
	Diazepam			C	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	
	Zolpidem			C	Unknown	Unk		Not Reported	
	Fexofenadine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	14351486	EXPEDITED (15-DAY)		HO, OT	FR-NOVOPROD- 579479		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Novorapid			S	Subcutaneous	Unk		Novo Nordisk	
	Xeloda			S	Oral	Unk		Not Reported	
	Primperan			S	Oral	Unk		Not Reported	
	Lipanthyl			S	Oral	Unk		Not Reported	
	Movicol			S	Oral	Unk		Not Reported	

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Pantoprazole	S	Oral	Unk	Not Reported
Escitalopram	S	Oral	Unk	Not Reported
Abasaglar	S	Subcutaneous	Unk	Not Reported
Fondaparinux Sodium	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16114803	NON-EXPEDITED		OT	CA-AMGEN- CANSP2019044230		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Oral	1 Dosage Form, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Oral	1 Dosage Form, Qd		Not Reported
	Xeljanz			S	Oral	1 Dosage Form, Bid		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16600443	EXPEDITED (15-DAY)		OT	DE-HETERO- HET2019DE00975		48 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Pancreatitis; Skin Ulcer; Skin Ulcer	Escitalopram			S	Oral	Qd		Hetero
	Ledipasvir W/Sofosbuvir			S	Oral	90 Mg, Q.D.		Not Reported
	Ribavirin			S	Oral	600 Mg, Q.D.		Not Reported

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	Ribavirin	S	Oral	600 Mg (400mg-0-200 Mg)	Not Reported
	Ribavirin	S	Oral	400 Mg, Bid	Not Reported
	Ribavirin	S	Oral	600 Mg, Bid	Not Reported
	Braunovidon	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16771080	EXPEDITED (15-DAY)		DS	US-TORRENT-00009144		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Withdrawal Syndrome; Impaired Quality Of Life; Sexual Dysfunction	Escitalopram			S	Oral	Dosage Of 5-10 Mg		Torrent	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16797514	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-059121			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Hypertension; Muscle Spasms; Tremor	Escitalopram			S	Unknown	10 Milligram		Aurobindo	
	Escitalopram			S	Unknown	5 Milligram		Aurobindo	
	Tegretal			S	Unknown	Unk		Not Reported	
	Tegretal			S	Unknown	400 Milligram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16797910	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2019-FR-1104865		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	1000 Milligram		Teva	
	Escitalopram			S	Oral	10 Milligram		Ivax	
	Propranolol			S	Oral	4000 Milligram		Actavis	

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12-Sep-2019	16797965	EXPEDITED (15-DAY)		HO, LT, OT	IL-MACLEODS PHARMACEUTICALS US LTD- MAC2019022898			Unknown	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Escitalopram			S	Oral	250 Milligram		Macleods	
	Quetiapine			S	Oral	3000 Milligram		Macleods	
	Venlafaxine			S	Oral	1000 Milligram		Macleods	
	Flecainide			S	Oral	2500 Milligram		Not Reported	
	Clonazepam			S	Oral	5 Milligram		Not Reported	
	Bisoprolol			S	Oral	25 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16798043	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX- 2019AP021644		79 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Hyponatraemia; Stress Cardiomyopathy	Mirtazapine			S	Unknown	45 Mg, Q.H.S.		Apotex	
	Desvenlafaxine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex	
	Oxazepam			C	Unknown	7.5 Mg, Qid		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Olmesartan			C	Unknown	Unk		Not Reported	
	Amiodarone			C	Unknown	Unk		Not Reported	
	Rivaroxaban			C	Unknown	Unk		Not Reported	
	Diazepam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16798177	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-219857		35 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Dyspnoea; Infection; Intentional Overdose; Loss Of Consciousness; Pulseless Electrical Activity; Thrombocytopenia; Unresponsive To Stimuli	Clonazepam			S	Oral	5 Mg, Unk		Sun	
	Flecainide Acetate			S	Oral	2500 Mg, Unk		Sun	
	Quetiapine			S	Oral	3000 Mg, Unk		Sun	
	Venlafaxine			S	Oral	1000 Mg, Unk		Sun	
	Escitalopram			S	Oral	250 Mg, Unk		Not Reported	
	Bisoprolol			S	Oral	25 Mg, Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16798321	EXPEDITED (15-DAY)		HO	NL-ACCORD-154619			Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Osteoporosis	Escitalopram			S		1x Pd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799331	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019388392		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Xanax			S	Oral	9 Df, Single		Pfizer	
	Escitalopram Oxalate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799360	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2019M1085843		91 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Hypokalaemia; Hyponatraemia	Perindopril			S	Oral	8 Milligram, Qd		Not Reported	
	Amlodipine			S	Oral	10 Milligram, Qd		Not Reported	
	Fludex /00340101/			S	Oral	Inconnue		Mylan	
	Zelitrex			S	Oral	6 Dosage Form, Qd		Mylan	

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	Ditropan	S	Oral	2 Dosage Form, Qd	Mylan
	Seroplex	S	Oral	1 Dosage Form, Qd	Mylan
	Movicol /01749801/	C	Oral	2 Dosage Form, Qd	Mylan
	Paracetamol	C	Oral	3 Dosage Form, Qd	Mylan
	Cortancyl	C	Oral	2 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799978	NON-EXPEDITED			US-TEVA-2019-US-1105745			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Depression; Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown			Ivax	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16800966	EXPEDITED (15-DAY)		OT	PHHY2019FI211224		34 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Behaviour Disorder; Drug Ineffective For Unapproved Indication; Intentional Product Use Issue; Intentional Self-Injury; Multiple Drug Therapy	Carbamazepine			S	Unknown	Unk		Novartis	
	Candesartan Cilexetil			S	Unknown	16 Mg, Qd		Not Reported	
	Quetiapine			S	Unknown	Unk		Not Reported	
	Topiramate			S	Unknown	Unk		Not Reported	
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported	
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
	Pantoprazole			S	Unknown	20 Mg, Qd		Not Reported	
	Bisoprolol			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported	
	Amitriptyline			S	Unknown	Unk		Not Reported	

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Macrogol 3350	S	Unknown	Unk, 3 Bags / Day	Not Reported
Levomepromazine	S	Unknown	100 Mg, Qd	Not Reported
Melatonin	S	Unknown	3 Mg, Qd	Not Reported
Citalopram	S	Unknown	Unk	Not Reported
Lorazepam	S	Unknown	3 Mg, Qd	Not Reported
Oxcarbazepine	C	Unknown	900 Mg, Qd	Not Reported
Valproate Sodium	C	Unknown	1200 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16801579	EXPEDITED (15-DAY)		DE, HO, OT	CH-ASTRAZENECA-2019SF09219		78 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Beloc Zok			S	Oral			Not Reported	
	Aspirin Cardio			S	Unknown			Not Reported	
	Quetiapin Sandoz			S	Oral	12.5 Mg,1-2x/24h		Not Reported	
	Quetiapin Sandoz			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Cipralex			S	Oral			Not Reported	
	Dexilant			S	Oral	60.0mg Unknown		Not Reported	
	Pregabalin Pfizer			S	Unknown			Not Reported	
	Pantoprazole			S	Oral			Not Reported	
	Temesta (Lorazepam)			S	Unknown			Not Reported	
	Toviaz			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16801697	EXPEDITED (15-DAY)		HO, LT, OT	IL-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00342		35 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Overdose; Unresponsive To Stimuli	Quetiapine			S	Oral	3000 Mg		Jubilant	

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Escitalopram	S	Oral	250 Mg	Jubilant
Clonazepam	S	Oral	5 Mg	Not Reported
Venlafaxine	S	Oral	1000 Mg	Not Reported
Flecainide	S	Oral	2500 Mg	Not Reported
Bisoprolol	S	Oral	25 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802007	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1084465			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Burnout Syndrome; Drug Interaction; Drug Intolerance; Heart Rate Increased; Hyperhidrosis; Hypertension; Palpitations; Panic Attack; Product Use Issue; Restlessness; Stress	Escitalopram			S		Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Cipralex /01588501/			S	Unknown	5 Milligram, Qd		Mylan
	Cipralex /01588501/			S	Unknown	10 Milligram		Mylan
	Cipralex /01588501/			S	Unknown	7.5 Milligram, Qod		Mylan
	Ibuprofen			S	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802226	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1107764		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aptyalism; Drug Ineffective; Overdose; Panic Disorder	Amitriptyline			S	Oral	20 Milligram Daily;		Not Reported
	Buspirone			S	Oral	5 Milligram Daily;		Teva
	Escitalopram			S	Oral			Ivax
	Zyprexa			S	Oral	2.5 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802368	EXPEDITED (15-DAY)		HO	KR-ALLERGAN-1936868US			Female	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Mental Impairment; Off Label Use		Escitalopram Oxalate - Bp		S	Unknown	Unk	Allergan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802379	EXPEDITED (15-DAY)		OT	KR-ALLERGAN-1936875US			Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Product Administered To Patient Of Inappropriate Age; Underdose	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802792	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-059417			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram			S	Unknown	Unk		Aurobindo	
	Xanax			S	Oral	9 Dosage Form		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	13940299	NON-EXPEDITED			US-MALLINCKRODT-T201606073			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Pressure Increased; Dizziness; Limb Discomfort; Muscle Rigidity; Somnolence; Yawning	Pamelor			S	Oral	Unk		Mallinckrodt	
	Escitalopram			S	Unknown	5 Mg, Unk		Not Reported	
	Aspirin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	14389660	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018015554		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebrovascular Accident	Pantoprazole	S	Oral	Unk	Pfizer
	Xeloda	S	Oral	Unk	Not Reported
	Novorapid	S	Subcutaneous	Unk	Not Reported
	Primperan	S	Oral	Unk	Not Reported
	Lipanthyl	S	Oral	Unk	Not Reported
	Movicol	S	Oral	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	Unk	Not Reported
	Abasaglar	S	Subcutaneous	Unk	Not Reported
	Fondaparinux Sodique	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	14651809	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-015001		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	Unk		Aurobindo
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Primperan			S	Oral	Unk		Not Reported
	Xeloda			S	Oral	Unk		Not Reported
	Movicol			S	Oral	Unk		Not Reported
	Fondaparinux Sodium			S	Subcutaneous	Unk		Not Reported
	Abasaglar			S	Subcutaneous	Unk		Not Reported
	Lipanthyl			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	14678740	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-015719		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Pantoprazole			S	Oral	Unk ()		Aurobindo

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Escitalopram Film-Coated Tablets	S	Oral	Unk ()	Aurobindo
Novorapid	S	Subcutaneous	Unk ()	Not Reported
Lipanthyl	S	Oral	Unk ()	Not Reported
Primperan	S	Oral	Unk ()	Not Reported
Fondaparinux Sodium	S	Subcutaneous	Unk ()	Not Reported
Movicol	S	Oral	Non Renseignée ()	Not Reported
Abasaglar	S	Subcutaneous	Unk ()	Not Reported
Xeloda	S	Oral	Unk ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16122591	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019132015		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Xeljanz			S	Oral	1 Dosage Form, Bid		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Pantoprazole			S	Oral	1 Dosage Form, Qd		Pfizer
	Escitalopram Oxalate			S	Oral	1 Dosage Form, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16616927	EXPEDITED (15-DAY)		HO	FR-ZYDUS-038753		81 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Traumatic Haemothorax	Escitalopram			S	Oral			Cadila
	Eliquis			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16733443	NON-EXPEDITED		DS, OT	CA-AMGEN- CANCT2019059800		45 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Pressure Abnormal; Cluster Headache; Constipation; Depression; Diarrhoea; Dysarthria; Hemiplegia; Hemiplegic Migraine; Influenza; Lower Respiratory Tract Infection; Malaise; Migraine; Muscle Spasms; Oropharyngeal Pain; Pain; Palpitations; Personality Change; Pyrexia; Serotonin Syndrome; Speech Disorder; Tremor; Viral Infection	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Aimovig			S	Subcutaneous	140 Milligram, Qmo		Amgen
	Mmr			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram Oxalate			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16767736	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2019M1081639			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram Mylan			S	Unknown	Unk		Mylan
	Methotrexate Mylan			S	Unknown	Unk		Mylan
	Metoprolol Mylan			S	Unknown	Unk		Mylan
	Salbutamol			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Mylan

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Ibuprofen Stada	S	Unknown	Unk	Mylan
Prednisolon Stada	S	Unknown	Unk	Mylan
Golimumab	S	Unknown	Unk	Mylan
Pantozol /01263204/	S	Unknown	Unk	Mylan
Implanon	S	Unknown	Unk	Mylan
Ibuprofen Hormosan	S	Unknown	Unk	Mylan
Metoprolol Hexal	S	Unknown	Unk	Mylan
Salbutamol Stada	S	Unknown	Unk	Mylan
Ibuprofen	S	Unknown	Unk	Mylan
Prednisolone	S	Unknown	25 Milligram	Mylan
Prednisolone	S	Unknown	Unk	Mylan
Escitalopram Stada	S	Unknown	Unk	Mylan
Escitalopram Hexal	S	Unknown	Unk	Mylan
Prednisolon Jenapharm	S	Unknown	Unk	Mylan
Ibuprofen	S	Unknown	Unk	Mylan
Amitriptylin	S	Unknown	Unk	Mylan
Prednisolon /00016201/	S	Unknown	Unk	Mylan
Metoprolol	S	Unknown	Unk	Mylan
Escitalopram	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16791568	EXPEDITED (15-DAY)	LT		IL-ALLERGAN-1936621US			Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Loss Of Consciousness; Pulseless Electrical Activity; Respiration Abnormal	Escitalopram Oxalate - Bp			S	Unknown	Overdose: 250 Mg		Allergan
	Flecainide			S	Unknown	2500 Mg		Not Reported
	Quetiapine			S	Unknown	3000 Mg		Not Reported
	Venlafaxine			S	Unknown	1000 Mg		Not Reported
	Bisoprolol			S	Unknown	25 Mg		Not Reported

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Clonazepam			S		Unknown		5 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Sep-2019	16803241	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1105667		60 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Escitalopram (Oxalate D')			S	Oral	28 Dosage Forms		Ivax		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Sep-2019	16803566	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-040500		31 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Escitalopram			S	Oral			Cadila		
	Quetiapine			S	Oral			Not Reported		
	Propranolol			S	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Sep-2019	16803583	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-040601		35 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anaemia; Cardiac Arrest; Circulatory Collapse; Dyspnoea; Infection; Intentional Overdose; Pulse Absent; Pulseless Electrical Activity; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Escitalopram			S	Oral			Cadila		
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm		
	Bisoprolol			S	Oral			Not Reported		
	Flecainide			S	Oral			Not Reported		
	Quetiapine			S	Oral			Not Reported		
	Clonazepam			S	Oral			Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804051	EXPEDITED (15-DAY)		HO, OT	AU-ACCORD-154878		79 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S				Not Reported	
	Amlodipine			C				Not Reported	
	Rivaroxaban			C				Not Reported	
	Amiodarone			C				Not Reported	
	Olmesartan/Olmesartan			C				Not Reported	
	Medoxomil								
	Diazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804055	EXPEDITED (15-DAY)		HO, LT, OT	IL-ACCORD-154876		35 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiac Arrest; Cardiotoxicity; Infection; Intentional Overdose; Thrombocytopenia	Clonazepam			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Flecainide			S	Oral			Not Reported	
	Bisoprolol			S	Oral			Not Reported	
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804292	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1105891		45 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Sopor	Escitalopram Oxalate			S	Unknown			Ivax	
	Xanax			S	Oral			Not Reported	

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13-Sep-2019	16804504	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1084487		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hyperhidrosis; Nausea; Night Sweats; Oedema	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported	
	Escitalopram			S	Unknown	5 Milligram, Qd		Not Reported	
	Tirosint			C	Unknown	Initially Given Every 4 Days With A Goal Of Reaching Daily Dosing		Mylan	
	Armour Thyroid			C	Unknown	7.5 Mg On Mondays And Thursdays		Mylan	
	Biotin			C	Unknown			Mylan	
	Dexilant			C	Unknown			Mylan	
	Fish Oil			C	Unknown			Mylan	
	Glucosamine Chondroitin /01430901/			C	Unknown			Mylan	
	Magnesium			C	Unknown			Mylan	
	Premarin			C	Unknown			Mylan	
	Selenium			C	Unknown			Mylan	
	Vitamin B 12			C	Unknown			Mylan	
	Vitamin D3			C	Unknown	5000 Units Daily		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804751	EXPEDITED (15-DAY)		DS	FR-ASTRAZENECA-2019SF26553		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma; Subdural Haematoma	Inexium			S	Oral			Astrazeneca	
	Kardegic			S	Oral			Not Reported	
	Seroplex			S	Oral			Not Reported	
	Inegy			S	Unknown			Not Reported	
	Keppra			C				Not Reported	

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	Tenormine			C					Not Reported
	Tiapridal			C					Not Reported
	Coaprovel			C					Not Reported
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13-Sep-2019	16805766	NON-EXPEDITED			US-APOTEX-2019AP017832		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Treatment Failure	Risperidone			S	Unknown	Unk		Apotex	
	Fluoxetine			S	Unknown	Unk		Apotex	
	Fluvoxamine			S	Unknown	Unk		Apotex	
	Aripiprazole			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	Unk		Apotex	
	Quetiapine			S	Unknown	200 Mg, Per Day		Apotex	
	Venlafaxine			S	Unknown	Unk		Not Reported	
	Clonidine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16807184	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1085289		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Escitalopram			S	Oral	Unk		Not Reported	
	Spironolactone			S	Oral	Unk		Not Reported	
	Diltiazem Mylan			S	Oral	Unk		Mylan	
	Pantoprazole			S	Oral	Unk		Not Reported	
	Trileptal			S	Oral	Unk		Mylan	
	Tinzaparine Sodique			S	Subcutaneous	Unk		Mylan	
	Lacosamide			S	Oral	Unk		Mylan	
	Bactrim			S	Oral	Unk		Mylan	

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13-Sep-2019	16807292	EXPEDITED (15-DAY)		DE	JP-ALLERGAN-1935061US			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Belsomra			C	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16807301	EXPEDITED (15-DAY)		HO	NL-ALLERGAN-1937420US			Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Osteoporosis	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd (1x Pd)		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16807370	NON-EXPEDITED			PHEH2019US036908			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Lorazepam			S	Unknown	1 Mg, Qd		Novartis	
	Lorazepam			S	Unknown	1 Mg, Prn		Novartis	
	Lexapro			S	Unknown	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2019	16726678	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1093613		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Headache; Hot Flush	Escitalopram			S	Unknown			Ivax	
	Trazodone			S	Unknown			Barr	
	Citalopram			S	Unknown			Not Reported	
	Fluoxetine			S	Oral			Not Reported	

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Lurasidone	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Alprazolam	S	Oral	Not Reported

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15-Sep-2019	16807871	EXPEDITED (15-DAY)		OT	PHHY2019FI205677		34 YR	Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Behaviour Disorder; Drug Ineffective; Off Label Use	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol			S				Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Metoprolol			S				Not Reported
	Candesartan Sandoz			S	Unknown	16 Mg, Qd		Not Reported
	Candesartan Sandoz			S				Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Escitalopram			S				Not Reported
	Trileptal			S	Unknown	900 Mg, Qd		Novartis
	Trileptal			S				Novartis
	Topiramate			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported
	Risperidone			S	Unknown	3 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	20 Mg, Qd		Not Reported
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported
	Valproate			S	Unknown	1200 Mg, Qd		Not Reported
	Valproate			S				Not Reported
	Valproate			S				Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Melatonin			S	Unknown	3 Mg, Qd		Not Reported
	Levomepromazine			S	Unknown	100 Mg, Qd		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported

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Amitriptyline	S	Unknown	Unk	Not Reported
Lorazepam	S	Unknown	3 Mg, Qd	Not Reported
Macrogol	S	Unknown	Unk (3350 With Dosage 3 Bags/Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2019	16807953	EXPEDITED (15-DAY)		HO	US- ELI_LILLY_AND_COMP ANY-US201909004154			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coma; Hypothermia; Insomnia; Off Label Use; Somnolence; Suicidal Behaviour; Suicidal Ideation	Prozac			S	Unknown	20 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	40 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	60 Mg, Unknown		Eli Lilly And Co
	Prozac			S	Unknown	80 Mg, Unknown		Eli Lilly And Co
	Lamictal			S	Unknown	Unk, Unknown		Not Reported
	Lamictal			S	Unknown	6000 Mg, Unknown		Not Reported
	Lexapro			S	Unknown	Unk, Unknown		Not Reported
	Lexapro			S	Unknown	8000 Mg, Unknown		Not Reported
	Seroquel			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	Unk, Unknown		Not Reported
	Klonopin			S	Unknown	80 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16454865	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-210942		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Spinal Fracture	Escitalopram			S	Oral	10 Milligram, Daily		Not Reported
	Risperidone			S	Oral	1 Milligram, Daily		Ranbaxy
	Agomelatine			S	Oral	25 Milligram, Daily		Not Reported
	Phenergan 25 Mg, Comprime			S	Oral	25 Milligram, Daily		Not Reported

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Enrobe						
Lormetazepam	S	Oral	2 Milligram, Daily			Not Reported
Clotiazepam	S	Oral	Non			Not Reported
Tilcotil	C	Unknown	()			Not Reported
Atorvastatine	C	Unknown	()			Not Reported
Kardegic	C	Unknown	()			Not Reported
Esomeprazole	C	Unknown	()			Not Reported
Ramipril	C	Unknown	()			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16661874	EXPEDITED (15-DAY)		DE, HO, OT	CH-TOPROL ACQUISITION LLC- 2019-TOP-000759		78 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Interstitial Lung Disease; Respiratory Failure	Metoprolol Succinate			S	Oral	50 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Ciprallex /01588501/			S	Oral	10 Mg, Bid		Not Reported
	Dexilant			S	Oral	60 Mg, Unk		Not Reported
	Aspirin Cardio			S		100 Mg, Qd		Not Reported
	Pregabalin			S		50 Mg, Qid		Not Reported
	Toviaz			S	Oral	8 Mg, Qd		Not Reported
	Temesta /00273201/			S		2.2 Mg, Bid		Not Reported
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported
	Sandoz Quetiapine Xrt 50mg			S	Oral	12.5 Mg,1-2x/24h		Not Reported
	Sandoz Quetiapine Xrt 50mg			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16756241	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2019M1081100		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Bradycardia; Loss Of Consciousness; Malaise; Syncope; Withdrawal Syndrome	Telmisartan	S	Unknown	Unk	Not Reported
	Seroplex	S	Oral	15 Milligram, Qd	Mylan
	Seroplex	S	Oral	10 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16785711	EXPEDITED (15-DAY)		HO, LT	IL-PFIZER INC-2019378445		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Overdose	Venlafaxine Hcl			S	Oral	1000 Mg, Unk		Pfizer
	Bisoprolol			S	Oral	25 Mg, Unk		Not Reported
	Flecainide			S	Oral	2500 Mg, Unk		Not Reported
	Quetiapine			S	Oral	3000 Mg, Unk		Not Reported
	Escitalopram			S	Oral	250 Mg, Unk		Not Reported
	Clonazepam			S	Oral	5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16807987	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190906065			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Tylenol			S	Topical	%Frequency%		Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Voltaren /00372301/			S	Unknown			Not Reported
	Nortriptyline			S	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab, Recombinant Unspecified			C	Unknown			Not Reported

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16-Sep-2019	16808776	EXPEDITED (15-DAY)		HO, OT	AU-CIPLA LTD.- 2019AU06237			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram, 5 Days		Invagen	
	Diazepam			C	Unknown	Unk		Not Reported	
	Mirtazapine			C	Unknown	45 Milligram, At Night		Not Reported	
	Oxazepam			C	Unknown	7.5 Milligram, Qid		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Amiodarone			C	Unknown	Unk		Not Reported	
	Rivaroxaban			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16808848	EXPEDITED (15-DAY)		HO	MX-TORRENT- 00000155		78 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Surgery	Escitalopram			S	Oral	One 10 Mg Tablet Per Day, Orally		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16808865	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-220689		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block; Generalised Tonic-Clonic Seizure; Hypotension; Sinus Bradycardia; Somnolence	Quetiapine			S	Oral	In Total		Sun	
	Escitalopram			S	Oral	In Total		Not Reported	
	Propranolol			S	Oral	In Total		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16809148	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022941			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Escitalopram 10mg Tablet			S	Oral	10 Milligram, Qd		Macleods	
	Ventolin			C		2 Dosage Form, Prn		Not Reported	
	Otomize			C	Unknown	Unk		Not Reported	
	Duloxetine			C	Unknown	1 Dosage Form, Qd, Night		Not Reported	
	Pregabalin			C	Unknown	2 Dosage Form, Qd		Not Reported	
	Hydroxocobalamin			C	Intramuscular	1 Dosage Form, 2 Month		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16810240	EXPEDITED (15-DAY)		HO	SE-MYLANLABS- 2019M1085470		64 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy; Syncope	Escitalopram			S	Oral	Titrerad 10 Mg Till 12,5 Mg Under Terapitiden.		Not Reported	
	Escitalopram			S	Oral	15 Milligram, Qd		Not Reported	
	Alfuzosin			C		Unk		Mylan	
	Mirtazapin			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16811360	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC- 2019398076		90 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amaurosis; Blindness	Spironolactone			S	Oral	50 Mg, 1x/Day		Pfizer	
Unilateral; Cardiac Failure; Extensor Plantar	Bisoprolol Fumarate			S	Oral	5 Mg, (Twice A Day)		Not Reported	
Response; Hyperreflexia; Hypoaesthesia;	Escitalopram Oxalate			S	Oral	10 Mg, 1x/Day		Not Reported	

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Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis	Lisinopril	S	Oral	5 Mg, 1x/Day	Not Reported
Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia;	Omeprazole	S	Oral	20 Mg, 1x/Day	Not Reported
Pupillary Reflex Impaired; Respiratory Tract Infection;	Alendronic Acid	S	Oral	70 Mg, Weekly	Not Reported
Thermohypoaesthesia; Urinary Retention	Furosemida [Furosemide]	S	Oral	60 Mg, 1x/Day	Not Reported
	Hierro [Ferrous Sulfate]	S	Oral	256.3 Mg, 1x/Day	Not Reported
	Ipratropio Bromuro	S	Respiratory (inhalation)	2 Inh Every 8 Hours	Not Reported
	Sintrom	S	Oral	1 Mg, 1x/Day	Not Reported
	Alopurinol	S	Oral	100 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16811579	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-1933792US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Weight Gain;	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan
Gingival Bleeding;	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan
Increased Appetite;	Theralene			S	Unknown	2 Tablets In The Evening		Not Reported
Narrow Anterior Chamber Angle	Lexomil			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16314505	EXPEDITED (15-DAY)		LT, OT	DE-JNJFOC-20190509081		75 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest;	Reminyl			S	Unknown			Not Reported
Drug Interaction;	Reminyl			S	Unknown			Not Reported
Electrocardiogram Qt Prolonged; Syncope;	Reminyl			S	Unknown			Not Reported
Torsade De Pointes	Dipiperon			S	Unknown			Not Reported
	Cipralelex			S	Unknown			Not Reported
	Cipralelex			S	Unknown			Not Reported
	Cipralelex			S	Unknown			Not Reported

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Cipralex	S	Unknown	Not Reported
Esidrix	S	Unknown	Not Reported
Esidrix	S	Unknown	Not Reported
Captohexal	S	Unknown	Not Reported
Captohexal	S	Unknown	Not Reported
Trazodone	S	Unknown	Not Reported
Calciumcarbonate	C	Unknown	Not Reported
Marcumar	C	Unknown	Not Reported
Amlodipine	C	Unknown	Not Reported
Amlodipine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16776365	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019382024		38 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Ramipril			S	Unknown	2.5 Mg, Daily		Pfizer
	Atorvastatin Calcium			S	Unknown	10 Mg, Daily		Pfizer
	Spironolactone			S	Unknown	25 Mg, Daily		Pfizer
	Bisoprolol Fumarate			S	Unknown	2.5 Mg, Daily		Not Reported
	Furosemide			S	Unknown	20 Mg, Daily		Unknown
	Melatonin			S	Unknown	2 Mg, Daily		Not Reported
	Amisulpride			S	Unknown	300 Mg, Daily		Not Reported
	Escitalopram Oxalate			S	Unknown	15 Mg, Daily		Not Reported
	Ferrograd [Ferrous Sulfate]			S	Unknown	325 Mg, Daily		Not Reported
	Omeprazole			S	Unknown	20 Mg, Daily		Not Reported
	Testosterone			S	Unknown	1 G, Daily (Every 10-14 W)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16796322	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019164157		14 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	In Total		Glaxosmithkline
	Diazepam			S	Oral	In Total		Glaxosmithkline
	Ibuprofen			S	Oral	In Total		Glaxosmithkline
	Paracetamol			S	Oral	In Total		Glaxosmithkline
	Escitalopram			S	Oral	In Total		Glaxosmithkline
	Dietary Supplement			S	Oral	In Total		Glaxosmithkline
	Colchicine			S	Oral	In Total		Glaxosmithkline
	Diane			S	Oral	In Total		Not Reported
	Cialis			S	Oral	In Total		Not Reported
	Donormyl (Doxylamine Succinate)			S	Oral	In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16813964	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS- 2019GMK043204			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, Bid		Glenmark
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Domperidone			S	Unknown	10 Mg, Bid		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Tid		Not Reported
	Temazepam			S	Oral	30 Mg, Od		Not Reported
	Tylenol W/Codeine			S	Oral	2 Df, Tid		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16814077	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALVOGEN-2019- ALVOGEN-101321		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Anaemia; Cardiac Arrest; Infection; Intentional Overdose; Thrombocytopenia	Flecainide	S	Oral	Not Reported
	Bisoprolol	S	Oral	Not Reported
	Escitalopram	S	Oral	Not Reported
	Quetiapine	S	Oral	Not Reported
	Clonazepam	S	Oral	Not Reported
	Venlafaxine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16815342	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM- 2019-05178		22 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Methadone Hydrochloride			S	Unknown	Unk		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16815369	EXPEDITED (15-DAY)			FR-ALKEM LABORATORIES LIMITED-FR-ALKEM- 2019-05154		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Escitalopram			S	Unknown	Unk		Not Reported
	Dihydroergotamine			S	Unknown	Unk		Not Reported
	Oxazepam			S	Unknown	Unk		Not Reported
	Pipamperone			S	Unknown	Unk		Not Reported
	Loprazolam			S	Unknown	Unk		Not Reported

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Dipotassium Clorazepate	S	Unknown	10 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16815977	EXPEDITED (15-DAY)		DE, HO	ES-ACCORD-154523		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Allopurinol			S	Oral	100 Mg, Qd		Accord
	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
	Furosemide			S	Oral	60 Mg, Qd		Accord
	Lisinopril			S	Oral	5 Mg, Qd		Accord
	Spiroonolactone			S	Oral	50 Mg, Qd		Accord
	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
	Alendronate Sodium/Alendronic Acid			S	Oral	70 Mg, Qwk		Not Reported
	Iron			S	Oral	256.3 Mg, Qd		Not Reported
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
	Ipratropium			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported
	Sintrom			S	Oral	1 Mg, Qd, Strength: 1 Mg Tablets, 60 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16815988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00021828		40 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration	Ventolin			C	Respiratory (inhalation)	As Necessary		Unknown
	Otomize			C				Unknown
	Duloxetine			C		Night		Unknown
	Escitalopram			S				Unknown
	Pregabalin			C				Unknown
	Hydroxocobalamin			C	Intramuscular			Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817061	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS- 2019GMK043219			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder	Gabapentin			S	Oral	300 Mg, Tid (1 Every 1 Day)		Glenmark	
	Gabapentin			S	Oral	600 Mg, Bid, Capsule (2 Every 1 Days)		Glenmark	
	Acetaminophen W/Codeine Phosphate			S	Oral	2 Df, Tid (3 Every 1 Day)		Not Reported	
	Cipralex /01588501/			S	Oral	20 Mg, Unk		Not Reported	
	Clonazepam			S	Unknown	0.5 Mg, Tid (3 Every 1 Day)		Not Reported	
	Domperidone			S	Unknown	10 Mg, Bid (2 Every 1 Day)		Not Reported	
	Iron Sulphate			S	Unknown	300 Mg, Tid (3 Every 1 Day)		Not Reported	
	Temazepam			S	Oral	30 Mg, Od (1 Every 1 Day)		Not Reported	
	Wellbutrin			S	Oral	150 Mg, Bid (2 Every 1 Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817079	EXPEDITED (15-DAY)		HO, OT	AU-MACLEODS PHARMACEUTICALS US LTD- MAC2019022942			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram		Macleods	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Rivaroxaban			C	Unknown	Unk		Not Reported	
	Amiodarone			C	Unknown	Unk		Not Reported	
	Olmesartan			C	Unknown	Unk		Not Reported	

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Diazepam			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817992	EXPEDITED (15-DAY)		DS	ES-MYLANLABS-2019M1086769		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Derealisation; Disturbance In Attention; Feeling Abnormal; Palpitations; Somnolence	Alprazolam			S		0.25 In The Morning, And Sometimes In The Evening Night		Not Reported	
	Escitalopram			S		5 Milligram, Qd		Not Reported	
	Rhodiola /02220301/			C		Unk		Mylan	
	Pantoprazol /01263201/			C		Unk Unk, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16818397	EXPEDITED (15-DAY)		DE, HO	ES-ALLERGAN-1937398US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Omeprazol			S	Oral	20 Mg, Qd		Not Reported	
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported	
	Alendronico Acido (Alendronate Sodium)			S	Oral	70 Mg, Qwk		Not Reported	
	Furosemida			S	Oral	60 Mg, Qd		Not Reported	
	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported	
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported	
	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Not Reported	
	Sintrom			S	Oral	1 Mg, Qd		Not Reported	
	Espironolactona			S	Oral	50 Mg, Qd		Not Reported	
	Alopurinol			S	Unknown	100 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	14908305	EXPEDITED (15-DAY)		HO, LT, OT	DE-PFIZER INC-2018201596		21 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Drug Interaction; Serotonin Syndrome; Status Epilepticus	Esomeprazole Magnesium			S		40 Mg, Unk		Unknown	
	Linezolid			S	Intravenous (not otherwise specified)	2 Df, Daily (1-0-1)		Pfizer	
	Linezolid			S		Unk		Pfizer	
	Escitalopram			S		5 Ug, As Needed		Not Reported	
	Levetiracetam			C		1.5 G, 2x/Day (1-0-1)		Not Reported	
	Ivabradine			C		7.5 Mg, 2x/Day		Not Reported	
	Cotrimoxazol			C	Intravenous (not otherwise specified)	960 Mg (2 Df), Daily, 1-0-1		Not Reported	
	Cotrimoxazol			C				Not Reported	
	Naloxone/Tilidine			C		10 Gtt, As Needed (Tilidine/Naloxon 25/2mg)		Not Reported	
	Scopolamin			C	Transdermal	Unk (Change Every 3 Days)		Not Reported	
	Baclofen			C		5 Mg, Unk (2-1-2-1)		Not Reported	
	Prednisolone			C		10 Mg, Unk		Not Reported	
	Prednisolone			C		7.5 Mg, 1x/Day (1-0-0)		Not Reported	
	Prednisolone			C		5 Mg, 1x/Day		Not Reported	
	Lorazepam			C		1 Mg, Daily, 0-0-1		Not Reported	
	L-Thyroxin			C		75 Ug, 1x/Day (1-0-0)		Not Reported	
	Floxal			C		Unk, 4x/Day (Both Eyes)		Not Reported	
	Floxal			C				Not Reported	
	Floxal			C				Not Reported	
	Novalgine [Metamizole Sodium]			C		1 G, Unk		Not Reported	
	Noradrenalin [Norepinephrine]			C		Unk		Not Reported	
	Polamidon			C		10 Mg, Unk		Not Reported	

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18-Sep-2019	15760654	NON-EXPEDITED			US-PFIZER INC-2018525513		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	
	Zocor			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16138961	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0910		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Escitalopram Oxalate			S	Oral			Not Reported	
	Pantoprazole Magnesium			S	Oral			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Plaquenil Sulfate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16656595	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1084342		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Discomfort;	Calcium Carbonate	S	Unknown		Not Reported
Anger; Anxiety; Arthropod	Pantoprazole	S	Unknown		Teva
Bite; Blood Pressure	Amlodipine	S	Unknown	10 Milligram Daily;	Teva
Increased; Blood Pressure	Hydromorphone	S	Oral		Actavis
Systolic Increased;	Escitalopram	S	Unknown		Ivax
Bronchitis;	Ergocalciferol	S	Unknown		Not Reported
Cerebrovascular Accident;	Sandostatin	S	Intramuscular		Not Reported
Contusion; Cough; Crying;	Sandostatin	S	Subcutaneous		Not Reported
Depressed Mood;	Sandostatin	S	Intramuscular		Not Reported
Depression; Diarrhoea;	Sandostatin	S	Intramuscular		Not Reported
Drug Hypersensitivity;	Acetaminophen	C	Unknown		Not Reported
Emotional Distress;	Gabapentin	C	Unknown		Not Reported
Erythema; Fall; Fatigue;	Olanzapine	C	Unknown		Not Reported
Feeling Jittery; Gait	Resotran Film-Coated	C	Unknown		Not Reported
Disturbance; Head	Perindopril	C			Not Reported
Banging; Headache;	Prednisone	C			Not Reported
Hypoacusis; Inappropriate					
Schedule Of Product					
Administration; Joint					
Swelling; Malaise;					
Malignant Neoplasm					
Progression; Mental					
Disorder; Muscular					
Weakness;					
Nasopharyngitis; Nausea;					
Nervousness; Pain In					
Extremity; Peripheral					
Swelling; Pneumonia;					
Pollakiuria; Productive					
Cough; Psychiatric					
Symptom; Rash; Rib					
Fracture; Screaming;					
Suicidal Ideation; Suicide					
Attempt; Tremor;					
Unresponsive To Stimuli;					
Vasculitis; Wound; Wrist					
Fracture					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16820596	EXPEDITED (15-DAY)		HO, OT	AU-LUPIN PHARMACEUTICALS INC.-2019-05968		79 YR	Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Hyponatraemia; Stress Cardiomyopathy	Escitalopram			S	Unknown	10 Milligram		Lupin
	Amlodipine			C	Unknown	Unk		Not Reported
	Rivaroxaban			C	Unknown	Unk		Not Reported
	Diazepam			C	Unknown	Unk		Not Reported
	Olmesartan			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	45 Milligram, Qd (At Night)		Not Reported
	Oxazepam			C	Unknown	7.5 Milligram, Qid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16820643	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1107586		101 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Milligram Per Day		Actavis
	Escitalopram			S	Oral	10 Milligram Per Day		Ivax
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16820901	EXPEDITED (15-DAY)		HO, LT, OT	IL-ALKEM LABORATORIES LIMITED-IL-ALKEM- 2019-07994		35 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Overdose	Quetiapine Fumarate			S	Oral	3000 Milligram		Alkem
	Flecainide			S	Oral	2500 Milligram		Not Reported

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Venlafaxine	S	Oral	1000 Milligram	Not Reported
Escitalopram	S	Oral	250 Milligram	Not Reported
Bisoprolol	S	Oral	25 Milligram	Not Reported
Clonazepam	S	Oral	5 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16820976	EXPEDITED (15-DAY)	HO		TR-ALKEM LABORATORIES LIMITED-TR-ALKEM- 2019-03822		56 YR	Female	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Recurrence; Drug Ineffective; Tardive Dyskinesia; Treatment Noncompliance	Aripiprazole			S	Unknown	10 Milligram, Qd		Alkem
	Aripiprazole			S	Unknown	30 Milligram		Alkem
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	4 Milligram, Qd		Not Reported
	Risperidone			S	Unknown	2 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	10 Milligram, Qd		Not Reported
	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported
	Haloperidole			S	Unknown	20 Milligram, Qd		Not Reported
	Biperiden			S	Unknown	4-10 Mg/Day		Not Reported
	Biperiden			S	Unknown	4 Milligram, Qd		Not Reported
	Diazepam			S	Unknown	10 Milligram, Qd		Not Reported
	Valproic Acid			S	Unknown	1500 Milligram, Qd		Not Reported
	Amisulpride			S	Unknown	800 Milligram, Qd		Not Reported
	Amisulpride			S	Unknown	400 Milligram		Not Reported
	Lithium			S	Unknown	900 Milligram, Qd		Not Reported

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18-Sep-2019	16821767	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2019-ES-1107690		90 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Alendronico Acido (Alendronate Sodium)			S	Oral	70 Mg, Qwk		Actavis	
	Alopurinol			S	Oral	100 Mg, Qd		Actavis	
	Bisoprolol			S	Oral	5 Mg, Bid		Duramed	
	Escitalopram			S	Oral	10 Mg, Qd		Ivax	
	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Actavis	
	Lisinopril			S	Oral	5 Mg, Qd		Not Reported	
	Omeprazole			S	Oral	20 Mg, Qd		Teva	
	Furosemida			S	Oral	60 Mg, Qd		Not Reported	
	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported	
	Sintrom 1 Mg Comprimidos , 60 Comprimidos			S	Oral	1 Mg, Qd		Not Reported	
	Espironolactona			S	Oral	50 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16821924	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019398427		14 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hypotension; Intentional Overdose; Malaise	Ibuprofen			S	Oral	4400 Mg, Single		Pfizer	
	Diane			S	Oral	21 Df, Single		Not Reported	
	Cialis			S	Oral	40 Mg, Single		Not Reported	
	Diclofenac			S	Oral	5000 Mg, Single		Not Reported	
	Colchicine			S	Oral	6 Mg, Single		Not Reported	
	Diazepam			S	Oral	480 Mg, Single		Not Reported	
	Paracetamol			S	Oral	2 G, Single		Not Reported	

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	Escitalopram	S	Oral	820 Mg, Single	Not Reported
	Donormyl [Doxylamine Succinate]	S	Oral	300 Mg, Single	Not Reported

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18-Sep-2019	16822786	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019401379		101 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Mg, Qd		Pfizer	
	Escitalopram Oxalate			S	Oral	10 Mg, Qd		Not Reported	
	Diosmectite			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
	Econazole			C	Unknown	Unk		Not Reported	
	Levetiracetam			C	Unknown	Unk		Not Reported	
	Calciferol [Ergocalciferol]			C		Unk		Not Reported	
	Valpromide			C	Unknown	Unk		Not Reported	
	Dexpanthenol			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16823010	NON-EXPEDITED		OT	US-CELGENEUS-USA-20190903593			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Rash; Rib Fracture; Upper Respiratory Tract Infection	Revlimid			S	Oral	25 Milligram		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Revlimid			S	Oral	15 Milligram		Celgene	
	Revlimid			S	Oral	10mg-25 Mg		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Lexapro			S	Unknown			Not Reported	

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18-Sep-2019	16823268	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1937603US			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Ventolin			C	Respiratory (inhalation)			Not Reported	
	Otomize			C	Unknown			Not Reported	
	Duloxetine			C	Unknown	Night		Not Reported	
	Pregabalin			C	Unknown			Not Reported	
	Hydroxocobalamin			C	Intramuscular			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16823570	NON-EXPEDITED			US-PFIZER INC-2019402897			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Ciprofloxacin			S		Unk		Unknown	
	Escitalopram Oxalate			S		Unk		Not Reported	
	Methylnaltrexone			S		Unk		Not Reported	
	Ranolazine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	14654580	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007730			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue;	Citalopram			S	Unknown	Unk		Apotex	
	Escitalopram			S	Unknown	10 Mg, Unk		Apotex	

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Mental Impairment; Sexual Dysfunction	Escitalopram	S	Unknown	7.5 Mg, Unk	Apotex
	Escitalopram	S	Unknown	5 Mg, Unk	Apotex
	Cipralex /01588501/	S	Unknown	7.5 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	5 Mg, Unk	Not Reported
	Cipralex /01588501/	S	Unknown	10 Mg, Unk	Not Reported
	Trintellix	S	Unknown	10 Mg, Qd	Not Reported
	Trintellix	S			Not Reported
	Trintellix	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16212212	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS- 2019GMK040668			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Gabapentin			S	Oral	600 Mg, Bid		Glenmark
	Gabapentin			S	Oral	600 Mg, Unk		Glenmark
	Clonazepam			S	Oral	0.5 Mg, Tid		Not Reported
	Clonazepam			S	Oral	0.5 Mg, Unk		Not Reported
	Domperidone			S	Oral	10 Mg, Bid		Not Reported
	Domperidone			S	Oral	10 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Escitalopram			S	Oral	Unk		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Tid		Not Reported
	Iron Sulphate			S	Oral	300 Mg, Unk		Not Reported
	Temazepam			S	Oral	30 Mg, Od		Not Reported
	Temazepam			S	Oral	30 Mg, Unk		Not Reported
	Tylenol With Codeine			S	Oral	2 Df, Tid		Not Reported
	Vitalux /01586901/			S	Oral	Unk, Bid		Not Reported
	Vitalux /01586901/			S	Oral	Unk		Not Reported
	Wellbutrin			S	Oral	150 Mg, Bid		Not Reported

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Wellbutrin	S	Oral	150 Mg, Bid	Not Reported
Escitalopram Oxalate	S	Oral	20 Mg, Unk	Not Reported
Tylenol With Codeine	S	Oral	2 Df, Tid	Not Reported
Tylenol With Codeine	S	Oral	2 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16577089	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 2334		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug Ineffective; Heart Rate Increased; Hepatic Enzyme Increased; Hypertension; Hypotension; Rheumatoid Arthritis; Somnolence; Vein Collapse; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Cipralex			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abilify			C	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sertraline Hydrochloride			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Fluoxetine			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16653601	EXPEDITED (15-DAY)		OT	DE- GLAXOSMITHKLINE- DE2019136203		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Prednisolone			S	Unknown	25 Mg, Unk		Glaxosmithkline	
	Escitalopram			S	Unknown	Unk		Glaxosmithkline	
	Salbutamol			S	Unknown	Unk		Glaxosmithkline	
	Prednisolone			S	Unknown	2.5 Mg, Unk		Glaxosmithkline	
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline	
	Fluticasone Furoate + Vilanterol Trifenatate			S	Unknown	6 Months Before Diagnosis		Glaxosmithkline	
	Salbutamol Stada			S	Unknown	Unk		Not Reported	
	Metoprolol Stada			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	1 Df, We		Not Reported	
	Prednisolon Jenapharm			S	Unknown	Unk		Not Reported	
	Golimumab			S	Unknown	Unk		Not Reported	
	Pantozol (Pantoprazole Sodium Sesquihydrate)			S	Unknown	Unk		Not Reported	
	Metoprolol Mylan			S	Unknown	Unk		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
	Implanon			S	Unknown	Unk		Not Reported	
	Metoprolol Hexal			S	Unknown	Unk		Not Reported	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Prednisolon Stada			S	Unknown	Unk		Not Reported	
	Amitriptylin			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	

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Ibuprofen Stada			S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16825004	EXPEDITED (15-DAY)		HO, LT	US-ORCHID HEALTHCARE-2074640		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiac Arrest; Circulatory Collapse; Infection; Overdose; Suicide Attempt; Thrombocytopenia; Unresponsive To Stimuli	Venlafaxine Hydrochloride			S	Unknown			Orchid	
	Flecainide			S	Unknown			Not Reported	
	Quetiapine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16825306	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.- 2019AU06381			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Delusion; Eczema; Emotional Distress; Eosinophil Count Decreased; Feeling Cold; Frustration Tolerance Decreased; Haemoglobin Decreased; Hallucination, Auditory; Hyperhidrosis; Intentional Self-Injury; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mental Impairment; Metamyelocyte Count Increased; Monocyte Count Decreased; Myelocyte Count Increased	Escitalopram			S	Unknown	Unk		Invagen	
	Clozaril			S	Unknown	Unk, Tablet		Not Reported	
	Paliperidone			S	Unknown	Unk		Not Reported	
	Olanzapine			S	Unknown	Unk		Not Reported	
	Movicol			C	Unknown	Unk		Not Reported	
	Senna Alexandrina			C	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	
	Calcium Carbonate			C	Unknown	Unk		Not Reported	
	Lurasidone Hydrochloride			C	Unknown	Unk		Not Reported	
	Zuclopenthixol			C	Unknown	Unk		Not Reported	
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported	
	Vitamin B 12 Lichtenstein			C	Unknown	Unk		Not Reported	
	Metformin			C	Unknown	Unk		Not Reported	

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Mirtazapine	C	Unknown	Unk	Not Reported
Caltrate [Calcium Carbonate;Colecalciferol]	C	Unknown	Unk	Not Reported

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19-Sep-2019	16825777	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1108128			Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Osteoporosis	Escitalopram			S		1 Dosage Forms, 1x Pd		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16825804	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1108995		40 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration	Escitalopram			S	Unknown	10 Milligram		Ivax
	Ventolin			C	Respiratory (inhalation)	2 Dosage Forms		Not Reported
	Otomize			C		3 Dosage Forms		Not Reported
	Duloxetine			C		Night, 1 Dosage Forms		Not Reported
	Pregabalin			C		2 Dosage Forms		Not Reported
	Hydroxocobalamin			C	Intramuscular	1 Dosage Forms		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16825954	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1109307		14 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Mg Per Total		Actavis
	Diazepam			S	Oral	480 Mg Per Total		Barr
	Escitalopram			S	Oral	820 Mg Per Total		Ivax
	Paracetamol			S	Oral	2 Gm Per Total		Not Reported
	Ibuprofene			S	Oral	4400 Mg Per Total		Actavis

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Complement Alimentaire	S	Oral	45 Dosage Forms	Not Reported
Diane, Comprime Enrobe	S	Oral	21 Dosage Forms	Not Reported
Cialis	S	Oral	40mg Per Total	Not Reported
Colchicine	S	Oral	6mg Per Total	Not Reported
Donormyl (Doxylamine Succinate)\Sodium Phosphate Dibasic\Sodium Bromide\Sodium Sulfate)	S	Oral	300mg Per Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16826019	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-155076		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported
	Quetiapine			S	Oral			Not Reported
	Chlormadinone Acetate/Ethinylestradiol			S		Unk		Not Reported
	Trigoa			C	Oral	(6x Lng 50microg/Ee 30microg: 5x Lng 75microg/Ee 40microg: 10x Lng 125microg/Ee 30microg)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16826146	EXPEDITED (15-DAY)		OT	BR-TORRENT-00005108			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage; Insomnia	Lamitor			S	Oral	Administered At Night		Torrent
	Depo-Provera			C	Intramuscular	Every 3 Months		Pfizer
	Venvanse			C		Unknown		Shire
	Lamitor			S	Oral	Unknown		Torrent
	Escitalopram			S	Oral	Unknown		Unknown

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16828843	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1087454			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported	
	Trigoa			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16829712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110357		30 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Arthralgia; Blood Iron Decreased; Exposure During Pregnancy; Lung Infection; Melanocytic Naevus; Rheumatoid Arthritis; Rheumatoid Factor Increased	Acetaminophen W/Codeine Phosphate			S	Unknown			Actavis	
	Escitalopram Oxalate			S	Unknown			Ivax	
	Pantoprazole Magnesium			S	Unknown	30 Milligram Daily;		Teva	
	Salbutamol			S	Unknown			Barr	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Imodium			S	Unknown			Not Reported	
	Loperamide Hydrochloride			C	Unknown			Not Reported	
	Multivitamins			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16829726	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110668		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster;	Escitalopram Oxalate			S	Oral	1 Dosage Forms Daily;		Ivax	
	Methotrexate			S	Unknown			Barr	

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Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Pantoprazole Magnesium	S	Oral	1 Dosage Forms Daily;	Teva
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	2 Dosage Forms Daily;	Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	14374564	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-159672		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Escitalopram			S	Oral	Non Renseignee		Not Reported
	Pantoprazole			S	Oral	Non Renseignee		Sun
	Xeloda			S	Oral	Non Renseignee		Not Reported
	Novorapid			S	Subcutaneous	Non Renseignee		Not Reported
	Primperan			S	Oral	Non Renseignee		Not Reported
	Lipanthyl			S	Oral	Non Renseignee		Not Reported
	Movicol			S	Oral	Non Renseignee		Not Reported
	Abasaglar			S	Subcutaneous	Non Renseignee		Not Reported
	Fondaparinux Sodique			S	Subcutaneous	Non Renseignee		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	15949217	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-011237		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Use Issue; Maternal Exposure	Nulojix			S	Intravenous (not otherwise specified)	300 Mg (5mg/Kg), Q4wk		Bristol Myers Squibb	

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During Pregnancy; Premature Delivery	Envarsus	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Miacalcin	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Imitrex /01044801/	S	Unknown	Unk	Not Reported
	Lexapro	S	Unknown	Unk	Not Reported
	Phenergan /00033001/	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16328331	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-027611		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Anuria;	Amlodipine Tablets			S	Oral	Unk		Aurobindo	
Blindness; Blindness	Amlodipine Tablets			S	Oral	150 Milligram, Unk		Aurobindo	
Cortical; Cardiogenic	Escitalopram Tablets			S	Unknown	60 Milligram, Once A Day		Aurobindo	
Shock; Cerebral Infarction;	Escitalopram Tablets			S	Oral	Unk		Aurobindo	
Circulatory Collapse;	Escitalopram Mylan			S	Oral	Unk		Not Reported	
Colour Blindness;	Epinephrine			S	Unknown	30 Microgram, Unk		Not Reported	
Condition Aggravated; Csf	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Pressure Increased;	Potassium Chloride			S	Oral	Unk		Not Reported	
Cytotoxic Oedema;	Risperidone			S	Unknown	6 Milligram, Once A Day		Not Reported	
Depressed Level Of Consciousness;	Risperidone			S	Oral	6 Milligram, Once A Day		Not Reported	
Electrocardiogram P Wave Abnormal;	Risperidone			S	Oral	Unk		Not Reported	
Electrocardiogram St Segment Depression;	Vasopressin			S	Unknown	Unk		Not Reported	
Electrocardiogram T Wave Amplitude Decreased;	Norepinephrine Bitartrate			S	Unknown	30 Microgram, Unk		Not Reported	
Electrocardiogram T Wave Inversion;	Glucose			S	Unknown	Unk		Not Reported	
Electrocardiogram U Wave Present; Embolism;	Mylan Escitalopram 10			S	Oral	Unk		Not Reported	
Embolism Arterial; Hyperdynamic Left	Activated Charcoal			C	Unknown	Unk		Not Reported	

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Ventricle; Hypoglycaemia;	Calcium Gluconate	C	Unknown	Unk	Not Reported
Hypokalaemia;	Dextrose	C	Unknown	Unk	Not Reported
Hypotension;	Epinephrine	C	Unknown	Unk	Not Reported
Hypothermia; Intentional	Escitalopram	C	Unknown	Unk	Not Reported
Overdose; Ischaemia;	Glucagon	C	Unknown	Unk	Not Reported
Optic Atrophy; Optic Nerve	Insulin	C	Unknown	Unk	Not Reported
Injury; Overdose;	Norepinephrine	C	Unknown	Unk	Not Reported
Pulmonary Oedema;	Potassium Chloride	C	Unknown	Unk	Not Reported
Renal Tubular Necrosis;	Risperidone	C	Unknown	Unk	Not Reported
Retinal Ischaemia;	Vasopressin	C	Unknown	Unk	Not Reported
Reversible Cerebral	Amlodipine	C	Unknown	Unk	Not Reported
Vasoconstriction	Norepinephrine;Procaine	C	Unknown	Unk	Not Reported
Syndrome; Shock;	Hydrochloride				
Tachycardia; Toxicity To					
Various Agents; Visual					
Impairment					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16477295	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-035133		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Amlodipine Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
Anger; Anxiety; Arthropod	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
Bite; Blood Pressure	Pantoprazole			S	Unknown	Unk		Aurobindo
Increased; Blood Pressure	Calcium Carbonate			S	Oral	Unk		Not Reported
Systolic Increased;	Ergocalciferol			S	Oral	Unk		Not Reported
Bronchitis;	Hydromorphone			S	Oral	Unk		Not Reported
Cerebrovascular Accident;	Sandostatin			S	Intramuscular	20 Milligram		Not Reported
Contusion; Cough; Crying;	Sandostatin			S	Intramuscular	30 Milligram, Once A Month		Not Reported
Depressed Mood;								
Depression; Diarrhoea;								
Emotional Distress;								
Erythema; Fall; Fatigue;								
Feeling Abnormal; Feeling								
Jittery; Gait Disturbance;								
Head Banging; Headache;								
Hypertension; Hypoacusis;								
Inappropriate Schedule Of								

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Product Administration; Joint Swelling; Malaise; Malignant Neoplasm Progression; Mental Disorder; Muscular Weakness; Nasopharyngitis; Nausea; Nervousness; Pain In Extremity; Peripheral Swelling; Pneumonia; Pollakiuria; Productive Cough; Psychiatric Symptom; Rash; Rib Fracture; Screaming; Suicidal Ideation; Suicide Attempt; Tremor; Unresponsive To Stimuli; Vasculitis; Wound; Wrist Fracture	Acetaminophene Gabapentin Olanzapine Perindopril Prednisone Prednisone Prucalopride Succinate Resotran	C C C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk 4 Milligram, Once A Day 35 Milligram Unk Unk Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16646616	EXPEDITED (15-DAY)		OT	DE-ACCORD-149359		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Escitalopram			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Accord
	Ibuprofen Hormosan			S	Unknown	Unk		Not Reported
	Pantozol			S	Unknown	Unk		Not Reported
	Metoprolol Hexal			S	Unknown	Unk		Not Reported
	Escitalopram Stada			S	Unknown	Unk		Not Reported
	Escitalopram Hexal			S	Unknown	Unk		Not Reported
	Metoprolol Mylan			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Metoprolol Stada			S	Unknown	Unk		Not Reported
	Ibuprofen Hexal			S	Unknown	Unk		Not Reported

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Ibuprofen Stada	S	Unknown	Unk	Not Reported
Salbutamol Stada	S	Unknown	Unk	Not Reported
Escitalopram Mylan	S	Unknown	Unk	Not Reported
Prednisolon Stada	S	Unknown	Unk	Not Reported
Implanon	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
Methotrexate Mylan	S	Unknown	Unk, Qw	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
Salbutamol	S	Unknown	Unk	Not Reported
Ellipta [Fluticasone Furoate\Vilanterol Trifenatate]	S		Unk (6 Months Before Diagnosis)	Not Reported
Vilanterol Trifenatate/Fluticasone Furoate	S	Unknown	Unk (6 Months Before Diagnosis)	Not Reported
Amitriptyline	S	Unknown		Accord
Prednisolone	S	Unknown	2.5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831380	EXPEDITED (15-DAY)		HO	FR-ZYDUS-040669		101 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Orthostatic Hypotension	Ramipril			S	Oral			Zydus Pharm
	Escitalopram			S	Oral			Cadila
	Diosmectite			C				Not Reported
	Paracetamol			C				Not Reported
	Econazole			C				Not Reported
	Levetiracetam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Valpromide			C				Not Reported
	Dexpanthenol			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831382	EXPEDITED (15-DAY)		DE, HO	ES-ZYDUS-040713		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac	Escitalopram			S	Oral			Cadila
Failure; Extensor Plantar	Omeprazole			S	Oral			Not Reported
Response; Hyperreflexia;	Furosemide			S	Oral			Not Reported
Hypoaesthesia;	Lisinopril			S	Oral			Not Reported
Hypoaesthesia;	Alendronic Acid			S	Oral			Not Reported
Multimorbidity; Muscular	Iron			S	Oral			Not Reported
Weakness; Neuromyelitis	Bisoprolol			S	Oral			Not Reported
Optica Spectrum Disorder;	Ipratropium/Ipratropium Bromide			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhaled		Not Reported
Optic Ischaemic	Sintrom			S	Oral			Not Reported
Neuropathy; Pneumonia;	Spironolactone			S	Oral			Not Reported
Pupillary Reflex Impaired;	Allopurinol			S	Oral			Not Reported
Respiratory Tract								
Infection; Sight Disability;								
Thermohypoaesthesia;								
Urinary Retention								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831503	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR- APL-2019-059873		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Hypoglycaemia;	Amlodipine Tablets			S	Unknown	150 Milligram, Daily		Aurobindo
Hypokalaemia; Optic	Escitalopram Tablets			S	Unknown	60 Milligram, Daily		Aurobindo
Atrophy; Pulmonary	Epinephrine			S	Unknown	30 Milligram		Not Reported
Oedema; Reversible	Glucose			S	Unknown	Unk		Not Reported
Cerebral Vasoconstriction	Norepinephrine Bitartrate			S	Unknown	30 Milligram		Not Reported
Syndrome	Risperidone			S	Unknown	6 Milligram		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Activated Charcoal			C	Unknown	Unk		Not Reported

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	Insulin		C	Unknown	Unk			Not Reported	
	Insulin		C	Unknown	Unk			Not Reported	
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20-Sep-2019	16831507	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2019-060608			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Incorrect Dose Administered	Paracetamol			S	Unknown	Unk		Aurobindo	
	Tramadol			S	Unknown	100 Milligram, Two Times A Day		Aurobindo	
	Tramadol			S	Unknown	500 Milligram, Four Times/Day		Aurobindo	
	Escitalopram Sandoz			S	Unknown	10 Mg, Bid		Not Reported	
	Urbanyl			C	Unknown	2 Dosage Form, Once A Day (20 Units Not Specified)		Not Reported	
	Depakine Chrono			C	Unknown	3 Milligram, Once A Day (1.5 Mg, Bid)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831581	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ACCORD-155222		73 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram			S		Increased To Its Current Dose 3 Months Ago		Not Reported	
	Venlafaxine/Venlafaxine Hydrochloride			S				Not Reported	
	Erythromycin			S				Not Reported	
	Furosemide			C				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Escitalopram			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831780	EXPEDITED (15-DAY)		OT	MY-TORRENT-00000193		71 YR	Male	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hypersensitivity	Risperidone			S		Unknown		Unknown	
	Atorvastatin			C		Unknown		Unknown	
	Escitalopram			S		Unknown		Unknown	
	Amlodipine			C		Unknown		Unknown	
	Acetylsalicylic Acid			C		Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16832076	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-060514		101 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Orthostatic Hypotension	Ramipril			S	Oral	5 Milligram, Once A Day		Aurobindo	
	Escitalopram			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Diosmectite			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
	Econazole			C	Unknown	Unk		Not Reported	
	Levetiracetam			C	Unknown	Unk		Not Reported	
	Cholecalciferol			C	Unknown	Unk		Not Reported	
	Valpromide			C	Unknown	Unk		Not Reported	
	Dexpanthenol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16832103	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-059864		83 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Balance Disorder;	Amlodipine Tablets			S	Unknown	2.5 Milligram, Daily		Aurobindo	

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Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Escitalopram Tablets	S	Unknown	Unk	Aurobindo
	Escitalopram Tablets	S	Unknown	10.0 Milligram, Daily	Aurobindo
	Ramipril	S	Unknown	5.0 Milligram, Daily	Aurobindo
	Codeine	S	Unknown	30.0 Milligram, Two Times A Day	Not Reported
	Furosemide	S	Unknown	20.0 Milligram, Daily	Not Reported
	Furosemide	S	Unknown	40.0 Milligram, Daily	Not Reported
	Glyceryl Trinitrate	S	Transdermal	0.4 Milligram, Two Times A Day	Not Reported
	Metoprolol	S	Unknown	25.0 Milligram, Daily	Not Reported
	Oxazepam	S	Unknown	10 Milligram, Two Times A Day	Not Reported
	Zopiclone	S	Unknown	2.5 Milligram, Daily	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported
	Vitamin C	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16834340	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1087775		73 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis	Escitalopram			S	Oral	1 Dosage Form, Qd		Not Reported	
	Pradaxa			S	Oral	75 Milligram, Qd		Mylan	
	Seropram /00582602/			S	Oral	1 Dosage Form, Qd		Mylan	

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20-Sep-2019	16834609	EXPEDITED (15-DAY)		OT	JP-ASTRAZENECA-2019SF31648		85 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Quetiapine			S	Oral			Zeneca	
	Quetiapine			S	Oral			Zeneca	
	Escitalopram			S				Not Reported	
	Mirtazapine			S				Not Reported	
	Olanzapine			S				Not Reported	
	Sulpiride			C				Not Reported	
	Clotiazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16834701	EXPEDITED (15-DAY)		DE, HO	ES-BAUSCH-BL-2019-025762		90 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amaurosis; Cardiac Failure; Extensor Plantar Response; Hyperreflexia; Hypoaesthesia; Hypoaesthesia; Multimorbidity; Muscular Weakness; Neuromyelitis Optica Spectrum Disorder; Optic Ischaemic Neuropathy; Pneumonia; Pupillary Reflex Impaired; Respiratory Tract Infection; Sight Disability; Thermohypoaesthesia; Urinary Retention	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhalated		Bausch And Lomb	
	Omeprazol			S	Oral			Not Reported	
	Lisinopril			S	Oral			Not Reported	
	Alendronico Acido (Alendronate Sodium)			S	Oral			Not Reported	
	Furosemida			S	Oral			Not Reported	
	Hierro Sulfato (Ferrous Sulfate)			S	Oral			Not Reported	
	Bisoprolol			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Sintrom			S	Oral	60 Tablets		Not Reported	
	Espironolactona			S	Oral			Not Reported	
	Alopurinol			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16834802	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20190918084			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Convulsive Threshold Lowered; Drug Interaction; Epilepsy; Fatigue; Overdose	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	
	Escitalopram Sandoz			S	Unknown			Not Reported	
	Depakine Chrono			C	Unknown	1.5 Mg, 2/Day		Not Reported	
	Urbanyl			C	Unknown	2 Df, 1/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2019	16080835	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013728		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Tablets			S	Unknown	Unk		Aurobindo	
	Citalopram			S	Unknown	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo	
	Topiramate			S	Oral	Unk		Aurobindo	
	Oxazepam			S	Unknown	Unk		Not Reported	
	Oxazepam			S	Unknown	Unk		Not Reported	
	Temazepam			S	Oral	Unk		Not Reported	
	Naloxone			S	Intramuscular	Unk		Not Reported	
	Ramipril			C	Endocervical	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Spirolactone			C	Unknown	Unk		Not Reported	
	Advair			C	Unknown	Unk		Not Reported	
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported	
	Clopidogrel			C	Unknown	Unk		Not Reported	

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	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Ipratropium	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Spironolactone	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Clopidogrel	C	Unknown	Unk	Not Reported
	Fluticasone;Salmeterol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2019	16714604	EXPEDITED (15-DAY)		HO, LT, OT	BE-ACCORD-151488		65 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Pallor; Torsade De Pointes; Vomiting	Escitalopram			S		Unk		Not Reported	
	Tacrolimus			S		Unk		Accord	
	Omeprazole			S		Form: Gastro-Resistant Coated Tablet		Not Reported	
	Sotalol			S		Unk		Not Reported	
	Bisoprolol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2019	16836462	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-060780		40 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Ventolin			C	Respiratory (inhalation)	2 Dosage Form, As Necessary		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Otomize	C	Unknown	3 Dosage Form, Once A Day	Not Reported
Duloxetine	C	Unknown	1 Dosage Form, Once A Day, Night	Not Reported
Pregabalin	C	Unknown	2 Dosage Form, Once A Day	Not Reported
Hydroxocobalamin	C	Intramuscular	1 Dosage Form, 2 Month	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2019	16836480	EXPEDITED (15-DAY)	OT		FI-AUROBINDO-AUR-APL-2019-061000		34 YR	Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Behaviour Disorder; Behaviour Disorder; Condition Aggravated; Drug Ineffective; Drug Ineffective For Unapproved Indication; Intentional Product Use Issue; Intentional Self-Injury; Multiple Drug Therapy; Product Use In Unapproved Indication	Olanzapine Film Coated Tablets			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Olanzapine Film Coated Tablets			S				Aurobindo
	Olanzapine Film Coated Tablets			S				Aurobindo
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Amitriptyline			S				Not Reported
	Candesartan			S	Unknown	16 Milligram, Once A Day		Not Reported
	Candesartan			S				Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Quetiapine			S				Not Reported
	Quetiapine			S				Not Reported
	Macrogol 3350			S	Unknown	3 Dosage Form, Once A Day, (3 Sachets Per Day)		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported
	Topiramate			S				Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Risperidone			S	Unknown	3 Milligram, Once A Day		Not Reported
	Risperidone			S	Unknown	4 Milligram, Once A Day		Not Reported
	Risperidone			S				Not Reported
	Escitalopram			S	Unknown	10 Milligram, Once A Day		Not Reported
	Escitalopram			S				Not Reported

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Levomepromazine	S	Unknown	100 Milligram, Once A Day	Not Reported
Levomepromazine	S			Not Reported
Levomepromazine	S			Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	20 Milligram, Once A Day	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Melatonin	S	Unknown	3 Milligram, Once A Day	Not Reported
Citalopram	S	Unknown	Unk	Not Reported
Citalopram	S			Not Reported
Citalopram	S			Not Reported
Lorazepam	S	Unknown	3 Milligram, Once A Day	Not Reported
Lorazepam	S			Not Reported
Lorazepam	S			Not Reported
Oxcarbazepine	C	Unknown	900 Milligram, Once A Day	Not Reported
Valproate Sodium	C	Unknown	1200 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	13893657	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017360842		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Hypoglycaemia;	Norepinephrine Bitartrate			S		30 Mcg/Minute		Pfizer	
Hypokalaemia; Optic	Norepinephrine Bitartrate			S		40 Mcg/Minute		Pfizer	
Atrophy; Overdose;	Norepinephrine Bitartrate			S		10 Mcg/Minute		Pfizer	
Pulmonary Oedema;	Amlodipine Besilate			S		150 Mg, Daily		Pfizer	
Reversible Cerebral	Glucose			S				Pfizer	
Vasoconstriction	Glucose			S	Intravenous bolus	Unk		Pfizer	
Syndrome	Epinephrine			S		30 Mcg/Minute		Pfizer	
	Epinephrine			S		40 Mcg/Minute		Pfizer	
	Epinephrine			S		25 Mcg/Minute		Pfizer	
	Epinephrine			S		10 Mcg/Minute		Pfizer	
	Vasopressin			S		Unk (2.4 Units/Hour)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Escitalopram	S	Oral	Unk	Not Reported
	Escitalopram	S		60 Mg, Daily	Not Reported
	Risperidone	S	Oral	6 Mg, Daily	Not Reported
	Risperidone	S	Oral	Unk	Not Reported
	Insulin	C	Intravenous bolus	Unk, 70 Units/Hour Infusion	Not Reported
	Insulin	C		70 lu, Unk	Not Reported
	Activated Charcoal	C		50 G, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	14861830	EXPEDITED (15-DAY)		HO	CA-TAKEDA- 2018TUS013693		20 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Concussion; Fall; Head Injury	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda	
	Vedolizumab			S	Intravenous (not otherwise specified)	300 Milligram		Takeda	
	Cipralex /01588501/ Pentasa			S	Unknown	Unk		Not Reported	
				C		4 Gram, Qd		Not Reported	
	Imuran /00001501/			C		150 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16080860	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-013835			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Ankylosing Spondylitis; Anxiety; Bruxism; Disturbance In Attention; Dizziness; Drug Ineffective; Fatigue; Mental Impairment; Sexual Dysfunction	Citalopram			S	Unknown	Unk		Aurobindo	
	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo	
	Escitalopram Tablets			S	Unknown	7.5 Milligram		Aurobindo	
	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo	
	Escitalopram Tablets			S	Unknown	20 Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trintellix	S	Unknown	10 Milligram, Once A Day	Not Reported
Trintellix	S			Not Reported
Trintellix	S			Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	50 Milligram	Not Reported
Infliximab	C	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	1000 Milligram	Not Reported
Nortriptyline	S	Oral	250 Milligram	Not Reported
Tylenol	S	Topical	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16150339	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL003472		52 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Interaction; Gastrointestinal Haemorrhage; Haemorrhage; Herbal Interaction; Hyperhidrosis; Myalgia; Urinary Tract Infection	Duloxetine Hydrochloride			S	Unknown	10 Mg, Qd		Not Reported
	Ciprofloxacin			S	Oral	500 Mg, Bid		Novartis
	Ciprofloxacin			S	Unknown	1500 Mg, Qd		Novartis
	Tramadol			S	Unknown	Unk		Not Reported
	Tramadol			S				Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Ginkgo Biloba			S	Unknown	Unk		Not Reported
	Ketoprofen			C	Oral	50 Mg, Tid		Not Reported
	Ketoprofen			C				Not Reported
	Zolpidem			C	Unknown	10 Mg, Qd (Each Evening)		Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16157660	EXPEDITED (15-DAY)		HO	IN-TORRENT-00002181		45 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Serotonin Syndrome	Divalproex			C				Unknown	
	Escitalopram			S				Unknown	
	Olanzapine			S				Unknown	
	Fluoxetine			S				Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16210441	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020621			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankylosing Spondylitis; Drug Ineffective	Escitalopram Tablets			S	Oral	20 Milligram, Daily		Aurobindo	
	Cimzia			S	Unknown	50 Milligram		Not Reported	
	Diclofenac Potassium			S	Unknown	50 Milligram		Not Reported	
	Naproxen			S	Unknown	Unk		Not Reported	
	Naproxen Sodium			S	Unknown	1000 Milligram, Daily		Not Reported	
	Nortriptyline			S	Oral	25 Milligram, Daily		Not Reported	
	Tylenol			S	Topical	Unk		Not Reported	
	Voltaren			S	Topical	Unk, Daily		Not Reported	
	Diclofenac			C	Unknown	Unk		Not Reported	
	Infliximab			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Infliximab			C	Intravenous (not otherwise specified)	600 Milligram		Not Reported	
	Infliximab			C	Intravenous (not otherwise specified)	700 Milligram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16210977	EXPEDITED (15-DAY)		OT	FR-ACCORD-122043		96 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Ramipril			S	Oral			Accord
	Exemestane			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Bisocet			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Seroplex			S	Oral			Not Reported
	Fluidabak			C	Ophthalmic			Not Reported
	Transipeg			C	Oral			Not Reported
	Potassium Gluconate			C	Oral	1 Table Spoon Per Day		Not Reported
	Levothyroxine			C	Oral			Not Reported
	Gluconate Sodium/Potassium Chloride/Sodium Acetate/Sodium Chloride			C	Oral	1 Cs Per Day Route		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16211393	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020682		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dehydration; Dysphagia; Mental Disorder; Product Use In Unapproved Indication	Escitalopram Tablets			S	Oral	20.0 Milligram		Aurobindo
	Gabapentin			S	Oral	600.0 Milligram, Two Times A Day		Aurobindo
	Clonazepam			S	Oral	0.5 Milligram, 3 Times A Day		Not Reported
	Domperidone			S	Oral	10.0 Milligram, Two Times A Day		Not Reported
	Iron Sulfate			S	Oral	300.0 Milligram, 3 Times A Day		Not Reported
	Temazepam			S	Oral	30.0 Milligram, Daily		Not Reported

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Tylenol With Codeine	S	Oral	2.0 Dosage Form, 3 Times A Day	Not Reported
Vitalux	S	Oral	Unk, Two Times A Day	Not Reported
Wellbutrin	S	Oral	150.0 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16476909	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-035615		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anger; Depressed Mood; Diarrhoea; Mental Disorder; Multiple Sclerosis	Escitalopram Tablets			S	Oral	Unk		Aurobindo
	Aubagio			S	Oral	14 Milligram, Once A Day		Not Reported
	Aubagio			S				Not Reported
	Acetaminophen			C	Oral	Unk		Not Reported
	Cbd Oil			C	Unknown	Unk		Not Reported
	Colloidal Silver			C	Oral	Unk		Not Reported
	Magnesium			C	Oral	Unk		Not Reported
	Vitamin D3			C	Oral	3000 International Unit, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16838332	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1111024		31 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Mg		Not Reported
	Escitalopram			S	Oral	20mg		Ivax

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16839277	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019394455		22 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Serotonin Syndrome	Linezolid Escitalopram	S S	Unk Unk	Pfizer Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16839349	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110716		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling; Liver Disorder; Liver Function Test Increased; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Escitalopram Oxalate			S		1 Dosage Forms Daily;		Ivax
	Methotrexate			S	Unknown			Barr
	Pantoprazole Magnesium			S		1 Dosage Forms Daily;		Teva
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Prednisone			S	Oral			Actavis
	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16839762	EXPEDITED (15-DAY)		DS	DE-MYLANLABS-2019M1088054		57 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Feeling Hot; Headache; Hyperhidrosis; Hypogeusia; Hyposmia; Pain In Extremity; Presyncope; Tremor	Escitalopram			S		5 Gtt Drops		Not Reported	
	Escitalopram			S		6-7 Tropfen		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16840166	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019405568		31 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pupils Unequal; Visual Impairment	Sertraline Hcl			S	Oral	50 Mg, Unk		Pfizer	
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16841666	EXPEDITED (15-DAY)		OT	FI-BAUSCH-BL-2019-026058		34 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder; Condition Aggravated; Multiple Drug Therapy; Therapy Non-Responder	Lorazepam			S	Unknown	Was Slowly Stopped		Not Reported	
	Levomepromazine			S	Unknown			Not Reported	
	Levomepromazine			S	Unknown	Gradually Stopped		Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Risperidone			S	Unknown	Reduced To 4-3 Mg/Day		Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Carbamazepine			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	Stopped Due To No		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					Response.	
	Pantoprazole	S	Unknown			Not Reported
	Bisoprolol	S	Unknown			Not Reported
	Macrogol 3350	S	Unknown		3350 With Dosage 3 Bags/Day	Not Reported
	Olanzapine	S	Unknown			Not Reported
	Quetiapine	S	Unknown			Not Reported
	Metoprolol	S	Unknown			Not Reported
	Topiramate	S	Unknown			Not Reported
	Candesartan	S	Unknown			Not Reported
	Melatonin	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16842120	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2019-061838		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cardiac Arrest;	Quetiapine			S	Unknown	3000 Milligram		Aurobindo
Dyspnoea; Infection;	Flecainide			S	Unknown	25. Milligram		Aurobindo
Overdose; Pulse Absent;	Venlafaxine			S	Unknown	1000 Milligram		Aurobindo
Pulseless Electrical	Escitalopram			S	Unknown	250 Milligram		Aurobindo
Activity; Suicide Attempt;	Bisoprolol			S	Unknown	25 Milligram		Aurobindo
Thrombocytopenia;	Clonazepam			S	Unknown	5 Milligram		Not Reported
Unresponsive To Stimuli								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16842121	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR- APL-2019-060872		88 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Interaction;	Escitalopram			S	Oral	1 Dosage Form, Daily		Aurobindo
Dyspnoea; Fall; Nightmare	Dextromethorphan Hydrobromide			S	Unknown	Unk		Not Reported

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	Ebixa		S	Oral	10 Milligram, Daily		Not Reported		
	Ebixa		S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16842135	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-060757		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ecchymosis	Escitalopram			S	Unknown	5 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	20 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	10 Milligram, Daily		Aurobindo	
	Escitalopram			S	Unknown	15 Milligram, Daily		Aurobindo	
	Omega-3 Fatty Acids			S	Unknown	Unk		Not Reported	
	Rivotril			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16842139	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-060445		17 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiogenic Shock; Intentional Overdose; Overdose; Seizure; Sympathomimetic Effect; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo	
	Wellbutrin			S	Oral	Unk		Not Reported	
	Quetiapine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16842141	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-060878		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin	Escitalopram			S	Oral	20 Milligram, Daily		Aurobindo	
	Venlafaxine			S	Oral	150 Milligram, Daily		Aurobindo	

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Syndrome; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	13960485	NON-EXPEDITED			US-FRI-1000075876			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Anxiety;	Lexapro			S	Oral	20 Mg, Qd		Allergan
Drug Ineffective;	Lexapro			S	Oral	20 Mg, Qd		Allergan
Headache; Nightmare;								
Product Dose Omission								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15327343	NON-EXPEDITED			US-ALLERGAN-1838059US		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder;	Lexapro			S	Oral	20 Mg		Allergan
Bedridden; Fall; Fatigue;	Lexapro			S	Oral	5 Mg, Qd		Allergan
Gait Disturbance; Malaise;	Lexapro			S	Oral	10 Mg, Qd		Allergan
Somnolence; Therapy	Lexapro			S	Oral	5 Mg, Qd		Allergan
Cessation; Wrong	Ampyra			S	Oral	10 Mg, Bid		Not Reported
Technique In Product	Ampyra			S	Oral	10 Mg, Bid		Not Reported
Usage Process	Ampyra			S	Unknown	10 Mg, Bid		Not Reported
	Dalfampridine			S				Not Reported
	Clonazepam			C	Unknown	1 Mg, Qd		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Ezetimibe			C	Unknown	10 Mg		Not Reported
	Gilenya			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	54 Mg		Not Reported
	Losartan			C	Unknown	100 Mg		Not Reported
	Neurontin			C	Unknown	600 Mg		Not Reported
	Pravastatin			C	Unknown	10 Mg		Not Reported

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Propranolol	C	Unknown	Unk	Not Reported
Vyvanse	C	Unknown	20 Mg	Not Reported
Vyvanse	C		Unk	Not Reported
Cymbalta	C	Oral	Unk	Not Reported
Gabapentin	C			Not Reported
Copaxone	C			Not Reported
Amlodipine	C		2.5 Mg	Not Reported
Memantine	C		Unk	Not Reported
Memantine	C		Unk	Not Reported
Rosuvastatin	C		10 Mg	Not Reported
Rosuvastatin	C		5 Mg	Not Reported
Topiramate	C		25 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15327355	NON-EXPEDITED			US-ALLERGAN-1838856US		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Synthroid			C	Oral	Unk		Not Reported	
	Hydrochlorothiazide			C	Oral	Unk		Not Reported	
	Norvasc			C	Oral	5 Mg, Unk		Not Reported	
	Protonix			C	Oral	Unk		Not Reported	
	Melatonin			C	Oral	Unk Unk, Prn		Not Reported	
	Statin			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15327366	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1838847US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fluid Retention; Off Label Use; Skin Fissures; Skin	Escitalopram Oxalate Unk			S	Unknown	Unk Unk, Unknown		Allergan	

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Odour Abnormal; Suicidal Ideation; Suicide Attempt; Weight Increased		Xarelto		S	Unknown	Unk Unk, Unknown		Not Reported	
		Aporex		S	Unknown	Unk Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15327469	NON-EXPEDITED			US-ALLERGAN-1831144US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg (1/2 Pill A Day For Two Week)		Allergan	
	Atorvastatin			C	Oral	Unk		Not Reported	
	Metoprolol			C	Oral	Unk		Not Reported	
	Lisinopril			C	Oral	Unk		Not Reported	
	Aspirin			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15739275	NON-EXPEDITED			US-ALLERGAN-1841976US		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15739276	NON-EXPEDITED			US-ALLERGAN-1840313US		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15739281	NON-EXPEDITED			US-ALLERGAN-1848633US		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective	Escitalopram Oxalate - Bp	S	Oral	20 Mg, Qd	Allergan
	Escitalopram Oxalate - Bp	S			Allergan
	Three Unspecified Heart Medications	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15739289	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851776US		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Confusional State; Dizziness; Feeling Abnormal; Muscle Spasms; Pain; Paraesthesia; Suicidal Ideation; Urinary Tract Infection	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan
	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan
	Vortioxetine			S	Oral	10 Mg, Qd		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported
	Tramadol			C	Oral	Unk		Not Reported
	Alprazolam			C	Oral	Unk		Not Reported
	Carvedilol			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15739297	NON-EXPEDITED			US-ALLERGAN-1852551US		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Abnormal	Escitalopram Oxalate Unk			S	Oral	Unk Unk, Unknown		Allergan
	Naltrexone Hcl			C	Oral	50 Mg, Qd		Not Reported
	Naltrexone Hcl			C				Not Reported
	Gabapentin			C	Oral	600 Mg, Tid		Not Reported
	Prozac			C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15869783	EXPEDITED (15-DAY)		HO	JP-ALLERGAN-1903558US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Activation Syndrome; Diarrhoea; Headache; Malaise; Nausea	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd (After Dinner)	Allergan
	Gasmotin	C	Oral	5 Mg, Qd	Not Reported
	Solanax	C	Oral	1.2 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16696741	NON-EXPEDITED			US-ALLERGAN-1908987US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Nausea; Vomiting	Lexapro			S	Unknown	Unk		Allergan	
	Morphine Sulfate Unk			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16696766	NON-EXPEDITED			US-ALLERGAN-1911657US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram Oxalate - Bp			S				Allergan	
	Morphine Sulfate Unk			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16696777	NON-EXPEDITED			US-ALLERGAN-1911124US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
	Morphine Sulfate Unk			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16702534	NON-EXPEDITED			US-ALLERGAN-1908936US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Weight Increased	Fetzima			S	Unknown	Unknown		Allergan	
	Lexapro			S	Unknown	Unknown		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16714638	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015048		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Amitriptyline			S	Unknown	Unknown		Unknown	
	Escitalopram			S	Unknown	Unknown		Mylan	
	Escitalopram			S	Unknown	Unknown		Unknown	
	Escitalopram			S	Unknown	Unknown		Hexal	
	Escitalopram			S	Unknown	Unknown		Stada	
	Golimumab			S	Unknown	Unknown		Unknown	
	Ibuprofen			S	Unknown	Unknown		Hexal	
	Ibuprofen			S	Unknown	Unknown		Torrent	
	Ibuprofen			S	Unknown	Unknown		Unknown	
	Ibuprofen			S	Unknown	Unknown		Stada	
	Implanon			S	Unknown	Unknown		Unknown	
	Methotrexate			S	Unknown	1 Week; Qw, 1df		Mylan	
	Metoprolol			S	Unknown	Unknown		Stada	
	Metoprolol			S		Unknown		Mylan	
	Metoprolol			S	Unknown	Unknown		Unknown	
	Metoprolol			S	Unknown	Unknown		Hexal	
	Pantozol			S	Unknown	Unknown		Unknown	
	Prednisolon			S	Unknown	Unknown		Stada	
	Prednisolone			S	Unknown	Unknown		Jenapharm	
	Prednisolone			S	Unknown	25 Mg, Unk		Unknown	
	Salbutamol			S	Unknown	Unknown		Stada	
	Salbutamol			S	Unknown	Unknown		Unknown	
	Ellipta			C		Unk (6 Months Before Diagnosis)		Unknown	
	Fluticasone And Vilanterol			S		6 Months Before		Unknown	

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Diagnosis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16734068	NON-EXPEDITED			US-ALLERGAN-1905252US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blunted Affect; Fatigue	Lexapro Celexa			S S				Allergan Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16734116	NON-EXPEDITED			US-ALLERGAN-1909215US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram Oxalate - Bp Citalopram Hydrobromide - Bp			S S	Unknown Unknown	Unk Unk		Allergan Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16734125	NON-EXPEDITED			US-ALLERGAN-1915717US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Dry Mouth; Headache; Initial Insomnia; Nausea; Paraesthesia; Poor Quality Sleep; Product Use In Unapproved Indication; Restlessness; Therapy Partial Responder	Lexapro Lexapro Celexa Abilify Abilify Trintellix Gabapentin			S S S S S S C				Allergan Allergan Allergan Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16734162	NON-EXPEDITED			US-ALLERGAN-1919600US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective	Lexapro	S	Unknown	Unk	Allergan
	Celexa	S	Unknown	Unk	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16811578	EXPEDITED (15-DAY)		OT	IE-ALLERGAN-1937397US			Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administered To Patient Of Inappropriate Age; Suicidal Ideation	Escitalopram Oxalate - Bp			S				Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16813457	EXPEDITED (15-DAY)		HO	PHHY2019FR210556		14 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Mg, Unk (In Total)		Not Reported
	Escitalopram			S	Oral	820 Mg, Unk (In Total)		Not Reported
	Paracetamol			S	Oral	2 G, Unk (In Total)		Not Reported
	Ibuprofen			S	Oral	4400 Mg, Unk (In Total)		Not Reported
	Donormyl (Doxylamine Succinate)\Sodium Phosphate Dibasic\Sodium Bromide\Sodium Sulfate)			S	Oral	300 Mg, Unk (In Total)		Not Reported
	Diazepam			S	Oral	480 Mg, Unk (In Total)		Not Reported
	Colchicine			S	Oral	6 Mg, Unk (In Total)		Not Reported
	Cialis			S	Oral	40 Mg, Unk (In Total)		Not Reported
	Diane			S	Oral	21 Df, Unk (In Total)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1113154		17 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Incorrect Dose Administered; Suicidal Ideation	Venlafaxine Hydrochloride	S	Teva
	Escitalopram	S	Ivax
	Ciprallex [Escitalopram]	S	Not Reported
	Ciprallex [Escitalopram]	S	Not Reported
	Effexor Xr	S	Not Reported
	Effexor Xr	S	Not Reported
	Quetiapine	C	Not Reported
	Seroquel	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842945	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1111983		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Base Excess Decreased; Confusional State; Fall; Hypoglycaemia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Lactic Acidosis; Pco2 Decreased	Escitalopram Oxalate			S	Unknown			Ivax
	Hydrochlorothiazide			S	Unknown			Ivax
	Metformin			S	Unknown	2 Gram Daily;		Actavis
	Metformin			S	Unknown			Actavis
	Apo-Gliclazide			S	Unknown			Not Reported
	Insulin			S	Unknown			Not Reported
	Insulin			S	Unknown			Not Reported
	Gliclazide			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Telmisartan			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842989	NON-EXPEDITED			US-ALLERGAN-1915126US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Escitalopram Oxalate - Bp			S				Allergan

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24-Sep-2019	16842990	NON-EXPEDITED			US-ALLERGAN-1914603US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Lexapro			S		10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842991	NON-EXPEDITED			US-ALLERGAN-1914883US		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Therapy Cessation	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Guanfacine			C	Oral	2 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842992	NON-EXPEDITED			US-ALLERGAN-1914807US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842994	NON-EXPEDITED			US-ALLERGAN-1918502US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate Unk			S	Unknown	10 Mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842995	NON-EXPEDITED			US-ALLERGAN-1918731US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hypersensitivity		Lexapro		S		Allergan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842996	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1917605US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Suicidal Ideation	Lexapro			S	Unknown	Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842997	NON-EXPEDITED			US-ALLERGAN-1916434US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842999	NON-EXPEDITED			US-ALLERGAN-1918122US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder	Lexapro			S				Allergan	
	Cymbalta			S				Not Reported	
	Xeljanz			C				Not Reported	
	Aspirin			C				Not Reported	
	Caltrate Gummy Bites 250mg-4			C				Not Reported	
	Prilosec			C				Not Reported	
	Vitamin B12			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843000	NON-EXPEDITED			US-ALLERGAN-1916415US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

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24-Sep-2019	16843005	NON-EXPEDITED			US-ALLERGAN-1918085US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843007	NON-EXPEDITED			US-ALLERGAN-1917255US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; White Blood Cell Count Decreased	Lexapro			S	Unknown			Allergan	
	Lexapro			S				Allergan	
	Valium			S	Unknown	Unk, Prn		Not Reported	
	Ibrance			S	Unknown	100 Mg		Not Reported	
	Ibrance			S	Unknown	125 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843008	NON-EXPEDITED			US-ALLERGAN-1915893US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatic Enzymes Increased	Lexapro			S	Unknown	Unk		Allergan	
	Praluent			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843009	NON-EXPEDITED			US-ALLERGAN-1918779US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Unknown	Unk		Allergan	

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24-Sep-2019	16843010	NON-EXPEDITED			US-ALLERGAN-1918664US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Drug Ineffective; Headache; Migraine; Vision Blurred	Lexapro			S				Allergan	
	Brexpiprazole			S				Not Reported	
	Abilify			S		Actual: 1/4 Tablet Or 1/2 Tablet Of A 2 Mg Tablet With Unknown Frequency		Not Reported	
	Buspirone			S		60 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843011	NON-EXPEDITED			US-ALLERGAN-1917431US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eczema	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843012	NON-EXPEDITED			US-ALLERGAN-1916508US		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hyperhidrosis; Nausea; Night Sweats; Night Sweats; Oedema; Oedema Peripheral	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	5 Mg, Qd		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Armour Thyroid			C	Unknown	7.5 Mg, Qd		Not Reported	
	Armour Thyroid			C	Unknown	Actual: On Mondays And Thursdays		Not Reported	
	Armour Thyroid			C	Unknown	7.5 Mg, Qd		Not Reported	
	Armour Thyroid			C	Unknown			Not Reported	
	Tirosint			C	Unknown	Actual: Every 4 Days With A Goal Of Reaching Daily		Not Reported	

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				Dosing	
Biotin	C	Unknown	10000 Mg, Qd		Not Reported
Biotin	C	Unknown	10,000 Mg Daily		Not Reported
Dexilant	C	Unknown	30 Mg, Qd		Not Reported
Dexilant	C	Unknown			Not Reported
Fish Oil	C	Unknown	1200 Mg, Qd		Not Reported
Fish Oil	C	Unknown			Not Reported
Glucosamine Chondroitin	C	Unknown	1500 Mg, Qd		Not Reported
Glucosamine Chondroitin	C	Unknown			Not Reported
Magnesium	C	Unknown	250 Mg, Qd		Not Reported
Magnesium	C	Unknown			Not Reported
Premarin	C	Unknown	0.625 Mg, Bid		Not Reported
Premarin	C	Unknown	.625 Mg		Not Reported
Selenium	C	Unknown	200 Mg, Qd		Not Reported
Selenium	C	Unknown	200 Mg Daily		Not Reported
Vitamin B12	C	Unknown	5000 Mg, Qd		Not Reported
Vitamin B12	C	Unknown	5000 Mg Daily		Not Reported
Vitamin D3	C	Unknown	5000 Iu, Qd		Not Reported
Vitamin D3	C	Unknown	5000 Units Daily		Not Reported
Escitalopram-Form-Unknown	S	Unknown			Not Reported
Escitalopram-Form-Unknown	S	Unknown			Not Reported
Escitalopram-Form-Unknown	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843014	NON-EXPEDITED			US-ALLERGAN-1916321US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843015	NON-EXPEDITED			US-ALLERGAN-1915561US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Bystolic			S	Unknown	Unk		Allergan	
	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843016	NON-EXPEDITED			US-ALLERGAN-1921944US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Weight Increased	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843017	NON-EXPEDITED			US-ALLERGAN-1923290US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dry Eye; Dry Mouth	Lexapro			S	Unknown	Unk		Allergan	
	Refresh Plus Pf			C	Ophthalmic	Unk		Not Reported	
	Sustaine			C	Ophthalmic	Unk		Not Reported	
	Sustaine Ultra			C	Ophthalmic	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843019	NON-EXPEDITED			US-ALLERGAN-1923997US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Abnormal	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843020	NON-EXPEDITED			US-ALLERGAN-1922466US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Burning Sensation; Drug Ineffective; Dysphagia; Hypersensitivity; Insomnia; Rash Pruritic; Tinnitus; Urticaria	Lexapro			S		Unk		Allergan	
	Rexulti			S		25 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843021	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1919669US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Product Administration Duration	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Aripiprazole			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Haloperidol			S	Unknown			Not Reported	
	Abilify			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843022	NON-EXPEDITED			US-ALLERGAN-1921093US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue	Lexapro			S	Unknown	Unk		Allergan	
	Humira			S	Subcutaneous	Unk, Single		Not Reported	
	Humira			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843023	NON-EXPEDITED			US-ALLERGAN-1921213US		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off	Lexapro			S	Unknown	Unk		Allergan	
	Effexor			C		Unk		Not Reported	

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Label Use	Plavix	C	Unk	Not Reported
	Crestor	C	Unk	Not Reported
	Lotranex	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843025	NON-EXPEDITED			US-ALLERGAN-1921911US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder	Lexapro			S	Unknown			Allergan
	Oxycodone			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843026	NON-EXPEDITED			US-ALLERGAN-1923067US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843027	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1921208US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Hallucination, Visual; Hyperhidrosis; Nausea; Thirst	Lexapro			S	Unknown			Allergan
	Amantadine			S	Oral	274 Mg, Qhs		Not Reported
	Amantadine			S	Oral	137 Mg, Qd		Not Reported
	Pramipexole Dihydrochloride			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Rasagiline Mesylate			C				Not Reported
	Gabapentin			C				Not Reported
	Rytary			C				Not Reported
	Synthroid			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843028	NON-EXPEDITED			US-ALLERGAN-1924860US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843029	NON-EXPEDITED			US-ALLERGAN-1925024US		29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Intentional Product Misuse; Off Label Use; Panic Attack	Lexapro			S	Oral	5 Mg, Qd		Allergan	
	Zyrtec			C	Oral	10 Mg, Qd		Not Reported	
	Prednisone			C	Oral	Unk		Not Reported	
	Prozac			C	Oral	10 Mg, Qd		Not Reported	
	Tylenol			C	Oral	Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843030	NON-EXPEDITED			US-ALLERGAN-1922439US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843031	NON-EXPEDITED			US-ALLERGAN-1924169US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843032	NON-EXPEDITED			US-ALLERGAN-1921002US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Dizziness; Drug Interaction; Dyskinesia; Flushing; Mania	Lexapro			S	Unknown	Unk		Allergan	
	Xadago			S	Unknown	50 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843034	NON-EXPEDITED			US-ALLERGAN-1921757US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Feeling Of Despair	Lexapro			S		10 Mg, Qhs		Allergan	
	Seroquel			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843035	NON-EXPEDITED			US-ALLERGAN-1921285US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843036	NON-EXPEDITED			US-ALLERGAN-1920251US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Lexapro			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843037	NON-EXPEDITED			US-ALLERGAN-1920094US		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Oral	Unk, Qod		Allergan	
	Lexapro			S	Oral	Unk, Qd		Allergan	

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	Lexapro		S						Allergan
	Ativan		C	Oral		Unk			Not Reported
	Ativan		C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843038	NON-EXPEDITED			US-ALLERGAN-1920772US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission; Stress; Weight Increased	Lexapro			S	Unknown	10 Mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843039	NON-EXPEDITED			US-ALLERGAN-1924175US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Restlessness	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843040	NON-EXPEDITED			US-ALLERGAN-1924441US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Muscle Spasms; Off Label Use; Tinnitus	Lexapro			S	Unknown			Allergan	
	Klonopin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843041	NON-EXPEDITED			US-ALLERGAN-1929170US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
	Ciprofloxacin			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843042	NON-EXPEDITED			US-ALLERGAN-1928579US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dyspnoea; Product Taste Abnormal; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	20 Mg, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843043	NON-EXPEDITED			US-ALLERGAN-1928624US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843044	NON-EXPEDITED			US-ALLERGAN-1929184US		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Mood; Drug Ineffective; Incorrect Dose Administered; Product Label Issue	Lexapro			S	Oral	20 Mg, Qhs		Allergan	
	Paxil			C	Unknown	Unk		Not Reported	
	Paxil			C				Not Reported	
	Prozac			C	Unknown	Unk		Not Reported	
	Prozac			C				Not Reported	
	Synthroid			C		Unk		Not Reported	
	Oxycodone			C				Not Reported	
	Gabapentin			C				Not Reported	
	Lorazepam			C		Unk		Not Reported	
	Vitamin B12			C				Not Reported	
	Centrum			C				Not Reported	
	Omega-3			C				Not Reported	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843047	NON-EXPEDITED			US-ALLERGAN-1927456US		48 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue	Escitalopram Oxalate Unk			S		Unk		Allergan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843048	NON-EXPEDITED			US-ALLERGAN-1929460US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event; Anxiety; Asthenia; Burning Sensation; Decreased Appetite	Lexapro			S	Unknown	Unk		Allergan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843049	NON-EXPEDITED			US-ALLERGAN-1929540US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dizziness	Escitalopram Oxalate - Bp			S		10 Mg		Allergan	
	Tramadol			S		50 Mg		Not Reported	
	Lyrica			S		20 Mg		Not Reported	
	Valium			S		5 Mg		Not Reported	
	Lidocaine			C	Topical	5%		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843050	NON-EXPEDITED			US-ALLERGAN-1925713US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Mania	Lexapro			S	Unknown			Allergan	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843051	NON-EXPEDITED			US-ALLERGAN-1927738US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tardive Dyskinesia	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843052	NON-EXPEDITED			US-ALLERGAN-1925291US		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Product Dispensing Error	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843053	NON-EXPEDITED			US-ALLERGAN-1926263US		21 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abnormal Behaviour; Drug Ineffective	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843054	NON-EXPEDITED			US-ALLERGAN-1928834US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Crying; Depressed Mood; Drug Ineffective	Lexapro			S	Oral			Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843055	NON-EXPEDITED			US-ALLERGAN-1928574US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Erythema; Flushing		Escitalopram Oxalate Unk		S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843056	NON-EXPEDITED			US-ALLERGAN-1928886US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Lethargy	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843057	NON-EXPEDITED			US-ALLERGAN-1926061US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia; Asthenia; Decreased Appetite; Decreased Interest; Disturbance In Attention; Feeling Guilty; Headache; Hypersomnia; Major Depression; Memory Impairment; Palpitations; Panic Attack; Post-Traumatic Stress Disorder; Psychomotor Retardation; Slow Speech; Suicidal Ideation	Lexapro			S	Unknown	20 Mg		Allergan	
	Venlafaxine			S	Unknown	150 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843058	NON-EXPEDITED			US-ALLERGAN-1928760US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dental Caries; Feeling Abnormal; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843059	NON-EXPEDITED			US-ALLERGAN-		98 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Aggression; Agitation; Drug Ineffective; Drug Intolerance; Mental Disorder	Lexapro			S	Oral	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843060	NON-EXPEDITED			US-ALLERGAN-1929350US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Drug Hypersensitivity	Lexapro			S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843062	NON-EXPEDITED			US-ALLERGAN-1926160US		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nephrolithiasis	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843063	NON-EXPEDITED			US-ALLERGAN-1927667US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Hallucination	Escitalopram Oxalate Unk			S		Unk		Allergan	
	Apokyn			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843064	NON-EXPEDITED			US-ALLERGAN-1929178US		23 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sexual Dysfunction	Lexapro			S	Unknown	Unk		Allergan	
	Latuda			S	Oral	40 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843065	NON-EXPEDITED			US-ALLERGAN-1927905US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Crying; Drug Ineffective; Feeling Abnormal; Heart Rate Increased; Homeless; Hyperhidrosis; Impaired Work Ability; Memory Impairment; Panic Attack; Tremor	Lexapro			S	Unknown	Unk, Unknown		Allergan	
	Abilify			S	Unknown	5 Mg, Unknown		Not Reported	
	Abilify			S	Unknown	2 Mg, Unknown		Not Reported	
	Abilify			S	Unknown	Unk		Not Reported	
	Gabapentin			S	Unknown	Unk, Unknown		Not Reported	
	Aripiprazole			S	Unknown	Unk Unk, Unknown		Not Reported	
	Lithium			C				Not Reported	
Paxil			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843068	NON-EXPEDITED			US-ALLERGAN-1930999US		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Disturbance In Attention; Dizziness; Feeling Abnormal; Growth Retardation; Headache	Escitalopram Oxalate Unk			S	Oral	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843069	NON-EXPEDITED			US-ALLERGAN-1933012US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hyperhidrosis; Nausea	Lexapro			S	Unknown	10 Mg		Allergan	
	Lexapro			S				Allergan	

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Escitalopram Oxalate Unk	S	Unknown	10 Mg, Unk	Allergan
Escitalopram Oxalate Unk	S			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843070	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1930328US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis	Escitalopram Oxalate Unk			S	Unknown			Allergan
	Estradiol Unk			S	Unknown			Allergan
	Genotropin Miniquik			S	Subcutaneous	0.6 Mg, Qd		Not Reported
	Hizentra			S	Unknown			Not Reported
	Hydrocortisone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported
	Nascobal			S	Unknown			Not Reported
	Promethazine			S	Unknown			Not Reported
	Montelukast Sodium			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported
	Acyclovir			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Rizatriptan			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Acetaminophen And Codeine			S	Unknown			Not Reported
	Levoxyl			S	Unknown			Not Reported
	Liothyronine Sodium			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Proair Hfa			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843072	NON-EXPEDITED			US-ALLERGAN-1932796US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Incorrect Dose Administered; Insomnia; Paraesthesia; Paraesthesia; Product Dose Omission; Withdrawal Syndrome	Lexapro			S	Unknown	5 Mg		Allergan	
	Lexapro			S	Unknown	10 Mg		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843073	NON-EXPEDITED			US-ALLERGAN-1930556US		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Irregular; Insomnia; Product Dose Omission; Sleep Disorder; Therapeutic Response Unexpected	Lexapro			S	Oral	5 Mg, Qam		Allergan	
	Sinemet			C	Oral	25/250 Every Bedtime		Not Reported	
	Rytari Er			C	Oral	48.75 Mg Qid(6 Am, Noon, 2 Pm And Dinner Time		Not Reported	
	Synthroid			C	Oral	Unk		Not Reported	
	Atorvastatin			C	Oral	Unk		Not Reported	
	Armodafinil			C		Unk		Not Reported	
	Move Free (Glucosaminechondroitin)			C	Oral	Unk		Not Reported	
	Stool Softener(Unspecified)			C	Oral	Unk		Not Reported	
	Coq 10			C	Oral	Unk		Not Reported	
	Multi-Vitamin (Unspecified)			C	Oral	Unk		Not Reported	
	Ginko Biloba			C	Oral	Unk		Not Reported	
	Saw Palmetto			C	Oral	Unk		Not Reported	
	Namzaric			C	Oral	28/10 Mg At Bedtime		Not Reported	
	Melatonin			C	Oral	Unk		Not Reported	
	Tadalafil			C	Oral	Unk		Not Reported	

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24-Sep-2019	16843074	NON-EXPEDITED			US-ALLERGAN-1930079US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843075	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1931550US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia; Platelet Count Decreased; Tinnitus	Lexapro			S		10 Mg, Qd		Allergan	
	Lexapro			S		20 Mg, Qd		Allergan	
	Ibrance			S		75 Mg		Not Reported	
	Ibrance			S		100 Unk		Not Reported	
	Ibrance			S		125 Mg		Not Reported	
	Zofran			C		4 Mg, Prn		Not Reported	
	Ativan			C		0.5 - 1 Mg Prn		Not Reported	
	Ativan			C				Not Reported	
	Tylenol			C		500 Mg, Prn		Not Reported	
	Tizanidine			C		Unk, Prn		Not Reported	
	Drobranol			C		2.5 Mg, Prn		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843076	NON-EXPEDITED			US-ALLERGAN-1932878US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nightmare	Lexapro			S	Unknown	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843077	NON-EXPEDITED			US-ALLERGAN-1930986US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration; Oesophageal Ulcer	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843078	NON-EXPEDITED			US-ALLERGAN-1932516US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Blood Pressure Fluctuation; Off Label Use; Palpitations	Lexapro			S				Allergan	
	Cymbalta			S				Not Reported	
	Xeljanz			C		5 Mg, Bid		Not Reported	
	Aspirin 81			C				Not Reported	
	Biotin			C				Not Reported	
	Caltrate			C				Not Reported	
	Prilosec			C				Not Reported	
	Vitamin B12			C				Not Reported	
	Meloxicam			C		7.5 Mg		Not Reported	
	Folic Acid			C		1 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843079	NON-EXPEDITED			US-ALLERGAN-1931526US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843080	NON-EXPEDITED			US-ALLERGAN-1931271US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abnormal Behaviour;	Escitalopram Oxalate Unk	S	30 Mg, Qd	Allergan
Feeling Jittery; Off Label Use; Wrong Technique In Product Usage Process	Escitalopram Oxalate Unk	S		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843082	NON-EXPEDITED			US-ALLERGAN-1850462US		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Somnolence	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843083	NON-EXPEDITED			US-ALLERGAN-1845685US		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	40 Unk, Unk		Allergan	
	Lexapro			S	Unknown	30 Mg, Qd		Allergan	
	Lexapro			S	Unknown	20 Mg, Unk		Allergan	
	Lexapro			S	Unknown	15 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843084	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1846326US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Depression; Drug Ineffective; Suicide Attempt	Lexapro			S	Oral	Unk, Unknown		Allergan	
	Latuda			C	Oral	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843085	NON-EXPEDITED			US-ALLERGAN-1933027US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Diarrhoea; Dyspepsia; Rash; Sexual Dysfunction		Lexapro	S		Allergan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843086	NON-EXPEDITED			US-ALLERGAN-1931527US		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843087	NON-EXPEDITED			US-ALLERGAN-1856562US		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Asthenia; Diplopia; Dizziness; Fatigue; Headache; Insomnia; Malaise; Movement Disorder; Somnolence; Vision Blurred; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
	Plavix			C		Unk		Not Reported	
	Norvasc			C		Unk		Not Reported	
	Incontinence Medication			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843088	NON-EXPEDITED			US-ALLERGAN-1840023US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
	Plaquenil			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843089	NON-EXPEDITED			US-ALLERGAN-1840810US		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Off Label Use	Lexapro	S	Oral	20 Mg, Tid	Allergan
	Diazepam	C	Oral	10 Mg, Qid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843091	NON-EXPEDITED			US-ALLERGAN-1846261US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Crying; Decreased Appetite; Disorientation; Fear; Feeling Abnormal; Food Intolerance; Nervousness; Nightmare; Off Label Use; Paraesthesia; Restlessness; Suicidal Ideation	Lexapro			S	Oral	5 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843092	NON-EXPEDITED			US-ALLERGAN-1844987US		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Constipation; Gastritis; Hiatus Hernia; Irritable Bowel Syndrome; Rash	Lexapro			S	Oral	1 Df, Qd		Allergan
	Pristiq			S	Unknown	25 Mg, Unk		Not Reported
	Levothyroxine			C	Oral	75 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	40 Mg, Qd		Not Reported
	Cardizem			C	Oral	240 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843094	NON-EXPEDITED			US-ALLERGAN-1842604US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Intentional Dose Omission	Lexapro			S	Oral	10 Mg, Unk		Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843095	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1851387US		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Expired Product Administered; Suicidal Ideation; Wrong Technique In Product Usage Process	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Meloxicam			C	Oral	40 Mg, Qpm		Not Reported	
	Synthroid			C	Oral	75 Mg, Qam		Not Reported	
	Simvastatin			C	Oral	40 Mg, Qd (At Lunch)		Not Reported	
	Mobic			C	Unknown	Unk		Not Reported	
	Allegra			C	Oral	Unknown		Not Reported	
	Triamterene			C	Oral	37.5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843096	NON-EXPEDITED			US-ALLERGAN-1855567US		19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843097	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1844958US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mood Altered; Seizure; Vision Blurred	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843098	NON-EXPEDITED			US-ALLERGAN-1846503US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Feeling Jittery; Product	Lexapro	S	Unknown	20 Mg, Unk	Allergan
Dose Omission; Vomiting	Lexapro	S	Unknown	10 Mg, Unk	Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843099	NON-EXPEDITED			US-ALLERGAN-1846224US		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Vision	Lexapro			S	Unknown	5 Mg, Unk		Allergan
Blurred; Wrong Technique	Lexapro			S	Unknown	10 Mg, Unk		Allergan
In Product Usage Process	Gabapentin			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Vit D			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843100	NON-EXPEDITED			US-ALLERGAN-1855709US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lexapro			S	Unknown	10 Mg, Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843101	NON-EXPEDITED			US-ALLERGAN-1840830US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Somnambulism	Lexapro			S	Unknown			Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843102	NON-EXPEDITED			US-ALLERGAN-1840809US		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Gait Inability; Movement Disorder; Somnambulism; Somnolence	Lexapro	S	Unknown	Unk Unk, Qd	Allergan
	Xeljanz	S	Oral	11 Mg, Qd	Not Reported
	Simponi	C		Unk	Not Reported
	Meloxicam	C	Oral	15 Mg, Qd	Not Reported
	Novolog	C		100 MI, Unk	Not Reported
	Lantus	C	Subcutaneous	15 Units, Qd	Not Reported
	Humalog	C	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843103	NON-EXPEDITED			US-ALLERGAN-1845145US		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Menstrual Disorder	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843104	NON-EXPEDITED			US-ALLERGAN-1843348US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Irritability; Nausea	Lexapro			S	Unknown	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843105	NON-EXPEDITED			US-ALLERGAN-1854268US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Sleep Disorder	Lexapro			S	Oral	20 Mg, Qd		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843106	NON-EXPEDITED			US-ALLERGAN-1844698US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Adverse Reaction; Drug Ineffective		Lexapro	S	Oral	Unk	Allergan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843107	NON-EXPEDITED			US-ALLERGAN-1841799US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843108	NON-EXPEDITED			US-ALLERGAN-1852402US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Lexapro			S	Unknown	30 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843109	NON-EXPEDITED			US-ALLERGAN-1852086US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Storage Error	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843110	NON-EXPEDITED			US-ALLERGAN-1856219US		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Lexapro			S	Unknown			Allergan	
Abdominal Pain;	Ampyra			S	Oral	10 Mg, Q12h		Not Reported	
Abdominal Pain Upper;	Tecfidera			S	Unknown	240 Mg, Qd		Not Reported	
Back Pain; Balance Disorder; Burning Sensation; Constipation; Decreased Appetite; Depression; Faeces	Tecfidera			S	Unknown	240 Mg, Bid		Not Reported	

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Discoloured; Feeling
Abnormal; Insomnia;
Muscular Weakness;
Nausea; Neck Pain;
Pruritus

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24-Sep-2019	16843111	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1849523US		20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Depressed Mood; Drug Dose Titration Not Performed; Fatigue; Lethargy; Suicidal Ideation	Lexapro			S	Unknown	Unk		Allergan
	Brexiprazole			S	Oral	2 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843112	NON-EXPEDITED			US-ALLERGAN-1843319US		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Fatigue; Pruritus Generalised	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Obeticholic Acid			S	Oral	5 Mg, Qd		Not Reported
	Obeticholic Acid			S	Oral	5 Mg, Qd		Not Reported
	Obeticholic Acid			S	Oral	10 Mg, Qd		Not Reported
	Aczone			C	Unknown	Unk		Not Reported
	Calcium Carbonate/ Vitamin D3			C	Unknown	Unk		Not Reported
	Estrace			C	Unknown	Unk		Not Reported
	Lofibra			C	Unknown	Unk		Not Reported
	Bactroban			C	Unknown	Unk		Not Reported
	Percocet			C	Unknown	Unk		Not Reported
	Deltasone			C	Unknown	Unk		Not Reported
	Ultracet			C	Unknown	Unk		Not Reported
	Actigall			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843117	NON-EXPEDITED			US-ALLERGAN-1903662US		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot; Hot Flush; Menopause; Palpitations; Sleep Disorder	Lexapro			S	Oral	10 Mg, Qhs		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843118	NON-EXPEDITED			US-ALLERGAN-1847504US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Incorrect Dose Administered; Off Label Use; Saliva Altered; Wrong Technique In Product Usage Process	Lexapro			S	Oral	7.5 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843120	NON-EXPEDITED			US-ALLERGAN-1902653US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Decreased	Lexapro			S	Unknown	20 Mg, Qd		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843121	NON-EXPEDITED			US-ALLERGAN-1844246US		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nervousness	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Aubagio			S	Oral	14 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843122	NON-EXPEDITED			US-ALLERGAN-1902322US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Tenderness	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Nexium			C	Unknown	Unk		Not Reported	
	Antihypertensives			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843126	NON-EXPEDITED			US-ALLERGAN-1901454US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Feeling Abnormal; Insomnia; Nausea	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843127	NON-EXPEDITED			US-ALLERGAN-1847536US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Ejaculation Disorder; Fatigue; Hallucination, Auditory	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843128	NON-EXPEDITED			US-ALLERGAN-1900616US		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Product Dose Omission	Lexapro	S	Unknown	10 Mg, Qd	Allergan
	Vraylar	C	Unknown	3 Mg, Qd	Not Reported
	Phentermine	C	Unknown	35 Mg, Qd	Not Reported
	Cocaine	C	Unknown	Unk (Abuse)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843129	NON-EXPEDITED			US-ALLERGAN-1901102US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown	Unknown		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843130	NON-EXPEDITED			US-ALLERGAN-1846516US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Breast Feeding	Lexapro			S	Transmammary	20 Mg, Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843132	NON-EXPEDITED			US-ALLERGAN-1902016US		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Fear; Feeling Abnormal; Thinking Abnormal	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843133	NON-EXPEDITED			US-ALLERGAN-1902324US		73 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Breast Pain; Breast Tenderness	Lexapro	S	Oral	20 Mg, Unk	Allergan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843134	NON-EXPEDITED			US-ALLERGAN-1900970US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mood Altered	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843135	NON-EXPEDITED			US-ALLERGAN-1847841US		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Off Label Use	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
	Aubagio			C	Oral	14 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843136	NON-EXPEDITED			US-ALLERGAN-1903501US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843137	NON-EXPEDITED			US-ALLERGAN-1849497US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Suicidal Ideation; Tremor	Lexapro			S	Unknown	30 Mg, Unk		Allergan	

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24-Sep-2019	16843139	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1902138US		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Lexapro			S	Unknown	Unk		Allergan	
	Northera			S	Oral	2 Capsules (600 Mg) In The Morning And 1 Capsule (300 Mg) At Noon		Not Reported	
	Tegretol			S	Unknown			Not Reported	
	Sodium Chloride			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843140	NON-EXPEDITED			US-ALLERGAN-1851106US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843141	NON-EXPEDITED			US-ALLERGAN-1900121US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843142	NON-EXPEDITED			US-ALLERGAN-1858292US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Inflammation; Pain	Lexapro			S	Unknown	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843143	NON-EXPEDITED			US-ALLERGAN-1906382US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843145	NON-EXPEDITED			US-ALLERGAN-1905614US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843146	NON-EXPEDITED			US-ALLERGAN-1859670US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Lisinopril			S	Unknown	Unk		Not Reported	
	Atenolol			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Not Reported	
	Calcium Channel Blockers			S	Unknown	Unk		Not Reported	
	Penicillin G			S	Unknown	Unk		Not Reported	
	Penicillins With Extended Spectrum			S	Unknown	Unk		Not Reported	
	Simvastatin			S	Unknown	Unk		Not Reported	
	Sulfacetamide Sodium			S	Unknown	Unk		Not Reported	
	Lovastatin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843147	NON-EXPEDITED			US-ALLERGAN-1905405US			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843148	NON-EXPEDITED			US-ALLERGAN-1858388US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Pruritus; Urticaria	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843149	NON-EXPEDITED			US-ALLERGAN-1906008US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Lexapro			S	Oral			Allergan	
	Wellbutrin			C	Oral	150 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843151	NON-EXPEDITED			US-ALLERGAN-1857514US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tremor	Lexapro			S	Unknown	Unk		Allergan	
	Repatha			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843152	NON-EXPEDITED			US-ALLERGAN-1900325US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Unknown	Unk		Allergan	
	Brexiprazole			S	Oral	2 Mg, Qd		Not Reported	

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Effexor			S		Unknown		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
24-Sep-2019	16843153	NON-EXPEDITED			US-ALLERGAN-1857439US			Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Sleep Disorder; Tinnitus	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
24-Sep-2019	16843154	NON-EXPEDITED			US-ALLERGAN-1906259US			Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Condition Aggravated	Lexapro			S	Unknown	Unk		Allergan		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
24-Sep-2019	16843155	NON-EXPEDITED			US-ALLERGAN-1906078US			Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Weight Fluctuation	Lexapro			S	Unknown	Unk		Allergan		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
24-Sep-2019	16843156	NON-EXPEDITED			US-ALLERGAN-1906513US			Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Drug Ineffective	Lexapro			S	Unknown	20 Mg, Unk		Allergan		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
24-Sep-2019	16843158	NON-EXPEDITED			US-ALLERGAN-1905925US			Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		

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Malaise	Lexapro		S	Unknown	Unk			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843159	NON-EXPEDITED			US-ALLERGAN-1906438US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Trintellix			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843160	NON-EXPEDITED			US-ALLERGAN-1857461US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Intentional Dose Omission; Migraine; Product Dose Omission; Sinus Disorder	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
	Lexapro			S	Unknown	10 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843161	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1857483US		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tremor	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan	
	Repatha			S	Unknown	140 Mg, Q2weeks		Not Reported	
	Levothyroxine			S	Unknown	0.5 Unk, Qd		Not Reported	
	Beta Blocker			C	Unknown	Unk, Unknown		Not Reported	
	Statins			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843162	NON-EXPEDITED			US-ALLERGAN-1906339US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Oral Mucosal Blistering		Escitalopram Oxalate Unk		S	Oral		Unk		Allergan
		Escitalopram Oxalate Unk		S					Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843164	NON-EXPEDITED			US-ALLERGAN-1858338US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Dose Omission; Off Label Use	Lexapro			S	Unknown	5 Mg, Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843165	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1905906US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicidal Ideation	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan	
	Levothyroxine			C	Oral	75 Mg, Qd		Not Reported	
	Atorvastatin			C	Oral	40 Mg, Qhs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843166	NON-EXPEDITED			US-ALLERGAN-1905323US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Decreased Appetite; Depressed Mood; Drug Ineffective; Haemorrhage; Weight Decreased	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Razepam			S	Unknown	Unk		Not Reported	
	Xanax			S	Unknown	Unk		Not Reported	
	Prempro			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843167	NON-EXPEDITED			US-ALLERGAN-1900308US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan
	Escitalopram Oxalate - Bp	S				Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843168	EXPEDITED (15-DAY)		HO	US-ALLERGAN-1856769US		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Off Label Use	Lexapro			S	Oral	10 Mg, Qd		Allergan
	Metformin			S	Oral	1000 Mg, Bid		Not Reported
	Lisinopril			S	Oral	20 Mg, Qd		Not Reported
	Trazodone			S	Oral	100 Mg, Qd		Not Reported
	Trazodone			S	Oral	50 Mg, Qd		Not Reported
	Glyburide			C		Unk		Not Reported
	Gemfibrozil			C		Unk		Not Reported
	Pravachol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Combivent			C		Unk		Not Reported
	Valium			C		Unk		Not Reported
	Victoza			C		Unk		Not Reported
	Lunesta			C		Unk		Not Reported
	Anorol			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Proair			C		Unk		Not Reported
	Medizime			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843170	NON-EXPEDITED			US-ALLERGAN-1857618US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission	Lexapro			S	Oral	Unk		Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843172	NON-EXPEDITED			US-ALLERGAN-1904221US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Trokendi Xr			C	Oral	200 Mg, Qd		Not Reported	
	Lamictal			C	Oral	150mg 2 Tablets Once A Day		Not Reported	
	Lamictal Invokamet			C C	Oral	150/500mg Tablet Twice A Day		Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843173	NON-EXPEDITED			US-ALLERGAN-1904459US		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843175	NON-EXPEDITED			US-ALLERGAN-1907218US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843177	NON-EXPEDITED			US-ALLERGAN-1904289US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Oral	10 Mg, Qd		Allergan	
	Lexapro			S	Oral	Unk		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843178	NON-EXPEDITED			US-ALLERGAN-1907738US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Response Decreased; Wrong Technique In Product Usage Process	Lexapro			S	Unknown	10 Mg, Unk		Allergan
	Protonix			C		40 Mg		Not Reported
	Gabapentin			C	Oral	300 Mg, Tid		Not Reported
	Meloxicam			C		15 Mg		Not Reported
	Cyclobenzaprine			C		10 Mg		Not Reported
	Calcium			C		1200 Mg		Not Reported
	Clonazepam			C		0.5 Mg, Prn		Not Reported
	Clonazepam			C				Not Reported
	Oxycodone / Acetaminophen			C		7.5-325mg As Needed		Not Reported
	Tylenol			C		325 Mg		Not Reported
	Aspirin			C		325 Mg		Not Reported
	Centrum Silver			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843179	NON-EXPEDITED			US-ALLERGAN-1903719US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypersensitivity; Nausea; Off Label Use; Vomiting	Lexapro			S	Unknown	Unk		Allergan
	Amitriptyline			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Effexor			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843181	NON-EXPEDITED			US-ALLERGAN-1908037US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fear; Feeling Abnormal; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843182	NON-EXPEDITED			US-ALLERGAN-1907295US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Abnormal	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843183	NON-EXPEDITED			US-ALLERGAN-1907308US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pregnancy; Premature Labour	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843184	NON-EXPEDITED			US-ALLERGAN-1907747US		58 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Somnolence	Lexapro			S	Unknown	Unk		Allergan	
	Effexor			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843185	NON-EXPEDITED			US-ALLERGAN-1904314US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Ejaculation Delayed; Erectile Dysfunction	Escitalopram Oxalate - Bp	S	Unknown	Unk		Allergan			
	Escitalopram Oxalate - Bp	S	Unknown	20 Mg, Unk		Allergan			
	Escitalopram Oxalate - Bp	S	Unknown	10 Mg, Unk		Allergan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843186	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1904096US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Interaction; Serotonin Syndrome	Lexapro			S	Unknown	Unk (Low Dose)		Allergan	
	Dextromethorphan Hydrobromide W/Guaifenesin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843188	NON-EXPEDITED			US-ALLERGAN-1907369US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorgasmia	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843189	NON-EXPEDITED			US-ALLERGAN-1907906US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Tacrolimus			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843190	NON-EXPEDITED			US-ALLERGAN-1907367US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843191	NON-EXPEDITED			US-ALLERGAN-1907907US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843192	NON-EXPEDITED			US-ALLERGAN-1907398US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Feeling Abnormal	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Unk		Allergan	
	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Unk		Allergan	
	Levothyroxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843193	NON-EXPEDITED			US-ALLERGAN-1904111US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843194	NON-EXPEDITED			US-ALLERGAN-1908483US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Lexapro			S	Unknown			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843195	NON-EXPEDITED			US-ALLERGAN-1907894US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Pain; Drug Ineffective; Gastroenteritis; Malaise		Lexapro	S	Unknown	Unk	Allergan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843196	NON-EXPEDITED			US-ALLERGAN-1904727US		16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843197	NON-EXPEDITED			US-ALLERGAN-1907407US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retching; Vomiting	Escitalopram Oxalate Unk			S	Unknown	Unk		Allergan	
	Metronidazole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843198	NON-EXPEDITED			US-ALLERGAN-1907563US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Tremor	Lexapro			S	Unknown	100 Mg, Unk		Allergan	
	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843199	NON-EXPEDITED			US-ALLERGAN-1904539US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Jittery; Headache; Muscle Spasms; Musculoskeletal Stiffness;	Lexapro			S	Unknown	Unk		Allergan	

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Palpitations; Panic Attack;
Tachyphrenia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843200	NON-EXPEDITED			US-ALLERGAN-1905295US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Migraine; Off Label Use	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843202	NON-EXPEDITED			US-ALLERGAN-1904272US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dizziness; Nausea; Paraesthesia	Lexapro			S	Oral	10 Mg, Unk		Allergan	
	Lexapro			S	Oral	20 Mg, Qd		Allergan	
	Blood Pressure Pill			C	Oral	Unk		Not Reported	
	Klonopin			C	Oral	Unk Unk, Qhs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843203	NON-EXPEDITED			US-ALLERGAN-1907213US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Gastrooesophageal Reflux Disease; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843205	NON-EXPEDITED			US-ALLERGAN-1907074US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea;	Lexapro			S	Unknown	Unk		Allergan	

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Hypersensitivity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843206	NON-EXPEDITED			US-ALLERGAN-1904537US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression	Lexapro			S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843207	NON-EXPEDITED			US-ALLERGAN-1908570US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use	Lexapro			S	Unknown	40 Mg, Unk		Allergan	
	Lexapro			S				Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843208	NON-EXPEDITED			US-ALLERGAN-1909392US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843209	NON-EXPEDITED			US-ALLERGAN-1909048US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Hyperhidrosis	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843210	NON-EXPEDITED			US-ALLERGAN-1909786US			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Anxiety; Drug Ineffective; Headache; Insomnia		Lexapro	S	Oral	1/4 Of A 20mg Tablet, Qd			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843211	NON-EXPEDITED			US-ALLERGAN-1906738US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843212	NON-EXPEDITED			US-ALLERGAN-1909233US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan	
	Trazodone			S	Unknown	Unk		Not Reported	
	Duloxetine			C	Oral	30 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843213	NON-EXPEDITED			US-ALLERGAN-1908978US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Lexapro			S	Unknown	Unk		Allergan	
	Xanax			C		Unk		Not Reported	
	Flexeril			C		Unk		Not Reported	
	Flexeril			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843214	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1910841US		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased	Lexapro			S	Oral	Unk		Allergan	

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843215	NON-EXPEDITED			US-ALLERGAN-1906571US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Crying; Feeling Abnormal; Food Refusal; Insomnia	Lexapro			S	Unknown			Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843216	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1908508US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dizziness; Hallucination	Lexapro			S	Unknown	Unk		Allergan	
	Lorazepam			C	Unknown	0.5 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843217	NON-EXPEDITED			US-ALLERGAN-1909242US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Insomnia; Panic Attack	Lexapro			S	Unknown	Unk, Unknown		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843218	NON-EXPEDITED			US-ALLERGAN-1909043US		75 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Swelling	Lexapro			S	Unknown	Unk		Allergan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843219	NON-EXPEDITED			US-ALLERGAN-1908061US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Drug Ineffective; Off Label Use	Lexapro	S	Unknown	40 Mg	Allergan
	Xanax	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843220	NON-EXPEDITED			US-ALLERGAN-1909627US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Lexapro			S				Allergan	
	Lexapro			S				Allergan	
	Lamotrigine			S				Not Reported	
	Lamotrigine			S				Not Reported	
	Buspirone			S				Not Reported	
	Buspirone			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843221	NON-EXPEDITED			US-ALLERGAN-1909295US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843222	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1909040US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Escitalopram Oxalate Unk			S	Unknown			Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843223	NON-EXPEDITED			US-ALLERGAN-1906556US		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Erythema; Off Label Use; Pruritus; Somnolence	Lexapro			S	Oral	30 Mg, Qd		Allergan	
	Cholesterol			C	Oral	Unk		Not Reported	

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Blood Pressure Medication			C		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Sep-2019	16843224	NON-EXPEDITED			US-ALLERGAN-1908558US			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro				S	Unknown	Unk		Allergan	
	Lexapro				S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Sep-2019	16843225	NON-EXPEDITED			US-ALLERGAN-1909014US			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Headache	Lexapro				S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Sep-2019	16843226	NON-EXPEDITED			US-ALLERGAN-1908490US			Male	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Drug Ineffective; Off Label Use	Lexapro				S	Unknown	30 Mg		Allergan	
	Lexapro				S	Unknown	20 Mg, Qd		Allergan	
	Xanax				C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Sep-2019	16843227	NON-EXPEDITED			US-ALLERGAN-1907068US		31 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Confusional State; Dizziness; Fatigue; Hyperhidrosis; Hypertension; Myalgia;	Escitalopram Oxalate Unk				S	Oral	20 Mg, Qpm		Allergan	
	Abilify				S	Oral	5 Mg, Qam		Not Reported	

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Panic Disorder; Salivary
Hypersecretion; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843228	NON-EXPEDITED			US-ALLERGAN-1906864US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue; Headache; Pharyngeal Swelling	Lexapro			S	Unknown	Unk		Allergan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843229	NON-EXPEDITED			US-ALLERGAN-1909019US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression; Dissociation; Emotional Distress; Emotional Poverty; Laboratory Test Abnormal; Off Label Use; Spinal Disorder	Lexapro			S	Oral	10 Mg, Qd		Allergan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843230	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1909293US			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Myocardial Infarction	Lexapro			S				Allergan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843233	NON-EXPEDITED			US-ALLERGAN-1910882US			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843234	NON-EXPEDITED			US-ALLERGAN-1911728US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843235	NON-EXPEDITED			US-ALLERGAN-1913782US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Lexapro			S	Unknown	Unk Unk, Unknown		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843237	NON-EXPEDITED			US-ALLERGAN-1910927US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown	10 Mg		Allergan	
	Multivitamin			C				Not Reported	
	Vitamin D3			C		10000 Units		Not Reported	
	Glucosamine & Chondroitin			C				Not Reported	
	Magnesium			C		100 Mg		Not Reported	
	Effexor Xr			C		75 Mg, Qd		Not Reported	
	Methotrexate			C		2.5 Mg		Not Reported	
	Lyrica			C		100 Mg		Not Reported	
	Buspirone Hcl			C		15 Mg		Not Reported	
	Acyclovir			C		200 Mg		Not Reported	
	Folic Acid			C		1 Mg		Not Reported	
	Hydroxychloroquine Sulfate			C				Not Reported	
	Estradiol			C	Transdermal	0.025 Mg		Not Reported	

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Trazodone	C	100 Mg	Not Reported
Claritin	C	10 Mg	Not Reported
PriLOSEC	C	20 Mg	Not Reported
Meloxicam	C	15 Mg	Not Reported
Prednisone	C	1 Mg	Not Reported
Apriso	C	0.375 G, Sr 24 Hr	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843238	NON-EXPEDITED			US-ALLERGAN-1911553US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
	Lexapro			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843239	NON-EXPEDITED			US-ALLERGAN-1912793US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Jittery; Insomnia; Irritability; Tremor	Lexapro			S	Unknown	10 Mg, Qam		Allergan	
	Lexapro			S	Unknown	5 Mg, Qam		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843240	NON-EXPEDITED			US-ALLERGAN-1912358US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Depression; Thinking Abnormal	Escitalopram Oxalate - Bp			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843241	NON-EXPEDITED			US-ALLERGAN-1911058US		60 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Skin Burning Sensation	Lexapro			S	Unknown	Unk		Allergan	
	Venlafaxine Xr			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843243	NON-EXPEDITED			US-ALLERGAN-1912624US		92 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mania; Product Dose Omission; Restlessness	Lexapro			S	Unknown	10 Mg, Qd		Allergan	
	Lexapro			S	Unknown	5 Mg, Qd		Allergan	
	Heart Medication			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843244	NON-EXPEDITED			US-ALLERGAN-1914083US		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Overdose	Lexapro			S	Unknown	25 Df, Single (Or Almost The Whole Bottle)		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843245	NON-EXPEDITED			US-ALLERGAN-1914340US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843246	NON-EXPEDITED			US-ALLERGAN-1914031US		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Off Label Use; Somnolence;	Lexapro			S	Oral	5 Mg, Qd		Allergan	

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Tremor	Lexapro	S	Oral	5 Mg, Qam	Allergan
	Lexapro	S	Oral	5 Mg, Qpm	Allergan
	Ativan	C			Not Reported
	Gabapentin	C			Not Reported
	Lantus	C			Not Reported
	Atenolol	C			Not Reported
	Lisinopril	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843247	NON-EXPEDITED			US-ALLERGAN-1912288US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Lexapro			S	Unknown	Unk		Allergan
	Xanax			C		Unk		Not Reported
	Restoril /00054301/			C		Unk		Not Reported
	Cytomel			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Hydrocortisone			C		Unk		Not Reported
	Liothyronine			C		Unk		Not Reported
	Levonorgestrel			C		Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Temazepam			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Multivitamin /00097801/			C		Unk		Not Reported
	Omega 3 /01333901/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843249	NON-EXPEDITED			US-ALLERGAN-1912045US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Agitation; Anxiety; Diabetes Mellitus	Escitalopram Oxalate - Bp	S	Oral	0.5 Mg	Allergan
	Vortioxetine	S	Oral	10 Mg Tablet	Not Reported
	Brexpiprazole	S	Oral	3 Mg, Qd	Not Reported
	Brexpiprazole	S	Oral	0.5 Mg, Qd	Not Reported
	Prozac	C	Unknown	Unk	Not Reported
	Lamictal	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
	Deplin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843250	NON-EXPEDITED			US-ALLERGAN-1913904US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Lexapro			S	Unknown	Unk		Allergan	
	Vivitrol			S	Intramuscular	380 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843252	NON-EXPEDITED			US-ALLERGAN-1910931US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Escitalopram Oxalate Unk			S				Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843253	NON-EXPEDITED			US-ALLERGAN-1914540US			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843256	NON-EXPEDITED			US-ALLERGAN-1910925US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Escitalopram Oxalate - Bp			S	Unknown	10 Mg		Allergan	
	Miralax			C		17 G		Not Reported	
	Advil			C		Unk		Not Reported	
	Dilaudid			C		Unk		Not Reported	
	Imodium			C		Unk		Not Reported	
	Tylenol			C				Not Reported	
	Pantoprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843257	NON-EXPEDITED			US-ALLERGAN-1912459US		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Movement Disorder	Lexapro			S	Unknown	20 Mg		Allergan	
	Latuda			S	Oral	20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843258	NON-EXPEDITED			US-ALLERGAN-1913522US		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Incorrect Dose Administered; Paraesthesia	Escitalopram Oxalate - Bp			S	Unknown	30 Mg, Unk		Allergan	
	Trintellix			S	Unknown	20 Milligram		Not Reported	
	Trintellix			S	Unknown	10 Milligram		Not Reported	
	Trintellix			S	Unknown	5 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843259	NON-EXPEDITED			US-ALLERGAN-1913471US		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Application Site Pruritus; Fatigue; Somnolence	Lexapro			S				Allergan	

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	Daytrana		S	Transdermal	Unk			Not Reported	
	Tylenol		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843264	NON-EXPEDITED			US-ALLERGAN-1914342US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Lexapro			S	Unknown	Unk		Allergan	
	Nitrofurantoin Monohydrate Unk			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843266	NON-EXPEDITED			US-ALLERGAN-1914514US		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Depression; Hyperphagia; Weight Increased	Lexapro			S	Unknown	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843412	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060957		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Pantoprazole			S	Oral	40 Milligram, Daily		Aurobindo	
	Toviaz			S	Oral	4 Milligram, Daily		Not Reported	
	Aczone			C	Topical	Unk		Not Reported	
	Azithromycin			C	Unknown	500 Milligram, Daily		Not Reported	
	Azithromycin			S	Unknown	250 Milligram, Daily		Not Reported	
	Benzoyl Peroxide;Clindamycin Phosphate			C	Topical	Unk, Daily		Not Reported	
	Budesonide			C	Nasal	55 Microgram, Two Times A Day		Not Reported	
	Calcium			C	Oral	500 Milligram, 3 Times A		Not Reported	

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				Day	
Cipralex	S	Oral	Unk		Not Reported
Constella	C	Oral	290 Microgram, Daily		Not Reported
Fish Oil;Tocopherol	C	Oral	Unk		Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Oral	2000 International Unit, Daily		Not Reported
Flovent Hfa	C	Oral	250 Microgram, Two Times A Day		Not Reported
Genteal	C	Ophthalmic	Unk		Not Reported
Otrivin	C	Nasal	Unk Unk, Two Times A Day		Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Daily		Not Reported
Polyvinyl Alcohol;Povidone	C	Ophthalmic	2 Gtt Drops, Cyclical		Not Reported
Quetiapine Fumarate	C	Oral	25 Milligram, Two Times A Day		Not Reported
Quetiapine Fumarate	C	Oral	100 Milligram, Daily		Not Reported
Valproate Sodium	C	Oral	250 Milligram, 3 Times A Day		Not Reported
Synthroid	C	Oral	150 Microgram, Daily		Not Reported
Toviaz	C	Unknown	Unk		Not Reported
Tylenol	C	Oral	Unk Unk, 3 Times A Day		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Zinc Gluconate	C	Unknown	50 Milligram, Daily		Not Reported
Zyloprim	C	Oral	100 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843662	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1111021			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Autoscopy; Seizure	Promethazine Hydrochloride	S	At Night.	Actavis
	Olanzapine	S		Teva
	Folic Acid	S		Actavis
	Azathioprine	S		Not Reported
	Escitalopram	S		Ivax
	Dihydrocodeine	S		Not Reported
	Ferrous Fumarate	S		Not Reported
			Each Morning.	
			Four Times A Day. Take With Or Just After Food.	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843833	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-221714		14 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypotension; Malaise	Ibuprofen		Y	S	Oral	In Total		Ranbaxy
	Paracetamol			S	Oral	In Total		Ohm Lab
	Escitalopram			S	Oral	In Total		Not Reported
	Diane, Comprime Enrobe			S	Oral	In Total		Not Reported
	Cialis			S	Oral	In Total		Not Reported
	Diclofenac			S	Oral	In Total		Not Reported
	Colchicine			S	Oral	In Total		Not Reported
	Diazepam			S	Oral	In Total		Not Reported
	Donormyl [Doxylamine Succinate]			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844268	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022998			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pupils Unequal; Visual Impairment	Escitalopram			S	Oral	20 Milligram		Macleods
	Sertraline			S	Oral	50 Milligram		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16844421	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR171595			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankylosing Spondylitis; Drug Ineffective	Voltaren (Diclofenac Diethylammonium Salt)			S	Topical	Unk		Glaxosmithkline	
	Diclofenac Potassium			S		50 Mg, Unk		Glaxosmithkline	
	Escitalopram			S	Oral	20 Mg, Unk		Glaxosmithkline	
	Cimzia			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
	Naproxen Sodium			S		1000 Mg, Unk		Not Reported	
	Nortriptyline			S	Oral	25 Mg, Unk		Not Reported	
	Tylenol			S	Topical	Unk		Not Reported	
	Diclofenac			C		Unk		Not Reported	
	Infliximab			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16844613	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000665			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anuria; Atrial Fibrillation; Cardiac Arrest; Clonus; Coma Scale Abnormal; Depressed Level Of Consciousness; Drug Ineffective; Drug Interaction; Extensor Plantar Response; Eye Movement Disorder; Hyperkalaemia; Hyperreflexia; Hypertension;	Venlafaxine Hydrochloride			S		225 Milligram		Alembic	
	Clonidine Hydrochloride			S	Intravenous (not otherwise specified)	150 Milligram		Alembic	
	Clonidine Hydrochloride			S	Intravenous (not otherwise specified)	75 Milligram		Alembic	
	Metoprolol Tartrate			S	Intravenous (not otherwise specified)	4 Milligram		Alembic	
	Metoprolol Tartrate			S	Intravenous (not otherwise specified)	1 Mg		Alembic	

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Hypotension; Muscle Rigidity; Mydriasis; Myocardial Infarction; Nervous System Disorder; Renal Failure; Serotonin Syndrome; Tachypnoea; Ventricular Fibrillation; Ventricular Tachycardia	Metoprolol Tartrate	S	Intravenous (not otherwise specified)	2.5 Mg	Alembic
	Erythromycin	S		Unk	Not Reported
	Escitalopram	S		15 Milligram	Not Reported
	Escitalopram	S		Had Been Increased To Its Current Dose 3 Months Ago	Not Reported
	Insulin	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Sodium Bicarbonate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844685	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1938580US			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Product Use In Unapproved Indication; Serotonin Syndrome	Escitalopram Oxalate - Bp			S	Oral	Overdose With 40mg Of Escitalopram		Allergan
	Paroxetine			S	Oral	80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16846059	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1938542US			Male	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16846583	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113005		90 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Duloxetine			S	Unknown			Teva
	Escitalopram			S	Unknown			Ivax

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Venlafaxine Hydrochloride

S

Unknown

Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16846600	EXPEDITED (15-DAY)		DS	FR-009507513-1909FRA006068		77 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Subdural Haematoma	Inegy			S		Unk		Merck
	Nexium (Esomeprazole Magnesium)			S	Oral	1 Dosage Form, Qd		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Qd		Not Reported
	Seroplex			S	Oral	1 Dosage Form, Qd		Not Reported
	Keppra			C		Unk		Not Reported
	Tenormine			C		Unk		Not Reported
	Tiapridal			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16847189	EXPEDITED (15-DAY)		HO	SE-ALLERGAN-1000013800			Male	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Infarction	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Baklofen			C		10 Mg, Unk		Not Reported
	Brufen			C		600 Mg, Unk		Not Reported
	Alvedon			C		1000 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16847208	EXPEDITED (15-DAY)		LT	JP-ALLERGAN-1929470US			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt	Escitalopram Oxalate - Bp			S	Oral	20 Mg, Qd		Allergan

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Prolonged; Extrasystoles	Escitalopram Oxalate - Bp	S	Oral	10 Mg, Qd	Allergan
	Abilify	C	Oral		Not Reported
	Paxil Cr	C	Oral		Not Reported
	Thyradin	C	Oral	100 Mg, 100 Mg/ Day	Not Reported
	Solanax	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	15676892	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-980395		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Ramipril			S	Oral	2.5 Milligram Daily;		Actavis
	Lamotrigine			S	Oral	100 Milligram Daily; 100 Mg, Qd		Teva
	Exemestane			S	Oral	25 Milligram Daily; 25 Mg, Qd		Not Reported
	Gabapentine			S	Oral	200 Milligram Daily; 200 Mg, Qd		Actavis
	Lasilix 10 Mg/ML, Solution Buvable			S	Oral	20 Milligram Daily; 10 Mg/ML, Solution Buvable Lasilix 10 Mg/ML, Solution Buvable, 20 Mg, Qd		Not Reported
	Aspirine Protect 100 Mg, Comprimé Gastro-Résistant			S	Oral	100 Milligram Daily;		Not Reported
	Bisoce 1,25 Mg, Comprimé Pelliculé			S	Oral	1.25 Milligram Daily; 1.25 Mg, Qd		Not Reported
	Seroplex 5 Mg, Comprimé Pelliculé			S	Oral	5 Milligram Daily; 5 Mg, Qd		Not Reported
	Fluidabak 1,5 %, Collyre En Solution			C	Ophthalmic	3 Gtt Daily; 3 Gtt Drops, Qd		Not Reported
	Transipeg 5,9 G, Poudre Pour Solution Buvable En Sachet			C	Oral	11.8 Gram Daily; 11.8 G, Qd		Not Reported
	Gluconate De Potassium			C	Oral	1 Df, Qd (1 Cs Per Day)		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt Daily; 30 Gtt Drops,		Not Reported

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Qd

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16548382	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1072415		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Balance Disorder; Bradycardia; Dizziness; Drug Ineffective; Fall; Headache; Hypotension; Mobility Decreased; Nausea; Orthostatic Hypotension; Pain; Panic Attack; Sleep Disorder	Amlodipine Besilate			S	Unknown	2.5 Milligram Daily;		Teva
	Codeine			S	Unknown	60 Milligram Daily;		Not Reported
	Escitalopram			S	Unknown	10 Milligram Daily;		Ivax
	Escitalopram			S	Unknown			Ivax
	Furosemide			S	Unknown	40 Milligram Daily;		Not Reported
	Furosemide			S	Unknown	20 Milligram Daily;		Not Reported
	Metoprolol			S	Unknown	25 Milligram Daily;		Actavis
	Ramipril			S	Unknown	5 Milligram Daily;		Actavis
	Zopiclone			S	Unknown	2.5 Milligram Daily;		Not Reported
	Glyceryl Trinitrate			S	Transdermal	.8 Milligram Daily;		Not Reported
	Oxazepam			S	Unknown	20 Milligram Daily;		Not Reported
	Clopidogrel			C				Not Reported
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Ergocalciferol			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Rabeprazole			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16665276	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190744218		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen			S	Unknown			Not Reported
	Ibuprofen Hexal			S	Unknown			Not Reported

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Pantozol /01263204/	S	Unknown	Unk	Not Reported
Amitriptylin	S	Unknown	Unk	Not Reported
Metoprolol Hexal	S	Unknown		Not Reported
Escitalopram Stada	S	Unknown		Not Reported
Escitalopram Hexal	S	Unknown		Not Reported
Metoprolol Mylan /00376902/	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Escitalopram	S	Unknown		Not Reported
Metoprolol Stada	S	Unknown		Not Reported
Ibuhexal /00109201/	S	Unknown		Not Reported
Ibuprofen Stada	S	Unknown		Not Reported
Salbutamol Stada	S	Unknown		Not Reported
Escitalopram Mylan	S	Unknown		Not Reported
Prednisolon Stada	S	Unknown		Not Reported
Implanon	S	Unknown		Not Reported
Metoprolol /00376903/	S	Unknown	Unk	Not Reported
Prednisolon Jenapharm	S	Unknown		Not Reported
Prednisolon /00016201/	S	Unknown		Not Reported
Methotrexate Mylan	S	Unknown		Not Reported
Ibuprofen Hormosan	S	Unknown		Not Reported
Salbutamol	S	Unknown		Not Reported
Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
Fluticasone;Vilanterol	S	Unknown	6 Months Before Diagnosis	Not Reported
Ellipta	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16705928	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1075230		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Agranulocytosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia	Escitalopram	S	Oral	1 Dosage Form, Qd	Not Reported
	Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
	Lasilix Special /00032601/	S	Oral	2 Dosage Form, Qd	Mylan
	Spironolactone	C	Oral	Unk	Mylan
	Bisoprolol /00802602/	C		Unk	Mylan
	Coumadine	C	Oral	2 Dosage Form, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16727272	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-054120		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased;	Citalopram			S	Oral	Unk		Aurobindo
Blood Creatine Phosphokinase Increased;	Altace			S	Unknown	Unk		Not Reported
Blood Potassium Increased; Blood Pressure Decreased; Bradycardia;	Ciprallex			S	Unknown	10.0 Milligram, Daily		Not Reported
Coma; Coma Scale Abnormal; Drug Interaction; Drug Screen Positive;	Ciprallex			S	Oral	140.0 Milligram, Daily		Not Reported
Electrocardiogram Abnormal;	Ciprallex			S	Unknown	10.0 Milligram		Not Reported
Electrocardiogram Qt Prolonged; Heart Rate Decreased;	Diazepam			S	Oral	Unk		Not Reported
Hyperkalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness;	Diazepam			S	Oral	1800.0 Milligram		Not Reported
Mechanical Ventilation; Opiates Positive; Overdose; Oxygen Saturation Decreased;	Diazepam			S	Unknown	10.0 Milligram		Not Reported
Sinus Tachycardia; Suicide Attempt	Lorazepam			S	Oral	30.0 Milligram		Not Reported
	Lorazepam			S	Oral	1.0 Milligram		Not Reported
	Morphine			S	Oral	30.0 Milligram, Daily		Not Reported
	Morphine			S	Unknown	100.0 Milligram		Not Reported
	Morphine			S	Unknown	2640.0 Milligram		Not Reported
	Morphine			S	Unknown	420.0 Milligram		Not Reported
	Morphine			S	Unknown	9500.0 Milligram		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Morphine			S	Unknown	15.0 Milligram		Not Reported
	Morphine			S	Oral	30 Milligram, Once A Day		Not Reported

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Oxycodone	S	Unknown	10.0 Milligram	Not Reported
Oxycodone	S	Oral	Unk	Not Reported
Oxycodone	S	Oral	20.0 Milligram	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	S	Oral	Unk	Not Reported
Zopiclone	S	Unknown	7.5 Milligram	Not Reported
Zopiclone	S	Oral	187.5 Milligram	Not Reported
Zopiclone	S	Oral	15.0 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16728083	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-054119		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Tablets			S	Unknown	1.5 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets			S	Topical	1 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets			S	Unknown	Unk		Aurobindo
	Rosuvastatin Tablet			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Apo-Escitalopram			S	Unknown	1 Dosage Form, Daily		Not Reported
	Apo-Escitalopram			S	Unknown	Unk		Not Reported
	Ciclopirox Olamine			S	Unknown	1 Dosage Form		Not Reported
	Emo Cort			S	Topical	1 Dosage Form, Daily		Not Reported
	Mylan Nitro SI			S	Oral	Unk		Not Reported
	Synthroid			S	Unknown	1 Dosage Form, Daily		Not Reported
	Apo-Trazodone			S	Unknown	1 Dosage Form, Daily		Not Reported
	Brilinta			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Clonazepam			S	Unknown	1 Dosage Form, 3 Times A Day		Not Reported
	Delatestryl			S	Unknown	0.5 Milliliter, 1 Every 2 Weeks		Not Reported

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Delatestryl	S	Unknown	1 Dosage Form, 1 Every 2 Week	Not Reported
Dexilant	S	Unknown	1 Dosage Form, Daily	Not Reported
Dexilant	S	Unknown	0.5 Milliliter, Once A Day	Not Reported
Diltiazem	S	Unknown	1 Dosage Form, Daily	Not Reported
Jamp Asa	S	Unknown	1 Dosage Form, Daily	Not Reported
Metonia	S	Unknown	1 Dosage Form, 3 Times A Day	Not Reported
Mylan Nitro SI	S	Oral	Unk	Not Reported
Mylan Nitro SI	S	Oral	1 Dosage Form	Not Reported
Nasonex	S	Nasal	Unk, Daily	Not Reported
Nitro Dur	S	Unknown	1 Dosage Form, Daily	Not Reported
Ratio-Zopiclone	S	Unknown	1 Dosage Form	Not Reported
Apo Tamsulosin	S	Unknown	1 Dosage Form, Daily	Not Reported
Tevabisoprol	S	Unknown	1 Dosage Form, Daily	Not Reported
Bisoprolol Teva	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Nasonex	S	Nasal	Unk, Once A Day	Not Reported
Trazodone	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Triatec [Caffeine Citrate/Codeine Phosphate/Paracetamol]	S	Unknown	1 Dosage Form, Four Times/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16808805	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190905053			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Tylenol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form:Solution Subcutaneous		Not Reported

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Diclofenac Potassium	S	Unknown	Not Reported
Escitalopram	S	Oral	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Nortriptyline	S	Oral	Not Reported
Voltaren	S	Topical	Not Reported
Infliximab, Recombinant	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16825446	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2019-US-012826			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Chest Pain; Swelling; Weight Decreased	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Unkown Dose		Jazz
	Lexapro			S		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Carafate			C		Unk		Not Reported
	Isosorbide Mononite			C		Unk		Not Reported
	Meclizine Hcl			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Keflex-C			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported
	Diphenhydramine Hydrochloride			C		Unk		Not Reported
	Breo Ellipta			C		Unk		Not Reported
	Mucinex			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported

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Prednisone	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Levothyroxine	C	Unk	Not Reported
Hydrocodone/Acetaminophen	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Cyclobenzaprine	C	Unk	Not Reported
Benzotropine Mesilate	C	Unk	Not Reported
Lisinopril	C	Unk	Not Reported
Nystatin	C	Unk	Not Reported
Pantoprazole Sodium	C	Unk	Not Reported
Robaxin	C	Unk	Not Reported
Abilify	C	Unk	Not Reported
Advair	C	Unk	Not Reported
Allegra Allergy	C	Unk	Not Reported
Amerge	C	Unk	Not Reported
Anaprox	C		Not Reported
Bentyl	C	Unk	Not Reported
Depakote	C		Not Reported
Dexamethasone	C	Unk	Not Reported
Cyclobenzaprine Hydrochloride	C	Unk	Not Reported
Flonase Allergy Relief	C	Unk	Not Reported
Modafinil	C	Unk	Not Reported
Seroquel	C	Unk	Not Reported
Ventolin Hfa	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Neurontin	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Calcium + Magnesium	C	Unk	Not Reported
Fibercon	C	Unk	Not Reported

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Imodium	C	Unk	Not Reported
Klonopin	C	Unk	Not Reported
Loperamide Hydrochloride	C	Unk	Not Reported
Lunesta	C	Unk	Not Reported
Medrol Dosepak	C	Unk	Not Reported
Meloxicam	C	Unk	Not Reported
Methocarbamol	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Welchol	C	Unk	Not Reported
Albuterol Sulfate	C	Unk	Not Reported
Astepro	C		Not Reported
Coreg	C	Unk	Not Reported
Dicyclomine-S	C	Unk	Not Reported
Epipen	C		Not Reported
Ibuprofen	C		Not Reported
Ipratropium/Albuterol	C		Not Reported
Isosorbide	C	Unk	Not Reported
Methylergonovine Maleate	C	Unk	Not Reported
Naproxen	C	Unk	Not Reported
Nitroglycerin	C		Not Reported
Pristiq	C	Unk	Not Reported
Zantac	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16835822	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1938343US			Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Haemorrhage; Melaena	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Marcoumar			S	Unknown	Dosage Adapted To Inr		Not Reported
	Calcimagon			C	Oral	Unk, Qd		Not Reported
	Cansartan			C	Oral			Not Reported

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Ciproxin	C	Oral	500 Mg, Qod	Not Reported
Cordarone	C	Oral	200 Mg, Qd	Not Reported
Deanxit Dragees	C	Oral		Not Reported
Euthyrox	C	Oral	50 Mg, Qd	Not Reported
Inderal	C	Oral		Not Reported
Luvit D3	C	Oral	7 Gtt, Bi-Weekly	Not Reported
Palexia	C	Oral	200 Mg, Qod	Not Reported
Rosuvastax	C	Oral	10 Mg, Qd	Not Reported
Torem	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16848305	EXPEDITED (15-DAY)		DE, HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-221618		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac	Omeprazole			S	Oral	20 Mg, Qd		Astrazeneca
Failure; Extensor Plantar	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
Response; Hyperreflexia;	Alendronic Acid			S	Oral	70 Mg, Qwk		Sun
Hypoaesthesia;	Allopurinol			S	Oral	100 Mg, Qd		Sun
Hypoaesthesia;	Lisinopril			S	Oral	5 Mg, Qd		Not Reported
Multimorbidity; Muscular	Furosemida			S	Oral	60 Mg, Qd		Not Reported
Weakness; Neuromyelitis	Hierro Sulfato (Ferrous Sulfate)			S	Oral	256.3 Mg, Qd		Not Reported
Optica Spectrum Disorder;	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
Optic Ischaemic	Ipratropio Bromuro			S	Respiratory (inhalation)	2 Inh Every 8 Hours Inhaled		Not Reported
Neuropathy; Pneumonia;	Sintrom 1 Mg Comprimidos , 60			S	Oral	1 Mg, Qd		Not Reported
Pupillary Reflex Impaired;	Comprimidos							
Respiratory Tract	Espironolactona			S	Oral	50 Mg, Qd		Not Reported
Infection; Sight Disability;								
Thermohypoaesthesia;								
Urinary Retention								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16848497	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113241		26 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Flushing; Headache; Hyperhidrosis; Nausea; Nervousness; Pain; Serotonin Syndrome; Tremor	Escitalopram Oxalate			S	Oral	20 Milligram Daily;		Ivax	
	Venlafaxine Hydrochloride			S	Oral	150 Milligram Daily;		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16848509	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-062428		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Citalopram Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo	
	Cipraxel			S	Oral	Unk		Not Reported	
	Clonazepam			C	Oral	0.5 Milligram		Not Reported	
	Flomax			C	Unknown	0.4 Milligram		Not Reported	
	Rosuvastatin Calcium			C	Unknown	10 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849074	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2018SP009309		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Amnesia; Aphasia; Breast Tenderness; Chills; Diarrhoea; Drug Withdrawal Syndrome; Feeling Abnormal; Gynaecomastia; Headache; Hyperhidrosis; Piloerection; Pyrexia;	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Bid		Strides	
	Buspirone Hydrochloride			S	Unknown	15 Mg, Tid		Strides	
	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Tid		Strides	
	Buspirone Hydrochloride			S	Unknown	15 Mg, Tid		Strides	
	Buspirone Hydrochloride			S	Unknown	15 Mg, Bid		Strides	
	Buspirone Hydrochloride			S	Unknown	7.5 Mg, Tid		Strides	

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Restlessness; Toothache	Buspirone Hydrochloride	S	Unknown	22.5mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	20 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	17.5mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg, Bid	Strides
	Buspirone Hydrochloride	S	Unknown	15 Mg, Qd	Strides
	Buspirone Hydrochloride	S	Unknown	10 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	7.5 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	5 Mg Per Day	Strides
	Buspirone Hydrochloride	S	Unknown	2.5 Mg Per Day	Strides
	Escitalopram	S	Unknown	5 Mg, Every Morning	Not Reported
	Escitalopram	S	Unknown	20 Mg, Qd	Not Reported
	Escitalopram	S	Unknown	10mg Every Morning	Not Reported
	Escitalopram	S	Unknown	Increased 15 Mg, Every Morning	Not Reported
	Escitalopram	S	Unknown	2.5 Mg/Week	Not Reported
	Lorazepam	S	Unknown	0.5 Mg, Bid, As Necessary	Not Reported
	Lorazepam	S	Unknown	Increased To 0.5-1 Mg Three Times A Day As Necessary	Not Reported
	Bupropion	S	Unknown	150 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	200 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	300 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	30 Mg, Every Morning	Not Reported
	Bupropion	S	Unknown	300 Mg, Every Morning	Not Reported
	Testosterone	S	Unknown	50 Mg/5g, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	10 Mg, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Every Morning	Not Reported
	Amfetamine W/Dexamfetamine	S	Unknown	20 Mg, Every Morning	Not Reported
	Lamotrigine	S	Unknown	Unk	Not Reported

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Lamotrigine	S	Unknown	150 Mg, At Bed Time	Not Reported
Benzotropine Mesylate	C	Unknown	0.5 Mg, Bid, Prn	Not Reported
Aripiprazole	C	Unknown	2 Mg, At Bed Time	Not Reported
Aripiprazole	C	Unknown	4 Mg, At Bed Time	Not Reported
Lithium	C	Unknown	600 Mg, At Bed Time	Not Reported
Lurasidone	C	Unknown	40 Mg, At Night	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849329	EXPEDITED (15-DAY)		HO, LT	IL-SCIEGEN PHARMACEUTICALS INC-2019SCILIT00267			Unknown	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Infection;	Quetiapine			S				Not Reported	
Intentional Overdose;	Flecainide			S				Not Reported	
Suicide Attempt;	Venlafaxine			S				Not Reported	
Thrombocytopenia;	Escitalopram			S				Not Reported	
Toxicity To Various	Bisoprolol			S				Not Reported	
Agents; Unresponsive To	Clonazepam			S				Not Reported	
Stimuli	Glucagon			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849413	EXPEDITED (15-DAY)		HO	NL-ACCORD-155748			Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram			S		1x Per Day 1 Tablet, Srtrength: 15 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849467	EXPEDITED (15-DAY)		HO, OT	DE-HETERO- HET2019DE01318		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram	S	Unknown	Unk	Hetero
	Quetiapin	S	Oral	Unk	Not Reported
	Bisoprolol	S	Unknown	1.25 Mg	Not Reported
	Chlormadinone W/Ethinylestradiol	S	Unknown	Unk	Not Reported
	Trigoa	C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849488	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2019-06036		31 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pupils Unequal; Visual Impairment	Sertraline			S	Oral			Lupin	
	Escitalopram			S	Oral	20 Milligram		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851517	EXPEDITED (15-DAY)		OT	KR-PFIZER INC- 2019409668			Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Xanax			S	Oral			Pfizer	
	Lexapro			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16852932	EXPEDITED (15-DAY)		OT	GR-ALLERGAN- 1938592US			Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia; Dyskinesia; Dysuria; Ecchymosis; Female Orgasmic Disorder; Nervousness;	Escitalopram Oxalate - Bp			S	Oral	1 Df, Qd		Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	
	Escitalopram Oxalate - Bp			S				Allergan	

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Restlessness; Tremor;
Weight

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16299002	EXPEDITED (15-DAY)		HO, OT	DE-ASTRAZENECA-2019SE67983		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Zeneca	
	Escitalopram			S	Oral	Unk		Not Reported	
	Bisoprolol			S	Oral	1.25mg Unknown		Not Reported	
	Chlormadinone/Ethinylestradiol			S	Unknown			Not Reported	
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16699147	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2014BE152355		65 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Interaction; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Off Label Use; Pallor; Torsade De Pointes; Vomiting	Bisoprolol			S	Unknown			Novartis	
	Escitalopram			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Omeprazole			S	Unknown	Gastroresistant Coated Tablet		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	

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26-Sep-2019	16792009	EXPEDITED (15-DAY)		OT	NZ-MYLANLABS-2019M1084180		75 YR	Male	NZL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ulcerative; Condition Aggravated; Diarrhoea Haemorrhagic	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16827844	NON-EXPEDITED			US-PFIZER INC-2016458580		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ciprofloxacin Hcl			S		Unk		Unknown	
	Sulfadiazine Silver			S		Unk		Pfizer	
	Penicillin G Sodium			S		Unk		Not Reported	
	Ceclor			S		Unk		Not Reported	
	Cefaclor			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
	Relafen			S		Unk		Not Reported	
	Ciprocinnide			S		Unk		Not Reported	
	Escitalopram Oxalate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16839183	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1087852		57 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Hypotension; Intentional Overdose; Somnolence	Escitalopram			S	Oral	14 Cp De 20 Mg + 27 Cp De 10 Mg		Not Reported	
	Lorazepam			S	Oral	72 Cp De 2.5 Mg		Mylan	
	Bupropion			C		Unk		Mylan	

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Acetylsalicylic Acid	C	Unk	Mylan
Diazepam	C	Unk	Mylan
Venlafaxine	C	Unk	Mylan
Olanzapine	C	Unk	Mylan
Topiramate	C	Unk	Mylan
Hydroxycarbamide	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16844567	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2019402441		34 YR	Male	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Behaviour Disorder; Drug Ineffective For Unapproved Indication; Intentional Self-Injury; Off Label Use	Lorazepam			S	Unknown	3 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Unknown	20 Mg, 1x/Day		Pfizer
	Levomepromazine			S	Unknown	100 Mg, 1x/Day		Not Reported
	Melatonin			S	Unknown	3 Mg, 1x/Day		Not Reported
	Risperidone			S	Unknown	4 Mg, 1x/Day		Not Reported
	Risperidone			S	Unknown	3 Mg, 1x/Day		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Oxcarbazepine			S	Unknown	900 Mg, 1x/Day		Not Reported
	Carbamazepine			S	Unknown	Unk		Not Reported
	Carbamazepine			S				Not Reported
	Escitalopram			S	Unknown	10 Mg, 1x/Day		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol			S				Not Reported
	Macrogol			S	Unknown	3350 With Dosage 3 Bags / Day		Not Reported
	Olanzapine			S	Unknown	10 Mg, 1x/Day		Not Reported
	Valproate			S	Unknown	1200 Mg, 1x/Day		Not Reported
	Valproate			S				Not Reported
	Valproate			S				Not Reported

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	Valproate	S						Not Reported
	Quetiapine	S	Unknown	Unk				Not Reported
	Metoprolol	S	Unknown	Unk				Not Reported
	Metoprolol	S						Not Reported
	Metoprolol	S						Not Reported
	Topiramate	S	Unknown	Unk				Not Reported
	Candesartan	S	Oral	16 Mg, 1x/Day				Not Reported
	Candesartan	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16853692	EXPEDITED (15-DAY)		HO, OT	DE-DRREDDYS-GER/GER/19/0114396		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown	Unk		Not Reported
	Quetiapine			S	Oral	Unk		Not Reported
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Not Reported
	Chlormadinone/Ethinylestradiol			S		Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50mcg/Ee 3050mcg; 5x Lng 75mcg/Ee 40mcg; 10x Lng 125mcg/Ee 30mcg)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16853734	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-062032		31 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Milligram		Aurobindo
	Escitalopram			S	Oral	20 Milligram		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16854333	EXPEDITED (15-DAY)		OT	GB-EMCURE PHARMACEUTICALS LTD-2019-EPL-0849		31 YR	Female	GBR

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pupils Unequal; Visual Impairment	Sertraline Hydrochloride			S	Oral	50 Milligram, Received Up To 25-Aug-2019		Heritage
	Escitalopram			S	Oral	20 Milligram, Received Up To 01-Jan-2012		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16854892	EXPEDITED (15-DAY)		HO, OT	DE-LUPIN PHARMACEUTICALS INC.-2019-06145		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine Fumarate			S	Oral	Unk		Lupin
	Escitalopram			S	Unknown	Unk		Lupin
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported
	Chlormadinone;Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16855701	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-PFIZER INC- 2019401857		73 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Venlafaxine Hcl			S		225 Mg, Unk		Pfizer
	Erythromycin			S		Unk		Not Reported
	Escitalopram			S		Increased To Its Current Dose 3 Months Ago		Not Reported
	Escitalopram			S		15 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported

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26-Sep-2019	16855915	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-MACLEODS PHARMACEUTICALS US LTD- MAC2019023027			Unknown	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram			S	Unknown	Unk, Increased To Its Current Dose 3 Months Ago		Macleods	
	Escitalopram			S	Unknown	15 Milligram		Macleods	
	Venlafaxine			S	Unknown	225 Milligram		Macleods	
	Erythromycin			S	Unknown	Unk		Not Reported	
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
	Furosemide			C	Intravenous (not otherwise specified)	1240 Milligram, Qid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16856099	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS- 2019M1090132		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Suicide Attempt	Bromazepam			S	Oral	180 Milligram, Qd		Not Reported	
	Escitalopram			S	Oral	120 Milligram, Total		Not Reported	
	Seresta			S	Oral	48 Dosage Form, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16856119	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1089067		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Loss Of Consciousness; Malaise	Zolpidem			S	Oral			Not Reported	
	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	

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Bisoprolol	S	Oral	10 Milligram, Qd	Not Reported
Fentanyl	S	Transdermal	1 Dosage Form, Tid	Not Reported
Lyrica	S	Oral	1 Dosage Form, Qd	Mylan
Lasilix /00032601/	S	Oral	1 Dosage Form, Qd	Mylan
Oxynormoro	S	Oral	3 Dosage Form, Qd	Mylan
Ebixa	S	Oral	1 Dosage Form, Qd	Mylan
Esomeprazole	C			Mylan
Diffu K	C			Mylan
Transipeg /00754501/	C			Mylan
Gaviscon /00902401/	C			Mylan
Okimus	C			Mylan
Eliquis	C			Mylan
Melaxose	C			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16856550	EXPEDITED (15-DAY)		DE, HO	ES-009507513-1909ESP006179		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Cardiac	Lisinopril			S	Oral	5 Mg, Qd		Merck
Failure; Extensor Plantar	Alendronate Sodium			S	Oral	70 Mg, Qwk		Merck
Response; Hyperreflexia;	Omeprazole			S	Oral	20 Mg, Qd		Not Reported
Hypoaesthesia;	Furosemide			S	Oral	60 Mg, Qd		Not Reported
Hypoaesthesia;	Iron (Unspecified)			S	Oral	256.3 Mg, Qd		Not Reported
Multimorbidity; Muscular	Bisoprolol			S	Oral	5 Milligram, Qd (5 Mg, Bid)		Not Reported
Weakness; Neuromyelitis	Ipratropium Bromide			S	Respiratory (inhalation)	2 Inh Every 8 Hours		Not Reported
Optica Spectrum Disorder;	Escitalopram			S	Oral	10 Mg, Qd		Not Reported
Optic Ischaemic	Sintrom			S	Oral	1 Mg, Qd (60 Tablets)		Not Reported
Neuropathy; Pneumonia;	Spironolactone			S	Oral	50 Mg, Qd		Not Reported
Pupillary Reflex Impaired;	Allopurinol			S	Oral	100 Mg, Qd		Not Reported
Respiratory Tract								
Infection; Sight Disability;								
Thermohypoaesthesia;								
Urinary Retention								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16856760	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1089105		83 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Torasemide			S	Oral	5 Milligram, Qd		Not Reported	
	Torasemide			S	Oral	10 Milligram, Dia		Not Reported	
	Escitalopram 10 Mg Film-Coated Tablets			S	Oral	10 Milligram, Qd		Mylan	
	Aldactone /00006201/			S	Oral	1-0-0		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16858959	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALLERGAN-1938985US			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Escitalopram Oxalate Unk			S	Unknown	15 Mg, Increased To Its Current Dose 3 Months Ago		Allergan	
	Escitalopram Oxalate Unk			S	Unknown	15 Mg		Allergan	
	Venlafaxine			S	Unknown			Not Reported	
	Erythromycin			S	Unknown			Not Reported	
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported	
	Furosemide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	15560099	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-966996		92 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Dyspnoea; Fatigue; Interstitial Lung Disease	Duloxetine Hydrochloride			S	Unknown			Teva	
	Duloxetine Hydrochloride			S	Unknown			Teva	
	Duloxetine Hydrochloride			S				Teva	
	Escitalopram			S	Unknown			Ivax	

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Escitalopram	S		Ivax
Escitalopram	S		Ivax
Venlafaxine Hydrochloride	S	Unknown	Teva
Venlafaxine Hydrochloride	S		Teva
Venlafaxine Xr	S	Unknown	37.5 Milligram Daily; Teva
Teva-Duloxetine Dr	S	Unknown	Teva
Venlafaxine	S	Unknown	Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	15626480	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2018-CA-976256		75 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage	Diclofenac			S	Oral	100 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral			Actavis
	Diclofenac Potassium			S	Oral	100 Milligram Daily;		Actavis
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Cipralex			S	Oral	10 Milligram Daily;		Not Reported
	Eliquis Film-Coated			C				Not Reported
	Pantoprazole Enteric-Coated Tablet			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Pantoprazole			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	15814346	EXPEDITED (15-DAY)		DE, OT	DK-009507513-2011SP051883		72 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Hypertrophy; Confusional State; Constipation; Dyspnoea; Fall; Hepatic Cirrhosis; Humerus Fracture; Hypertension;	Mirtazapine			S	Oral	30 Mg, Qd		Merck
	Mirtazapine			S		Unk		Merck
	Litrex (Lithium Citrate)			S	Oral	1 Df (In The Morning)		Not Reported
	Litrex (Lithium Citrate)			S	Oral	1.5 Dosage Form, Qpm		Not Reported

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Hyperventilation; Lactic Acidosis; Lacunar Infarction; Neuroleptic Malignant Syndrome; Organ Failure; Pyrexia; Renal Failure; Rhabdomyolysis; Urinary Tract Infection	Zeldox	S	Oral	80 Mg, Qd	Not Reported
	Cipraxel	S	Oral	30 Mg, Qd (Daily Dose Of 1 Tablet In The Morning And 1.5 Tablet In The Evening)	Not Reported
	Alprazolam	C		0.5 Mg, Daily	Not Reported
	Centyl Med Kaliumklorid	C	Unknown	1 Dosage Form, Qd	Not Reported
	Ferro Duretter	C	Unknown	100 Mg Qd	Not Reported
	Amlodipin Actavis (Amlodipine Maleate) Fragmin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16274304	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-024199		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Aurobindo
	Bisoprolol			S	Unknown	1.25 Milligram		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Chlormadinone;Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			S	Unknown	6x Lng 50µg/Ee 30µg; 5x Lng 75µg/Ee 40µg; 10x Lng 125µg/Ee 30µg		Not Reported
	Trigoa			S	Unknown	5x		Not Reported
	Trigoa			S	Unknown	6x		Not Reported
	Trigoa			S	Unknown	10x		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16338115	NON-EXPEDITED			US-PFIZER INC-2019212920		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Venlafaxine Hcl			S		Unk		Pfizer

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Glipizide	S	Unk	Pfizer
Duloxetine	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Carbamazepine	S	Unk	Not Reported

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27-Sep-2019	16859727	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2019-DE-1112535		49 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Escitalopram			S	Unknown	Unk		Ivax
	Quetiapine			S	Oral	Unk		Teva
	Zebeta			S	Unknown	1.25 Mg, Unk		Duramed
	Chlormadinone/Ethinylestradiol			S		Unk		Not Reported
	Trigoa			C	Oral	Unk (6x Lng 50ug/Ee 30ug; 5x Lng 75ug/Ee 40ug; 10x Lng 125ug/Ee 30ug)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16860441	EXPEDITED (15-DAY)		HO	NO-ALLERGAN-1938926US			Female	NOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Dysarthria; Fatigue; Malaise; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Elvanse			S	Oral	Dosage 60 + 40 Mg, Not Further Specified		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16860445	EXPEDITED (15-DAY)		OT	FI-ALLERGAN-1938963US			Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amniotic Cavity Infection; Failed Induction Of	Escitalopram Oxalate - Bp			S	Unknown	1 Df, Qd		Allergan

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Labour; Gestational Diabetes; Pregnancy	Gilenya	S	Unknown	Unk, Unknown	Not Reported
	Brintellix	C	Unknown	1 Df, Qd	Not Reported
	Edronax	C	Unknown		Not Reported
	Albetol	C	Unknown	1 Df, (1 To 2)	Not Reported
	Losatrix Comp	C	Unknown		Not Reported
	Vitamin D	C	Unknown	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16860683	EXPEDITED (15-DAY)		OT	PHHY2019CA223971			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Voltaren			S	Topical	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Novartis
	Escitalopram			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	1000 Mg, Unk		Not Reported
	Nortriptyline			S	Oral	25 Mg, Unk		Not Reported
	Tylenol			S	Topical	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16860854	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1113862		75 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Faeces Discoloured; Lower Gastrointestinal Haemorrhage; Product Use In Unapproved	Diclofenac Sodium			S	Oral	100 Milligram Daily;		Actavis
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Escitalopram			S	Oral	10 Milligram Daily;		Ivax
	Ibuprofen			S	Oral			Actavis

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Indication	Eliquis	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported

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27-Sep-2019	16860915	NON-EXPEDITED			US-PFIZER INC-2019415274			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Clindamycin			S		Unk		Pfizer	
	Bentyl			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16861692	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-222109		31 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pupils Unequal; Visual Impairment	Sertraline			S	Oral	50 Milligram, Unk		Sun	
	Escitalopram			S	Oral	20 Milligram, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16861896	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-06119		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Electrolytes Decreased; Blood Pressure Decreased; Dizziness; Feeling Abnormal; Gait Disturbance; Loss Of Consciousness; Vertigo	Escitalopram Oxalate			S	Oral	Unk Unk, Qd		Lupin	
	Lisinopril Tablets			S	Oral	Unk Unk, Qd		Lupin	
	Lisinopril Tablets			S	Oral	1 Dosage Form, Qd		Lupin	
	Metoprolol			S	Oral	Unk Unk, Qd		Not Reported	
	Metoprolol			S	Oral	1 Dosage Form, Qd		Not Reported	
	Metformin			C	Oral	Unk		Not Reported	

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Jardiance	C	Oral	Unk	Not Reported
Trajenta	C	Oral	Unk	Not Reported
Atorvastatin	C	Oral	Unk	Not Reported
Fenofibrate	C	Oral	Unk	Not Reported
Tenoretic	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862287	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00015581		49 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Trigoa			C	Oral	Unk (6x Lng 50g/Ee 30g; 5x Lng 75g/Ee 40g; 10x Lng 125g/Ee 30g)		Unknown	
	Bisoprolol			S	Unknown	1.25 Mg, Unk		Unknown	
	Quetiapine			S	Oral	Unknown		Unknown	
	Chlormadinone And Ethinylestradiol			S		Unknown		Unknown	
	Escitalopram			S	Unknown	Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862368	EXPEDITED (15-DAY)		OT	MY-AUROBINDO-AUR-APL-2019-061083		71 YR	Male	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hypersensitivity	Risperidone			S	Unknown	Unk		Aurobindo	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862630	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1939225US			Male	CHN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Function Abnormal	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Estazolam			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862878	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019023039			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Dyspnoea; Pulmonary Embolism	Quetiapine			S	Oral	Unk		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Bisoprolol			S	Unknown	1.25 Milligram		Not Reported
	Chlormadinone/Ethinylestradiol			S	Unknown	Unk		Not Reported
	Trigoa			C	Oral	Unk, 6x Lng 50?G/Ee 30?G; 5x Lng 75?G/Ee 40?G; 10x Lng 125?G/Ee 30?G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16863101	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT- 00015600		47 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Ramipril			C	Oral	1-0-0		Unknown
	Aripiprazol			S	Oral	1-0-0		Stada
	Bisoprolol			C	Oral	1-0-0		Unknown
	Escitalopram			S	Oral			Unknown
	Diazepam			C	Oral	1-1-1		Ratiopharm
	Chlorprothixen			S	Oral	30-30-30-100		Neuraxpharm
	Haloperidol			S	Oral	1-0-1		Ratiopharm

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27-Sep-2019	16863769	EXPEDITED (15-DAY)		DE	SE-BAUSCH-BL-2019-054459		73 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Feeling Abnormal; Serotonin Syndrome; Therapy Non-Responder	Venlafaxine			S	Unknown	Along With Mianserin		Not Reported	
	Venlafaxine			S	Unknown	With Escitalopram, (Totally Given For Over A Period Of 9 Months).		Not Reported	
	Erythromycin			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Escitalopram			S	Unknown	Dose Increased To 15 Mg (Totally Given For Over A Period Of 9 Months).		Not Reported	
	Mianserin			S	Unknown			Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Furosemide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16863911	EXPEDITED (15-DAY)		HO	NO-SHIRE-NO201931274			Unknown	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysarthria; Fatigue; Malaise; Visual Impairment	Elvanse			S	Oral	100 Milligram (Dosage 60 + 40 Mg)		Shire	
	Cipralext [Escitalopram]			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16864038	EXPEDITED (15-DAY)		DS, LT	IN-ALLERGAN-1939152US			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Escitalopram Oxalate Unk			S		Unk		Allergan	

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Ciprofloxacin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2019	16864499	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-156024		16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Constipation; Depression; Hypothyroidism; Suicidal Ideation; Temperature Intolerance	Escitalopram			S		10 Mg Per Day, 10 Days Earlier		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2019	16864501	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-155747		47 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	Long-Term Use		Not Reported	
	Aripiprazole Stada			S	Oral	Recording Medication - 26.08.2019; 1-0-0		Not Reported	
	Chlorprothixen Neuraxpharm (Chlorprothixene Hydrochloride)			S	Oral	30-30-30-100		Not Reported	
	Haloperidol Ratiopharm 5 Mg/Ml Solução Injectável			S	Oral	1-0-1		Not Reported	
	Ramipril			C	Oral	1-0-0; Intake Medication, Not Paused;		Not Reported	
	Bisoprolol			C	Oral	1-0-0; Intake Medication, Not Paused		Not Reported	
	Diazepam			C	Oral	1-1-1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2019	16864522	EXPEDITED (15-DAY)		OT	ES-ACCORD-155956		36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Generalised Tonic-Clonic Seizure	Trazodone Accord	S	Oral	100 Mg Efg Tablets, 30 Tablets (Blister Pvc / Al)	Not Reported
	Escitalopram Sandoz	S	Oral	10 Mg Orodispersible Tablets Efg, 56 Tablets	Not Reported
	Naltrexone Accord	C	Oral	50 Mg Film-Coated Tablets Efg, 28 Tablets	Not Reported
	Bromazepam Pens	C	Oral	3 Mg Efg Capsules, 30 Capsules	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16254208	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2019CA095349		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria;	Potassium Chloride			S	Oral	Unk		Novartis
Blindness; Blindness	Amlodipine			S	Oral	150 Mg, Qd		Not Reported
Cortical; Cardiogenic	Escitalopram			S	Oral	Unk		Not Reported
Shock; Cerebral Infarction;	Escitalopram			S	Unknown	60 Mg, Qd		Not Reported
Circulatory Collapse;	Norepinephrine Bitartrate Inj Usp			S	Intravenous (not otherwise specified)	30 Ug, Unk		Not Reported
Colour Blindness;	Risperidone			S	Oral	6 Mg, Qd		Not Reported
Condition Aggravated; Csf	Vasopressin			S	Unknown	Unk		Not Reported
Pressure Increased;	Potassium Chloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
Cytotoxic Oedema;	Escitalopram Mylan			S	Oral	Unk		Not Reported
Depressed Level Of	Epinephrine			S	Unknown	30 Ug, Unk		Not Reported
Consciousness;	Dextrose			S	Intravenous (not otherwise specified)	Unk		Not Reported
Electrocardiogram P Wave	Glucose			S	Unknown	Unk		Not Reported
Abnormal;	Glucagon			C	Unknown	Unk		Not Reported
Electrocardiogram St	Insulin			C	Unknown	Unk		Not Reported
Segment Depression;	Norepinephrine			C	Intravenous (not otherwise specified)	30 Ug, Unk		Not Reported
Electrocardiogram T Wave								
Amplitude Decreased;								
Electrocardiogram T Wave								
Inversion;								
Electrocardiogram U								
Wave Present; Embolism;								
Embolism Arterial;								
Hyperdynamic Left								
Ventricle; Hypoglycaemia;								
Hypokalaemia;								

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Hypotension;	Calcium Gluconate	C	Unknown	Unk	Not Reported
Hypothermia; Intentional	Activated Charcoal	C	Unknown	Unk	Not Reported
Overdose; Ischaemia;	Dextrose	C	Unknown		Not Reported
Optic Atrophy; Optic Nerve	Amlodipine	C	Oral	Unk	Not Reported
Injury; Overdose;	Risperidone	C	Unknown	Unk	Not Reported
Pulmonary Oedema;	Vasopressin	C	Unknown	Unk	Not Reported
Renal Tubular Necrosis;	Potassium Chloride	C	Unknown	Unk	Not Reported
Retinal Ischaemia;	Epinephrine	C	Unknown	Unk	Not Reported
Reversible Cerebral					
Vasoconstriction					
Syndromes; Shock;					
Tachycardia; Toxicity To					
Various Agents; Visual					
Impairment					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16328082	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027588			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Escitalopram Tablets			S	Sublingual	7.5 Milligram		Aurobindo
Agitation; Anxiety;	Escitalopram Tablets			S	Unknown	7.5 Milligram		Aurobindo
Bruxism; Disturbance In	Escitalopram Tablets			S	Unknown	10 Milligram		Aurobindo
Attention; Dizziness; Drug	Escitalopram Tablets			S	Unknown	5 Milligram		Aurobindo
Ineffective; Fatigue;	Citalopram			S	Unknown	Unk		Aurobindo
Feeling Abnormal; Feeling	Trintellix			S	Unknown	10 Milligram, Once A Day		Not Reported
Jittery; Gastrointestinal	Trintellix			S	Unknown	5 Milligram, Once A Day		Not Reported
Disorder; Lethargy; Mental	Trintellix			S				Not Reported
Impairment; Nervousness;	Cipralelex			S	Oral	2.5 Milligram, Once A Day		Not Reported
Product Use Issue;	Cipralelex			S	Oral	5.0 Milligram, Once A Day		Not Reported
Restlessness; Sexual	Cipralelex			S	Oral	7.5 Milligram		Not Reported
Dysfunction; Wrong	Cipralelex			S	Oral	10 Milligram		Not Reported
Technique In Product								
Usage Process								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16328115	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-027420		55 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Tablets			S	Oral	Unk		Aurobindo	
	Citalopram Tablets			S	Oral	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Oral	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Citalopram			S	Unknown	Unk		Aurobindo	
	Topiramate			S	Oral	Unk		Aurobindo	
	Oxazepam			S	Oral	Unk		Not Reported	
	Temazepam			S	Oral	Unk		Not Reported	
	Naloxone			S	Intramuscular	Unk		Not Reported	
	Naloxone			S	Intramuscular	Unk		Not Reported	
	Temazepam			S	Oral	Unk		Not Reported	
	Quetiapine Mylan			S	Oral	Unk		Not Reported	
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported	
	Clopidogrel			C	Unknown	Unk		Not Reported	
	Ferrous Gluconate			C	Unknown	Unk		Not Reported	
	Fluticasone			C	Unknown	Unk		Not Reported	
	Ipratropium			C	Unknown	Unk		Not Reported	
	Metoprolol			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Spironolactone			C	Unknown	Unk		Not Reported	
	Advair			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
	Fluticasone;Salmeterol			C	Unknown	Unk		Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	14937784	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2018-04001		89 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Unknown	Unk		Lupin
	Heparin			S	Subcutaneous	5000 Iu, Bid		Not Reported
	Lidocaine			C	Unknown	3 MI, Unk (A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 Mcg/MI)		Not Reported
	Hydromorphone			C	Unknown	Unk (10 Mcg/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion)		Not Reported
	Epinephrine			C	Unknown	Unk (A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 Mcg/MI)		Not Reported
	Bupivacaine			C	Unknown	1 Mg/MI, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16038942	EXPEDITED (15-DAY)		OT	PHHY2019CO047048		56 YR	Male	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Erythema; Haematuria; Prostatitis; Psoriasis; Skin Plaque	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Escitalopram Oxalate			S	Oral	20 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16125958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-028365		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Cough; Diabetes Mellitus; Herpes Zoster; Hypertension; Joint Stiffness; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qwk		Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Liver Disorder; Liver Function Test Increased; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown	Unk	Not Reported
	Escitalopram Oxalate	S	Oral	1 Dosage Form, Qd	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Oral	1 Dosage Form, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	1 Dosage Form, Bid	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Prednisone	S	Oral	12.5 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Clonazepam	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16569674	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-024906		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Asthenia; Blood Pressure Abnormal; Confusional State; Constipation; Decreased	Escitalopram Tablets Usp 10mg			S	Unknown	1 Dosage Form, Daily		Aurobindo
	Escitalopram Tablets Usp 10mg			S	Unknown	Dose Reduced		Aurobindo
	Zotac			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Appetite; Diarrhoea;	Zantac	C	Unknown	Unk	Not Reported
Dizziness; Drug	Ranitidine	C	Unknown	Unk	Not Reported
Withdrawal Syndrome; Dry	Librium	C	Unknown	Unk	Not Reported
Mouth; Dysuria; Feeling					
Jittery; Heart Rate					
Abnormal; Hyperhidrosis;					
Hypoaesthesia; Insomnia;					
Micturition Disorder;					
Muscle Disorder; Muscle					
Rigidity; Muscle Spasms;					
Pruritus Generalised;					
Pyrexia; Suicidal Ideation;					
Throat Tightness					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16762107	EXPEDITED (15-DAY)		OT	PHHY2019ES198861		44 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Torsade De Pointes	Olanzapine			S	Unknown	Unk		Novartis
	Salbutamol			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16843061	NON-EXPEDITED			PA-ALLERGAN-1929606US		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anger; Mood Swings	Vraylar			S		1.5 Mg, Qd		Allergan
	Lexapro			S				Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16843071	NON-EXPEDITED			US-ALLERGAN-1931553US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Dysarthria; Muscle	Vraylar			S				Allergan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasms	Lexapro	S	10 Mg	Allergan
	Seroquel	S	50 Mg	Not Reported
	Cholesterol Medication	C	Unk	Not Reported
	Blood Pressure Medication	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16865260	EXPEDITED (15-DAY)		OT	MY-MACLEODS PHARMACEUTICALS US LTD- MAC2019023052			Unknown	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hypersensitivity	Escitalopram			S	Unknown	Unk		Macleods
	Risperidone			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16865600	EXPEDITED (15-DAY)		HO	FR-ROCHE-2414222		14 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypotension; Malaise	Diazepam			S	Oral			Not Reported
	Dietary Supplement			S	Oral			Not Reported
	Diane			S	Oral			Not Reported
	Cialis			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Colchicine			S	Oral			Not Reported
	Ibuprofene			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Donormyl [Doxylamine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Succinate]

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16866604	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1114671			Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram Tablet, 15 Mg (Milligram)			S		15 Milligram Daily; 1x Per Day 1 Tablet		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16866661	EXPEDITED (15-DAY)		HO, OT	US-HETERO-HET2019US01340		16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothyroidism; Major Depression; Suicidal Ideation; Suicide Attempt	Escitalopram			S	Unknown	10 Mg, Qd		Hetero	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16866887	EXPEDITED (15-DAY)		OT	GB-ACCORD-118241			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoscopy; Seizure	Escitalopram			S	Oral	Morning		Not Reported	
	Mirtazapine			S		Night		Not Reported	
	Olanzapine			S		Also Received 10 Mg		Not Reported	
	Azathioprine			S		With Or Just After Food		Not Reported	
	Dihydrocodeine			S		Two To Be Taken Four Times A Day If Required.		Not Reported	
	Iron			S		Morning And Night, 210 Mg Also Received		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Morning	Not Reported
Promethazine	S	At Night.	Not Reported
Dihydrocodeine	S	Four Times A Day. Take With Or Just After Food.	Not Reported
Azathioprine	S	Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16868146	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091101		35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Clonazepam			S				Not Reported
	Procainamide			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16868271	EXPEDITED (15-DAY)		DE	FR-TAKEDA-2019TUS054412			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Condition Aggravated	Brintellix			S	Unknown	10 Milligram		Takeda
	Brintellix			S	Unknown	20 Milligram		Takeda
	Seroplex			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869159	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1938903US			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pupils Unequal; Visual Impairment	Escitalopram Oxalate - Bp			S	Oral			Allergan
	Sertraline			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869160	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1939228US			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoscopy; Seizure	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd, Each Morning		Allergan	
	Dihydrocodeine			S	Unknown	60 Mg, Qid, With Or Just After Food		Not Reported	
	Promethazine Hydrochloride			S	Unknown	25 Mg, Qhs		Not Reported	
	Olanzapine			S	Unknown	10 Mg, Qd		Not Reported	
	Ferrous Fumarate			S	Unknown	420 Mg, Qd		Not Reported	
	Folic Acid			S	Unknown	5 Mg, Qd		Not Reported	
	Azathioprine			S	Unknown	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869173	EXPEDITED (15-DAY)		HO	IT-ALLERGAN-1938923US			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Product Use In Unapproved Indication; Sopor	Escitalopram Oxalate - Bp			S	Oral			Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869249	EXPEDITED (15-DAY)		HO	PHHY2019CH222002		87 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Syncope; Vertigo; Vomiting	Quetiapine Sandoz			S	Unknown	Dose Increase Over Time		Novartis	
	Quetiapine Sandoz			S	Unknown	Quetiapine Xr Sandoz Ret. 200 Mg 0-0-1, Quetiapine 25 Mg 0-0.5-0		Novartis	
	Escitalopram			S	Unknown	Unk Ukn, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aspirin Cardio	C	Unknown	Unk Ukn, Unk	Not Reported
Vi-De 3	C	Unknown	Unk Ukn, Unk	Not Reported
Pantoprazol Mepha	C	Unknown	Unk Ukn, Unk	Not Reported
Vesicare	C	Unknown	Unk Ukn, Unk	Not Reported
Acidum Folicum Streuli	C	Unknown	Unk Ukn, Unk	Not Reported
Irbesartan	C	Unknown	Unk Ukn, Unk	Not Reported
Magnesiocard	C	Unknown	Unk Ukn, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869277	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1089967		43 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Escitalopram			S	Oral	15 Milliliter, Total		Not Reported	
	Vortioxetine Hydrobromide			C		Unk		Mylan	
	Sertraline			C		Unk		Mylan	
	Asenapine			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16870105	EXPEDITED (15-DAY)		HO	CN-ALLERGAN-1939774US			Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuroleptic Malignant Syndrome	Escitalopram Oxalate - Bp			S	Unknown	10 Mg, Qd		Allergan	
	Clozapine			S	Unknown	200 Mg, Qd		Not Reported	
	Clozapine			S	Unknown	100 Mg, Qd		Not Reported	
	Clozapine			S	Unknown	50 Mg, Qd		Not Reported	
	Risperidone			S	Unknown	4 Mg, Qd		Not Reported	
	Haloperidol			S	Unknown	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16870145	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1091557		79 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haematoma	Escitalopram			S	Oral	Unk		Not Reported	
	Xarelto			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	14942542	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2018-027745		89 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; Haemorrhage; Hypotension; Hypovolaemia; Oedema; Paralysis; Platelet Aggregation Inhibition; Platelet Count Decreased; Spinal Cord Compression	Escitalopram			S	Unknown	Unk		Aurobindo	
	Heparin			S	Subcutaneous	5000 U		Not Reported	
	Lidocaine			C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI		Not Reported	
	Hydromorphone			C	Unknown	10 ?G/MI Was Initiated During The Procedure And Maintained At 6 MI/H, Infusion ()		Not Reported	
	Epinephrine			C	Unknown	A Test Dose Of 3 MI Of Lidocaine 2% With Epinephrine 5 ?G/MI ()		Not Reported	
	Bupivacaine			C	Unknown	1 Milligram Per Millilitre		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16060805	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-011959			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoscopy; Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day, Morning		Aurobindo	
	Olanzapine Tablet			S	Unknown	5 Milligram, Once A Day		Aurobindo	
	Olanzapine Tablet			S	Unknown	10 Milligram, Once A Day		Aurobindo	
	Mirtazapine Film-Coated Tablet			S	Oral	30 Milligram, Once A Day, Night		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ferrous Fumarate	S	Unknown	Morning And Night	Not Reported
Ferrous Fumarate	S	Unknown	210 Milligram, Once A Day, Morning And Night	Not Reported
Folic Acid	S	Unknown	5 Milligram, Once A Day, Morning	Not Reported
Dihydrocodeine	S	Unknown	60 Milligram, Four Times Daily. With Or Just After Food/Meal, As Necessary	Not Reported
Azathioprine	S	Unknown	75 Milligram, Once A Day, Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported
Azathioprine	S	Unknown	25 Milligram, Once A Day, Morning, Lunch And Tea Time (With Or Just After Food/Meal)	Not Reported
Promethazine Hydrochloride	S	Unknown	25 Milligram, Once A Day, At Night	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16419463	NON-EXPEDITED			US-TEVA-2019-US-1051212			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Escitalopram Oxalate			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16529993	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2019-CA-1071068		1 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax	
Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor;	Gabapentin			S	Transplacental	1800 Milligram Daily;		Actavis	
	Nortriptyline			S	Transplacental	20 Milligram Daily;		Teva	
	Quetiapine			S	Transplacental			Teva	

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Trismus	Rabeprazole	S	Transplacental		Teva
	Zopiclone	S	Transplacental		Not Reported
	Benzotropine Mesylate	S	Transplacental	1.5 Milligram Daily;	Not Reported
	Methadose Dye Free,Sugar Free,Unflavored	S	Transplacental	70 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16616087	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP018418			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Drug Ineffective	Escitalopram			S	Oral	20 Mg, Qd		Apotex
	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	1000 Mg, Qd		Apotex
	Nortriptyline			S	Oral	25 Mg, Qd		Not Reported
	Cimzia			S	Unknown			Not Reported
	Tylenol /00020001/			S	Topical			Not Reported
	Voltaren /00372301/			S	Topical	Unk, Qd		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	600 Mg, Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	700 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16676510	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0112679		43 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deep Vein Thrombosis; Discomfort; Muscular	Escitalopram			S	Unknown	Unk		Not Reported

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Weakness; Myalgia	Ibuprofen	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Ibuprofen Hormosan	S	Unknown	Unk	Not Reported
	Pantozol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S			Not Reported
	Metoprolol Hexal	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	1 Df, Ow	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Ibuhexal	S	Unknown	Unk	Not Reported
	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Prednisolone Stada	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Prednisolone Jenapharm	S	Unknown	Unk	Not Reported
	Prednisolon	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
	Prednisolone	S	Unknown	2.5 Mg	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Fluticasone /Vilanterol	S	Unknown	Unk, 6 Months Before Diagnosis	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16701224	EXPEDITED (15-DAY)		HO, LT, OT	BE-ASTELLAS- 2014US019985		65 YR	Male	BEL

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Long Qt Syndrome; Product Use In Unapproved Indication; Torsade De Pointes	Tacrolimus			S	Unknown	Unk, Unknown Freq.		Astellas	
	Sotalol			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Sotalol			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Escitalopram			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Omeprazole			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16723676	EXPEDITED (15-DAY)		HO, LT, OT	BE-AUROBINDO-AUR-APL-2017-22429		65 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Arrhythmia; Blood Pressure Decreased; Drug Interaction; Drug Intolerance; Hypokalaemia; Labelled Drug-Drug Interaction Medication Error; Long Qt Syndrome; Loss Of Consciousness; Metabolic Disorder; Off Label Use; Pallor; Product Use In Unapproved Indication; Torsade De Pointes; Vomiting	Escitalopram			S	Unknown	Unk		Aurobindo	
	Bisoprolol			S	Unknown	Unk		Aurobindo	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Omeprazole			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16741552	EXPEDITED (15-DAY)		OT	CZ-ALLERGAN-1934780US			Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis	Escitalopram Oxalate Unk			S	Unknown	10 Mg,Unk		Allergan	
	Olanzapine			S	Unknown	20 Mg, Qd		Not Reported	
	Trazodone			S	Unknown	150 Mg		Not Reported	

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Lamotrigine	S	Unknown	25 Mg	Not Reported
Oxazepam	S	Unknown	15 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16838743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2567569-00		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis;	Humira			S	Subcutaneous			Not Reported
Contraindicated Product	Xeljanz			S	Oral			Not Reported
Administered; Cough;	Celebrex			S	Unknown			Not Reported
Diabetes Mellitus; Herpes	Methotrexate			S	Unknown			Not Reported
Zoster; Hypertension;	Sulfasalazine			S	Unknown			Not Reported
Joint Stiffness; Joint	Enbrel			S	Unknown			Not Reported
Swelling; Liver Disorder;	Escitalopram Oxalate			S	Oral			Not Reported
Liver Function Test	Pantoprazole Magnesium			S	Oral			Not Reported
Increased; Liver Function	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Test Increased; Pain;	Orencia			S				Not Reported
Rheumatoid Arthritis;	Pantoprazole			S	Oral			Not Reported
Therapeutic Product Effect	Remicade			S	Unknown			Not Reported
Decreased; Therapeutic	Tocilizumab			S	Unknown			Not Reported
Product Effect Decreased;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Treatment Failure	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

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01-Oct-2019	16872277	EXPEDITED (15-DAY)		OT	PHHY2019TN226009		38 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature; Drug Reaction With Eosinophilia And Systemic Symptoms; Face Oedema; Lymphadenopathy; Rash Generalised	Carbamazepine			S	Unknown	Unk		Novartis	
	Levomepromazine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16872421	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2019-DE-1114700		47 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Drug Interaction; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	Permanent Ingestion Dose : 10 Milligram		Ivax	
	Haloperidol Ratiopharm 10 Mg			S	Oral	1-0-1, 10 Milligram		Actavis	
	Chlorprothixen Neuraxpharm			S	Oral	30-30-30-100		Not Reported	
	Aripiprazol Stada 10 Mg			S	Oral	10 Milligram, Admission Medication - 26.08.2019 1-0-0		Not Reported	
	Ramipril 2.5 Mg			C	Oral	1-0-0, 2.5 Milligram Admission Medication, Not Paused		Not Reported	
	Bisoprolol 2.5 Mg			C	Oral	1-0-0, 2.5 Milligram Admission Medication, Not Paused		Not Reported	
	Diazepam-Ratiopharm 10 Mg			C	Oral	1-1-1, 10 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16872471	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091103		28 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Off Label Use	Escitalopram			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Clonazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16872474	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091107		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Off Label Use	Escitalopram			S	Unknown			Not Reported	
	Clonazepam			S	Unknown	4 Milligram		Not Reported	
	Clonazepam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16872488	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-063339		47 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticholinergic Syndrome; Blood Creatine Phosphokinase Increased; Blood Pressure Increased; Dehydration; Hyperthermia; Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome; Tachycardia; Tachypnoea; Transaminases Increased	Escitalopram			S	Oral	10 Milligram,Permanent Intake		Aurobindo	
	Chlorprothixen Neuraxpharm			S	Oral	30-30-30-100		Not Reported	
	Haloperidol-Ratiopharm			S	Oral	10 Milligram, Two Times A Day,1-0-1		Not Reported	
	Aripiprazol Stada			S	Oral	10 Milligram,Recording Medication - 26.08.2019; 1-0-0		Not Reported	
	Ramipril			C	Oral	2.5 Milligram,1-0-0;Admission Medication, Not Paused;		Not Reported	
	Bisoprolol			C	Oral	2.5 Milligram,1-0-0;Admission Medication, Not Paused;		Not Reported	
	Diazepam-Ratiopharm			C	Oral	10 Milligram,1-1-1		Not Reported	

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01-Oct-2019	16872648	EXPEDITED (15-DAY)		HO	NL-AUROBINDO-AUR- APL-2019-063421			Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Dyspnoea; Gait Disturbance; Heart Rate Decreased; Somnolence; Weight Increased	Escitalopram Film-Coated Tablets 15mg			S	Oral	15 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16873319	EXPEDITED (15-DAY)		HO	ES-MYLANLABS- 2019M1091131		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Inappropriate Antidiuretic Hormone Secretion	Escitalopram			S	Oral	Unk		Not Reported	
	Tiaprizal			S	Oral	100 Milligram, Q8h		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16873801	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-093171		93 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis	Eliquis			S	Oral	2 Dosage Form, Daily		Bristol Myers Squibb	
	Seroplex			S	Oral	5 Gtt Drops, Daily		Not Reported	
	Esomeprazole			C	Oral	20 Milligram, Daily		Not Reported	
	Oramorph [Morphine Sulfate]			C	Oral			Not Reported	
	Doliprane			C	Oral	4 Dosage Form, Prn		Not Reported	
	Risperdaloro			C	Oral	1 Dosage Form, Daily		Not Reported	
	Seresta			C	Oral	20 Milligram, Daily		Not Reported	
	Bisoce			C	Oral	1 Dosage Form, Daily		Not Reported	

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Midazolam			C	Intramuscular	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16873907	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1091115		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Drug Ineffective For Unapproved Indication; Off Label Use	Escitalopram			S	Unknown	20 Milligram, Qd		Not Reported	
	Clonazepam			S	Unknown	3 Milligram		Not Reported	
	Clonazepam			S				Not Reported	
	Metoprolol			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16874399	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2019-055040		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Hypoglycaemia; Oedema Peripheral; Weight Increased	Metformin			S	Unknown	2500 Mg		Santarus	
	Fenofibrate			S	Unknown	145 Mg		Not Reported	
	Victoza			S	Unknown	1.80 Mg		Not Reported	
	Escitalopram			S	Unknown	20 Mg		Not Reported	
	Budesonide;Formoterol			S	Unknown	2 Puf/Day		Not Reported	
	Olmesartan			S	Unknown	20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16874929	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2019-CA-1115011		1 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Withdrawal Syndrome Neonatal; Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor;	Rabeprazole			S	Transplacental			Teva	
	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax	
	Gabapentin			S	Transplacental	1800 Milligram Daily;		Ivax	
	Nortriptyline			S	Transplacental	20 Milligram Daily;		Teva	

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Trismus	Quetiapine	S	Transplacental		Teva
	Zopiclone	S	Transplacental		Not Reported
	Benzotropine Mesylate	S	Transplacental	1.5 Milligram Daily;	Not Reported
	Methadose Dye Free,Sugar Free,Unflavored	S	Transplacental	70 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	12579870	EXPEDITED (15-DAY)	HO, OT		PHHY2016PA099776		58 YR	Male	PAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alanine Aminotransferase Increased; Amnesia; Anaphylactic Reaction; Asphyxia; Asthenia; Blood Cholesterol Increased; Blood Lactate	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
Dehydrogenase Decreased; Blood Potassium Decreased; Blood Pressure Decreased; Blood Sodium Decreased; Blood Triglycerides Increased; Cardiac Disorder; Cardiac Dysfunction; Choking; Cold Type Haemolytic Anaemia; Dehydration; Dyskinesia; Dysstasia; Eosinophil Percentage Increased; Fatigue; Fear; Feeling Abnormal; Gastrointestinal Pain; Granulocyte Count Decreased; Haemoglobin Decreased; Heat Stroke; Hernia Pain; Ileus; Paralytic; Infection; Intervertebral Disc	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	0.5 Mg, Qod		Novartis
	Carbamazepine			S	Unknown	200 Mg, Q8h		Not Reported
	Amlodipine			S	Unknown	1 Df, Bid (One Every 12 Hours)		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported
	Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	10 Mg, Bid		Not Reported
	Fenofibrate			C	Unknown	250 Mg, Qn		Not Reported

Disorder; Intervertebral
Disc Protrusion;
Intervertebral Discitis;
Lethargy; Leukopenia;
Low Density Lipoprotein
Increased; Lymphocyte
Count Decreased;
Malaise; Mean Cell
Volume Increased;
Memory Impairment;
Mobility Decreased;
Monocyte Percentage
Increased; Multiple
Sclerosis Relapse; Muscle
Contractions Involuntary;
Muscle Disorder; Muscle
Rigidity; Muscle Spasticity;
Muscle Strain; Myalgia;
Myopathy; Nausea;
Neuralgia; Neuropathy
Peripheral; Nuchal
Rigidity; Pain; Plateletcrit
Decreased; Prescribed
Underdose; Red Blood
Cell Count Decreased;
Red Blood Cell
Sedimentation Rate
Increased; Red Cell
Distribution Width
Increased; Seizure;
Seizure; Sleep Disorder;
Somnolence; Speech
Disorder; Tonsillitis; Visual
Impairment; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16187606	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2019-018826		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Deep Vein Thrombosis; Discomfort; Muscular Weakness; Myalgia	Ibuprofen	S	Unknown	Unk	Aurobindo
	Escitalopram	S	Unknown	Unk	Aurobindo
	Pantozol	S	Unknown	Unk	Not Reported
	Implanon	S	Unknown	Unk	Not Reported
	Ibuprofen Hormosan	S	Unknown	Unk	Not Reported
	Metoprolol Hexal	S	Unknown	Unk	Not Reported
	Salbutamol Stada	S	Unknown	Unk	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Prednisolon Jenapharm	S	Unknown	Unk	Not Reported
	Metoprolol	S	Unknown	Unk	Not Reported
	Metoprolol Mylan	S	Unknown	Unk	Not Reported
	Amitriptylin	S	Unknown	Unk	Not Reported
	Prednisolon	S	Intracardiac	Unk	Not Reported
	Prednisolon	S	Unknown	25 Milligram	Not Reported
	Prednisolon	S	Unknown	2.5 Milligram	Not Reported
	Metoprolol Stada	S	Unknown	Unk	Not Reported
	Ibuprofen Stada	S	Unknown	Unk	Not Reported
	Prednisolon Stada	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Escitalopram Mylan	S	Unknown	Unk	Not Reported
	Escitalopram Stada	S	Unknown	Unk	Not Reported
	Escitalopram Hexal	S	Unknown	Unk	Not Reported
	Methotrexate Mylan	S	Unknown	1 Dosage Form, Every Week	Not Reported
	Ibuhexal	S	Unknown	Unk	Not Reported
	Fluticasone;Vilanterol	C	Unknown	Unk (6 Months Before Diagnosis)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16509339	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1069210		56 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Dislocation; Device Malfunction; Drug Ineffective	Amlodipine Besilate			S	Unknown	1.5 Dosage Forms Daily;		Teva
	Clonazepam			S	Unknown	3 Dosage Forms Daily;		Teva
	Diltiazem			S	Unknown	1 Dosage Forms Daily;		Teva
	Escitalopram Oxalate			S	Unknown	1 Dosage Forms Daily;		Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Escitalopram Oxalate			S	Unknown			Ivax
	Ratio-Zopiclone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown	1 Dosage Forms Daily;		Actavis
	Tevabisoprol			S	Unknown	1 Dosage Forms Daily;		Duramed
	Apo Escitalopram			S	Unknown			Not Reported
	Tamsulosin Cr Controlled-Release Tablet			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Apo-Trazodone			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Brilinta			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Ciclopirox Olamine			S	Unknown			Not Reported
	Delatestryl			S	Unknown			Not Reported
	Dexilant			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Emo Cort			S	Topical	1 Dosage Forms Daily;		Not Reported
	Jamp Asa 81mg Ec			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Metonia			S	Unknown	3 Dosage Forms Daily;		Not Reported
	Mylan-Nitro Sublingual Spray			S	Oral			Not Reported
	Mylan-Nitro Sublingual Spray			S	Oral			Not Reported
	Nasonex			S	Nasal			Not Reported
	Nitro-Dur			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Ratio-Zopiclone			S	Unknown			Not Reported
	Synthroid			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Triatec /00116401/			S	Unknown	4 Dosage Forms Daily;		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877554	NON-EXPEDITED			US-PFIZER INC-2019422947		50 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Cefdinir			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Naproxen Sodium			S		Unk		Pfizer
	Aspirin (E.C.)			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Pseudoephedrine			S		Unk		Not Reported
	Singula			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16878468	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2019-055844		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple-Drug Resistance	Venlafaxine			S	Unknown			Not Reported
	Venlafaxine			S	Oral	Extended Release		Not Reported
	Bupropion			S	Unknown			Not Reported
	Bupropion			S				Not Reported
	Lorazepam			S	Unknown			Not Reported

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Lorazepam	S			Not Reported
Fluoxetine	S	Unknown		Not Reported
Fluoxetine	S			Not Reported
Sertraline	S	Unknown		Not Reported
Sertraline	S			Not Reported
Paroxetine	S	Unknown		Not Reported
Paroxetine	S			Not Reported
Escitalopram	S	Unknown		Not Reported
Escitalopram	S			Not Reported
Duloxetine	S	Unknown		Not Reported
Duloxetine	S			Not Reported
Aripiprazole	S	Unknown		Not Reported
Aripiprazole	S			Not Reported
Quetiapine	S	Unknown		Not Reported
Quetiapine	S			Not Reported
Gabapentin	S	Unknown		Not Reported
Gabapentin	S			Not Reported
Pregabalin	S	Unknown		Not Reported
Pregabalin	S			Not Reported
Topiramate	S	Unknown		Not Reported
Topiramate	S			Not Reported
Alprazolam	S	Unknown		Not Reported
Alprazolam	S	Unknown	As Needed	Not Reported
Alprazolam	S			Not Reported
Methylphenidate	S	Unknown		Not Reported
Methylphenidate	S	Unknown		Not Reported
Modafinil	C		In Divided Doses	Not Reported
Fingolimod	C	Oral	3 Times Per Week	Not Reported
Omeprazole	C			Not Reported
Trospium	C		Xr (Extended Release)	Not Reported
Naproxen	C		As Needed	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	14349561	EXPEDITED (15-DAY)		CA, DE, DS, LT, OT	BE-MACLEODS PHARMACEUTICALS US LTD- MAC2017007867			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Malformation; Trisomy 18	Levocetirizine Dihydrochloride 5mg Tablet			S	Transplacental	5 Mg, Qd		Macleods	
	Pantoprazole			S	Transplacental	Unk		Macleods	
	Xanthium (Theophylline)			S	Transplacental	200 Mg, Qd		Not Reported	
	Nucala Powder For Solution For Injection			S	Transplacental	100 Mg, Unk, Gestation Period At Time Of Exposure- 1 Week, Powder For Solution For Injection		Not Reported	
	Ventolin			S	Transplacental	100 Mg, Unk		Not Reported	
	Pantomed [Pantoprazole]			S	Transplacental	Unk		Not Reported	
	D-Cure			S	Transplacental	25 Kiu, Unk		Not Reported	
	Flixotide			S	Transplacental	500 Mg, Qd, (250 Ug, Bid)		Not Reported	
	Relvar Ellipta			S	Transplacental	1 Df, Qd (Inhalation Powder, Pre-Dispensed)		Not Reported	
	Sipralexa			S	Transplacental	10 Mg, Z		Not Reported	
	Seretide			S	Transplacental	Unk		Not Reported	
	Avamys			S	Transplacental	2 Df, Qd (Unk Bid) (Nasal Spray)		Not Reported	
	Fluticasone Propionate			S	Transplacental	Unk, Qd (Inhalation Powder)		Not Reported	
	Vilanterol Trifenatate			S	Transplacental	1 Dosage Form, Qd (Inhalation Powder)		Not Reported	
	Xyzall			S	Transplacental	5 Milligram, Qd		Not Reported	
	Theophylline			S	Transplacental	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	15650766	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-056286		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Ramipril			S	Oral	2.5 Milligram, Once A Day		Aurobindo
	Lamotrigine			S	Oral	100 Milligram, Once A Day		Aurobindo
	Exemestane			S	Oral	25 Milligram, Once A Day		Not Reported
	Gabapentin			S	Oral	200 Milligram, Once A Day		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lasix			S	Oral	20 Milligram, Once A Day		Not Reported
	Aspirine Protect			S	Oral	100 Milligram, Once A Day		Not Reported
	Bisoc			S	Oral	1.25 Milligram, Once A Day		Not Reported
	Seroplex			S	Oral	5 Milligram, Once A Day		Not Reported
	Fluidabak			C	Ophthalmic	3 Gtt, Once A Day		Not Reported
	Transipeglib			C	Oral	11.8 Gram, Once A Day		Not Reported
	Gluconate De Potassium			C	Oral	1 Cs Par Jour		Not Reported
	Gluconate De Potassium			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt, Once A Day		Not Reported
	Potassium Chloride;Sodium Acetate;Sodium Chloride			C	Oral	Unk,1 Cs Par Jour Route		Not Reported
	Sodium Gluconate			C	Oral	Unk,1 Cs Par Jour Route		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	15663581	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980666			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective	Citalopram			S	Unknown			Actavis
	Cipralax			S	Unknown	10 Milligram Daily;		Not Reported

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Escitalopram			S		Unknown	10 Milligram Daily;		Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	15668452	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-980471		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Blood Albumin Decreased; Confusional State; Depressed Level Of Consciousness; Drug Interaction; Electrocardiogram Qt Prolonged; Heart Rate Increased; Irritability; Miosis; Overdose; Oxygen Saturation Decreased; Respiratory Alkalosis; Sinus Tachycardia; Somnolence; Suicide Attempt; Toxicity To Various Agents	Escitalopram Oxalate			S	Unknown			Ivax	
	Escitalopram Oxalate			S	Unknown			Ivax	
	Escitalopram Oxalate			S	Oral			Ivax	
	Quetiapine Fumarate			S	Unknown			Teva	
	Quetiapine Fumarate			S	Oral			Teva	
	Quetiapine Fumarate			S	Oral			Teva	
	Topiramate			S	Oral			Teva	
	Topiramate			S	Unknown	Form Of Admin : Not Specified		Teva	
	Citalopram Hydrobromide			S	Unknown			Not Reported	
	Citalopram Hydrobromide			S	Unknown			Not Reported	
	Citalopram Hydrobromide			S	Oral			Not Reported	
	Temazepam			S	Oral			Actavis	
	Temazepam			S	Unknown			Actavis	
	Oxazepam			S	Unknown			Not Reported	
	Oxazepam			S	Oral			Not Reported	
	Ctp 30			S	Unknown			Not Reported	
	Naloxone			S	Intramuscular	Form Of Admin : Not Specified		Not Reported	
	Naloxone			S	Intramuscular			Not Reported	
	Advair			C	Unknown			Not Reported	
	Atorvastatin Calcium			C	Unknown			Not Reported	
	Atorvastatin Calcium			C	Unknown			Not Reported	
	Clopidogrel (Unspecified Brand)			C	Unknown			Not Reported	

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Clopidogrel (Unspecified Brand)	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Furosemide	C	Unknown	Form Of Admin : Not Specified	Not Reported
Ipratropium	C	Unknown	Form Of Admin : Not Specified	Not Reported
Metoprolol	C	Unknown	Form Of Admin : Not Specified	Not Reported
Ramipril	C	Endocervical	Form Of Admin : Not Specified	Not Reported
Salbutamol	C	Other	Form Of Admin : Not Specified	Not Reported
Spironolactone	C	Unknown		Not Reported
Spironolactone	C	Unknown		Not Reported
Fluticasone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16836433	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-060867		14 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypotension; Malaise	Diclofenac			S	Oral	5000 Milligram, In Total		Not Reported
	Diazepam			S	Oral	480 Milligram, In Total		Not Reported
	Ibuprofen			S	Oral	4400 Milligram, In Total		Aurobindo
	Paracetamol			S	Oral	2 Gram, In Total		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	820 Milligram, In Total		Aurobindo
	Diane			S	Oral	21 Dosage Form, In Total		Not Reported
	Cialis			S	Oral	40 Milligram, In Total		Not Reported
	Colchicine			S	Oral	6 Milligram, In Total		Not Reported
	Donormyl [Doxylamine			S	Oral	300 Milligram, In Total		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16854030	EXPEDITED (15-DAY)		OT	GB-DRREDDYS-GER/UKI/19/0114321			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoscopy; Seizure	Olanzapine			S				Not Reported	
	Promethazine Hydrochloride			S		At Night.		Not Reported	
	Ferrous Fumarate			S				Not Reported	
	Azathioprine			S				Not Reported	
	Escitalopram			S		Each Morning.		Not Reported	
	Dihydrocodeine			S		Four Times A Day. Take With Or Just After Food.		Not Reported	
	Folic Acid			S				Not Reported	
	Mirtazapine			S	Oral	Night		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16880083	EXPEDITED (15-DAY)		HO	IT-ACCORD-156226		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Medication Error; Muscle Contractions Involuntary; Paraesthesia; Sopor	Escitalopram			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16880275	EXPEDITED (15-DAY)		DS, OT	AT-MYLANLABS-2019M1091285		25 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Aphasia; Bradyphrenia; Confusional State; Depressed Level Of Consciousness; Disturbance In Attention; Emotional Poverty;	Escitalopram			S	Unknown	10 Milligram		Not Reported	
	Escitalopram			S	Unknown	20 Milligram		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Erectile Dysfunction;
Fatigue; Feeling
Abnormal; Hyperhidrosis;
Hypoaesthesia; Illusion;
Loss Of Libido; Malaise;
Memory Impairment;
Orgasm Abnormal;
Orgasmic Sensation
Decreased; Personality
Change; Poisoning;
Tremor; Tunnel Vision

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16880505	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2019023087			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticholinergic Syndrome; Blood Creatine	Escitalopram			S	Oral	10 Milligram, Permanent Intake		Macleods
Phosphokinase Increased; Blood Pressure Increased;	Chlorprothixen Neuraxpharm			S	Oral	Unk, 30-30-30-100		Not Reported
Dehydration; Drug Interaction; Hyperthermia;	Haloperidol Ratiopharm			S	Oral	10 Milligram, Bid (1-0-1)		Not Reported
Hypokinesia; Muscle Rigidity; Neuroleptic Malignant Syndrome; Serotonin Syndrome;	Aripiprazol Stada			S	Oral	10 Milligram, Qd (1-0-0), Recording Medication- 26 08 2019		Not Reported
Tachycardia; Tachypnoea; Transaminases Increased	Ramipril			C	Oral	2.5 Milligram, Qd, Recording Medication, Not Paused		Not Reported
	Bisoprolol			C	Oral	2.5 Milligram, Qd (1-0-0), Recording Medication, Not Paused		Not Reported
	Diazepam-Ratiopharm			C	Oral	10 Milligram, Tid (1-1-1)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16880872	NON-EXPEDITED			US-PFIZER INC- 2019424527		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Flagyl	S	Unk	Pfizer
	Amoxicillin	S	Unk	Not Reported
	Lexapro	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16882368	EXPEDITED (15-DAY)		HO	CH-ALLERGAN-1940063US			Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Prescribed Overdose; Suicidal Ideation	Escitalopram Oxalate - Bp			S	Oral	30 Mg		Allergan
	Escitalopram Oxalate - Bp			S	Oral	10 Mg		Allergan
	Surmontil			S	Oral	Unk Mg		Not Reported
	Pregabalin			C	Oral			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Prostasan			C	Unknown			Not Reported
	Aspirin Cardio			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16882512	NON-EXPEDITED		OT	US-JAZZ-2018-US-010128		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affective Disorder; Back Pain; Depressive Symptom; Dizziness; Fatigue; Headache; Orthostatic Hypotension; Overweight; Poor Quality Sleep; Somnolence; Stress; Suicidal Ideation	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Lexapro			S				Not Reported
	Adderall			S				Not Reported
	Citalopram			S				Not Reported
	Vitamin D2			C				Not Reported
	Modafinil			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Anusol Plus H			C				Not Reported
	Symbicort			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16882808	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-063150		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Neutropenia; Pleural Effusion	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo	
	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Aurobindo	
	Avastin			S	Intravenous (not otherwise specified)	15 Milligram, 1 Every 3 Weeks		Not Reported	
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported	
	Carboplatin			S	Intravenous (not otherwise specified)	Unk, 1 Every 3 Weeks		Not Reported	
	Cipralex			S	Intravenous (not otherwise specified)	10 Milligram		Not Reported	
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, 1 Every 3 Weeks		Not Reported	
	Docetaxel			S	Intravenous (not otherwise specified)	75 Milligram/Sq. Meter, Trimester		Not Reported	
	Herceptin			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported	
	Herceptin			S	Unknown	8 Milligram/Kilogram, 1 Every 3 Weeks		Not Reported	
	Morphine			S	Intravenous (not otherwise specified)	2.5 Milligram		Not Reported	
	Tylenol			S	Unknown	Unk		Not Reported	
	Senna			C	Unknown	Unk		Not Reported	
	Docusate			C	Unknown	Unk		Not Reported	
	Trazodone			C	Unknown	Unk		Not Reported	
	Lactulose			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	13696842	EXPEDITED (15-DAY)		HO, OT	CO-INCYTE CORPORATION-2017IN005035			Unknown	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abnormal Behaviour; Agitation; Amnesia; Anal Haemorrhage; Anger; Anxiety; Arthralgia; Asthenia; Bone Pain; Boredom; Chest Discomfort; Chills; Cough; Cystitis; Decreased Appetite; Depression; Diarrhoea; Dizziness; Dyspnoea; Fall; Feeling Abnormal; Fungal Infection; Gastric Ulcer; Gastrointestinal Haemorrhage; General Physical Health Deterioration; Haematemesis; Headache; Heart Rate Increased; Hypersensitivity; Ill-Defined Disorder; Inappropriate Schedule Of Product Administration; Insomnia; Malaise; Mouth Haemorrhage; Muscle Spasms; Nausea; Pain; Pain In Extremity; Platelet Count Increased; Polycythaemia Vera; Pruritus; Psychiatric Symptom; Pyrexia; Rectal Haemorrhage; Renal Colic; Skin Disorder; Skin	Jakavi			S	Oral	5 Mg, Bid		Incyte	
	Jakavi			S	Oral	2 Df, Qd (5 Mg)		Incyte	
	Jakavi			S	Oral	15 Mg, Bid		Incyte	
	Jakavi			S	Unknown	20 Mg, Qd		Incyte	
	Jakavi			S	Oral	30 Mg, Qd		Incyte	
	Jakavi			S	Oral	Unk		Incyte	
	Jakavi			S	Oral	20 Mg, Q12h		Incyte	
	Jakavi			S	Oral	40 Mg, Qd		Incyte	
	Jakavi			S	Oral	20 Mg, Q12h		Incyte	
	Jakavi			S	Oral	40 Mg, Qd (Once)		Incyte	
	Esomeprazole			S	Unknown	Unk Unk, Qd		Not Reported	
	Loratadine			S	Unknown	Unk		Not Reported	
	Escitalopram			S	Unknown	10 Mg, Qd		Not Reported	
	Escitalopram			S	Unknown	Unk		Not Reported	
	Hydroxyurea			S	Unknown	Unk		Not Reported	
	Acetaminophen			C	Unknown	Unk		Not Reported	
	Aspirin /00002701/			C	Unknown	Unk		Not Reported	
	Dolex /01495801/			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

Haemorrhage; Sleep
Disorder; Sneezing;
Spleen Disorder;
Tuberculosis; Viral
Infection; Vision Blurred;
Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15644004	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2018477058		96 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Ramipril			S	Oral	2.5 Mg, 1x/Day		Pfizer
	Bisoprolol Fumarate			S	Oral	1.25 Mg, 1x/Day		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Mg, 1x/Day		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Exemestane			S	Oral	25 Mg, 1x/Day		Pfizer
	Gabapentine Pfizer			S	Oral	200 Mg, Qd		Pfizer
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported
	Lasilix			S	Oral	20 Mg, 1x/Day		Not Reported
	Gluconate De Potassium			C	Oral	1 Df, Qd (1 Cs Per Day)		Not Reported
	Transipeg [Macrogol]			C	Oral	11.8 G, 1x/Day		Not Reported
	Levothyroxine Sodique			C	Oral	30 Gtt Drops, Qd		Not Reported
	Fluidabak			C	Ophthalmic	3 Gtt Drops, Qd		Not Reported
	Gluconate Sodium/Potassium Chloride/Sodium Acetate/Sodium Chloride			C	Oral	1 Cs Par Jour Route		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15651346	EXPEDITED (15-DAY)		CA, HO	CA-TEVA-2018-CA- 978993		1 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crying; Drug Withdrawal Syndrome Neonatal;	Escitalopram			S	Transplacental	20 Milligram Daily;		Ivax

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Exposure During Pregnancy; Muscle Tone Disorder; Premature Baby; Sleep Disorder; Tremor; Trismus	Escitalopram	S	Transplacental	20 Milligram Daily;	Ivax
	Escitalopram	S	Transplacental	20 Milligram Daily;	Ivax
	Nortriptyline	S	Transplacental	20 Milligram Daily;	Teva
	Quetiapine	S	Transplacental		Teva
	Rabeprazole	S	Transplacental		Teva
	Zopiclone	S	Transplacental		Not Reported
	Benztropine Mesylate	S	Transplacental	1.5 Milligram Daily;	Not Reported
	Benztropine Mesylate	S	Transplacental	1.5 Milligram Daily;	Not Reported
	Gabapentin	S	Transplacental	1800 Milligram Daily;	Actavis
	Methadone	S	Transplacental	70 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16266075	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-TEVA-2019-CA-1042363		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria;	Amlodipine			S	Unknown			Teva
Blindness; Blindness	Amlodipine			S	Oral			Teva
Cortical; Cardiogenic	Amlodipine			S	Oral			Teva
Shock; Cerebral Infarction;	Escitalopram			S	Oral			Ivax
Circulatory Collapse;	Escitalopram			S	Unknown	60 Milligram Daily;		Ivax
Colour Blindness;	Risperidone			S	Oral			Pliva
Condition Aggravated; Csf	Risperidone			S	Oral			Pliva
Pressure Increased;	Risperidone			S	Unknown	6 Milligram Daily;		Pliva
Cytotoxic Oedema;	Epinephrine			S	Unknown			Not Reported
Depressed Level Of Consciousness;	Glucose			S	Unknown			Not Reported
Electrocardiogram P Wave Abnormal;	Mylan-Escitalopram			S	Oral			Not Reported
Electrocardiogram St Segment Depression;	Norepinephrine Bitartrate Inj			S	Unknown	Form Of Admin:Liquid Intravenous		Not Reported
Electrocardiogram T Wave Amplitude Decreased;	1mg/ML Usp							
Electrocardiogram T Wave Inversion;	Potassium Chloride			S	Oral			Not Reported
Electrocardiogram U	Potassium Chloride			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema; Renal Tubular Necrosis; Retinal Ischaemia; Reversible Cerebral Vasoconstriction Syndrome; Shock; Tachycardia; Toxicity To Various Agents; Visual Impairment	Vasopressin Injection, Usp Activated Charcoal Amlodipine Calcium Gluconate Dextrose Epinephrine Escitalopram Glucagon Insulin Norepinephrine Potassium Chloride Risperidone Vasopressin Injection, Usp	S C C C C C C C C C C C C	otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Form Of Admin:Not Specified Form Of Admin:Kit Form Of Admin:Not Specified	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16653236	EXPEDITED (15-DAY)			FR-VALIDUS PHARMACEUTICALS LLC-FR- 2019VAL000339			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis	Furosemide			S	Oral	20 Mg, Qd		Validus
	Escitalopram Oxalate			S	Oral	5 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	1.25 Mg, Qd		Not Reported
	Gabapentin			S	Oral	200 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Oral	100 Mg, Qd		Not Reported
	Lamotrigine			S	Oral	100 Mg, Qd		Not Reported
	Exemestane			S	Oral	25 Mg, Qd		Not Reported
	Ramipril			S	Oral	2.5 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gluconate De Potassium	C	Unk	Not Reported
Transipeg /00754501/	C	Unk	Not Reported
Levothyroxine Sodique	C	Unk	Not Reported
Fluidabak	C	Unk	Not Reported
Gluconate Sodium W/Potassium Chloride/Sodium	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16749512	EXPEDITED (15-DAY)		HO	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2019022727			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dystonia	Escitalopram			S	Oral	5 Milligram, Qd		Macleods

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16804506	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2019M1083269			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Mental Disorder; Suicidal Ideation; Wrong Technique In Product Usage Process	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S		Unk		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S	Unknown	Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Buspirone			S		Unk		Not Reported
	Escitalopram			S	Unknown	Reduce To 12.5 Mg Over 8 Weeks		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram	S	Unknown	15 Milligram	Not Reported
Escitalopram	S	Unknown	12.5 Mg In 6 Weeks (Cutting Bits To 5 Mg To Reach Approx.)	Not Reported
Escitalopram	S	Unknown	15 Milligram, Qd	Not Reported
Lorazepam	S		Unk	Mylan
Lorazepam	S		Unk	Mylan
Lorazepam	S		Unk	Mylan
Lorazepam	S		Unk	Mylan
Lorazepam	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16838634	EXPEDITED (15-DAY)		DE, HO, LT, OT	SE-ALEMBIC PHARMACUETICALS LIMITED- 2019SCAL000694			Unknown	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Myeloma Cast Nephropathy; Myocardial Infarction; Renal Failure; Serotonin Syndrome; Ventricular Fibrillation	Venlafaxine			S	Unknown			Alembic
	Escitalopram			S	Unknown	15 Mg		Not Reported
	Escitalopram			S				Not Reported
	Erythromycin			S	Unknown	Unknown		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unknown		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	1240 Mg/6 H		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16853673	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-061961			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoscopy; Seizure	Escitalopram Tablets			S	Unknown	10 Milligram, Once A Day (Each Morning.)		Aurobindo
	Mirtazapine Film-Coated Tablet			S	Oral	30 Milligram, Once A Day,		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Olanzapine Tablet	S	Unknown	Night 10 Milligram, Once A Day	Aurobindo
Azathioprine	S	Unknown	75 Milligram, Once A Day	Not Reported
Dihydrocodeine	S	Unknown	60 Milligram, As Necessary (Four Times A Day. Take With Or Just After Food)	Not Reported
Ferrous Fumarate	S	Unknown	420 Milligram, Once A Day	Not Reported
Folic Acid	S	Unknown	5 Milligram, Once A Day	Not Reported
Promethazine Hydrochloride	S	Unknown	25 Milligram, Once A Day (At Night)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16882878	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD- MAC2018010117			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Entacapone			S	Unknown	Unk		Macleods
	Escitalopram			S	Unknown	Unk		Macleods
	Trimethoprim			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Septrin			S	Unknown	Unk		Not Reported
	Cabergoline			S	Unknown	Unk		Not Reported
	Carbidopa			S	Unknown	Unk		Not Reported
	Stalevo			S	Unknown	Unk		Not Reported
	Levodopa			S	Unknown	Unk		Not Reported
	Duloxetine 90mg Capsule			C	Oral	90 Milligram		Not Reported
	Rivastigmine			C	Transdermal	4.6 Milligram, Patch		Not Reported
	Quetiapine			C	Unknown	25 Milligram		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported
	Co-Beneldopa Capsules			C	Oral	Unk, Co-Beneldopa		Not Reported

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Co-Beneldopa Capsules	C	Oral	25/100 Capsules	Not Reported
Co-Beneldopa Capsules	C	Oral	Unk, 50 Mg/12.5 Mg Capsules	Not Reported
Macrogol	C	Unknown	Unk, Co-Beneldopa 25/100 Mr Capsules	Not Reported
Adcal D3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16882950	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2019US06644			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affect Lability; Akathisia; Drug Ineffective; Drug Intolerance; Irritability	Escitalopram			S	Unknown	Unk		Invagen
	Escitalopram			S				Invagen
	Escitalopram			S				Invagen
	Olanzapine			S	Unknown	Unk		Invagen
	Clonazepam			S	Unknown	Unk		Not Reported
	Clonazepam			S				Not Reported
	Clonazepam			S				Not Reported
	Tetrabenazine			C	Unknown	Unk		Not Reported
	Tetrabenazine			C	Unknown	12.5 Milligram, Tid		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16883849	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019424971		40 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Hallucination, Auditory; Headache; Suicidal Ideation	Lorazepam			S		Unk		Pfizer
	Escitalopram			S		Unk		Not Reported

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04-Oct-2019	16884437	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2019-064606		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradypnoea; Coma	Escitalopram			S	Oral	200 Milligram		Aurobindo	
	Lormetazepam			S	Oral	3 Milligram		Not Reported	
	Imovane			S	Oral	30 Milligram		Not Reported	
	Actiskenan			S	Oral	210 Milligram		Not Reported	
	Toviaz			S	Oral	32 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16884449	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2019M1093022		79 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia; Stress Cardiomyopathy	Desvenlafaxine Succinate			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Mirtazapine			S	Unknown	45 Milligram, Qd		Not Reported	
	Oxazepam			C	Unknown			Mylan	
	Amlodipine			C	Unknown			Mylan	
	Olmesartan			C	Unknown			Mylan	
	Amiodarone			C	Unknown			Mylan	
	Rivaroxaban			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16884967	NON-EXPEDITED			US-PFIZER INC-2019424328		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gemfibrozil			S		Unk		Pfizer	
	Acetaminophen			S				Not Reported	

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Celexa [Citalopram Hydrobromide]	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Strattera	S	Unk	Not Reported
Atomoxetine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16885001	EXPEDITED (15-DAY)		HO, OT	DE-SA-2019SA200898		52 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Gastritis; Hiatus Hernia; Intra-Abdominal Haemorrhage; Jaundice; Lipase Increased; Malaise; Nausea; Pancreatitis Acute; Pyrexia; Tumour Marker Increased; Vomiting; Weight Decreased	Aubagio			S	Oral	14 Mg, Qd		Sanofi
	Citalopram			S				Not Reported
	Escitalopram			S		Unk		Not Reported
	Metypred [Methylprednisolone]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16885298	NON-EXPEDITED			US-BAYER-2019-177584			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Hypersensitivity	Bayer Aspirin 81 Mg			S				Bayer
	Aleve Caplet			S				Bayer
	Pregabalin			S	Oral	1 Df, Qid		Not Reported
	Pseudoephedrine			S				Not Reported
	Ibuprofen			S				Not Reported
	Keflex [Cefalexin Monohydrate]			S				Not Reported
	Amoxicillin			S				Not Reported
	Singula			S				Not Reported
	Biaxin			S				Not Reported
	Macrodantin			S				Not Reported
	Flagyl 250			S				Not Reported
	Lisinopril			S				Not Reported

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Cefdinir	S	Not Reported
Lexapro	S	Not Reported
Prednison	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16886785	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	CA-TEVA-2019-CA-1115767		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Anuria; Blindness; Blindness Cortical; Cardiogenic Shock; Cerebral Infarction; Circulatory Collapse; Colour Blindness; Condition Aggravated; Csf Pressure Increased; Cytotoxic Oedema; Depressed Level Of Consciousness; Electrocardiogram P Wave Abnormal; Electrocardiogram St Segment Depression; Electrocardiogram T Wave Amplitude Decreased; Electrocardiogram T Wave Inversion; Electrocardiogram U Wave Present; Embolism; Embolism Arterial; Hyperdynamic Left Ventricle; Hypoglycaemia; Hypokalaemia; Hypotension; Hypothermia; Intentional Overdose; Ischaemia; Optic Atrophy; Optic Nerve Injury; Overdose; Pulmonary Oedema;	Amlodipine Escitalopram Escitalopram Escitalopram Oxalate Risperidone Risperidone Epinephrine Glucose Norepinephrine Bitartrate Inj 1mg/ML Usp Potassium Chloride Potassium Chloride Vasopressin Inj Usp Activated Charcoal Calcium Gluconate Dextrose Glucagon Insulin Norepinephrine/Procaine Hydrochloride			S S S S S S S S S S S S C C C C C	Oral Unknown Oral Oral Oral Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Oral Unknown Unknown Unknown Unknown Unknown Unknown	60 Milligram Daily;		Teva Ivax Ivax Ivax Actavis Actavis Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Renal Tubular Necrosis;
Retinal Ischaemia;
Reversible Cerebral
Vasoconstriction
Syndrome; Shock;
Tachycardia; Toxicity To
Various Agents; Visual
Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16887212	EXPEDITED (15-DAY)		HO, OT	CH-ALLERGAN-1939887US			Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administered To Patient Of Inappropriate Age	Escitalopram Oxalate - Bp			S	Oral	Mistakenly Take 20 Drops (Equal To 20 Mg) At Once; In Total		Allergan
	Feniallerg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16887238	EXPEDITED (15-DAY)		OT	AT-ALLERGAN-1940215US			Male	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Akathisia; Overdose	Escitalopram Oxalate - Bp			S		Overdose: 40mg		Allergan
	Mirtazapine			S		90 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887571	NON-EXPEDITED			US-TEVA-2019-US-1117217			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Escitalopram			S	Unknown			Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887640	EXPEDITED (15-DAY)		HO, OT	DE-HETERO-HET2019DE01347		47 YR	Male	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticholinergic Syndrome;	Escitalopram			S	Oral	10 Mg Permanent Intake		Hetero	
Blood Creatine	Ramipril			C	Oral	Unk, Qd Admission		Not Reported	
Phosphokinase Increased;						Medication, Not Paused;			
Blood Pressure Increased;	Aripiprazole			S	Oral	10 Mg		Not Reported	
Dehydration;	Bisoprolol			C	Oral	2.5 Mg, Qd		Not Reported	
Hyperthermia;	Diazepam			C	Oral	10 Mg, Tid		Not Reported	
Hypokinesia; Muscle	Chlorprothixen Neuraxpharm			S	Oral	Unk 30-30-30-100		Not Reported	
Rigidity; Neuroleptic	Haloperidol			S	Oral	10 Mg, Bid		Not Reported	
Malignant Syndrome;									
Serotonin Syndrome;									
Tachycardia; Tachypnoea;									
Transaminases Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2019	16887643	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2019-064029		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Medication Error;	Escitalopram			S	Oral	25 Gtt Drops, Total		Aurobindo	
Muscle Contractions									
Involuntary; Paraesthesia;									
Sopor									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2019	16788234	EXPEDITED (15-DAY)		DE, HO	ES-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2019- 12-10		90 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amaurosis; Cardiac	Atrovent			S	Respiratory	2 Inh Every 8 Hours		Boehringer Ingelheim	
Failure; Extensor Plantar					(inhalation)	Inhaled			
Response; Hyperreflexia;	Omeprazol [Omeprazole]			S	Oral	20 Mg, Qd		Not Reported	
Hypoaesthesia;	Lisinopril			S	Oral	5 Mg, Qd		Not Reported	
Hypoaesthesia;	Alendronate Sodium Hydrate			S	Oral	70 Mg, Qwk		Not Reported	
Multimorbidity; Muscular	Furosemide			S	Oral	60 Mg, Qd		Not Reported	
Weakness; Neuromyelitis									
Optica Spectrum Disorder;									
Optic Ischaemic									

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Neuropathy; Pneumonia;	Iron Sulfate	S	Oral	256.3 Mg, Qd	Not Reported
Pupillary Reflex Impaired;	Bisoprolol	S	Oral	5 Mg, Bid	Not Reported
Respiratory Tract	Escitalopram	S	Oral	10 Mg, Qd	Not Reported
Infection; Sight Disability;	Sintrom	S	Oral	1 Mg, Qd, 60 Tablets	Not Reported
Thermohypoaesthesia;	Spironolactone	S	Oral	50 Mg, Qd	Not Reported
Urinary Retention	Allopurinol	S	Oral	100 Mg, Qd	Not Reported