FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

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The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Cover page Case ID(s) with an asterisk ('*') indicate an invalid status and are not captured in the body of the report.

Esub Case ID(s) Submitted:

6687881 6691894 6899800 15545805 16469566 16477295 16656595

16717259

Run by: STEPPERH

Date - Time: 22-JAN-2020 12:57 PM

Total number of cases (Esub): 8

Total number of inactive cases: 0

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6687881

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** N **Country:** USA **Event Date:** 01-Jan-2003 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 06-Feb-2009 **Mfr Rcvd Date:** 26-Jan-2009 **Mfr Control #:** US-TYCO HEALTHCARE/MALLINCKRODT-T200801054 **Application #:** 018163

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	RESTORIL				UNK, qd	DEPRESSION	Oct-2003	2007
2	CYMBALTA				UNK, qd	DEPRESSION	Oct-2003	May-2007
3	CYMBALTA					ANXIETY		
4	LEXAPRO				UNK, qd	DEPRESSION	Oct-2003	2006
5	LEXAPRO					ANXIETY		
6	NEURONTIN				UNK	AMNESIA	Oct-2003	May-2007
7	NEURONTIN					RESTLESS LEGS SYNDROME		
8	RESTORIL					ANXIETY		
9	SEROQUEL				UNK, qd	DEPRESSION	Oct-2003	May-2007
10	SEROQUEL					ANXIETY		
11	TRAZODONE HYDROCHLORIDE				UNK	DEPRESSION	Oct-2003	May-2007
12	TRAZODONE HYDROCHLORIDE					ANXIETY		
13	WELLBUTRIN				UNK, qd	DEPRESSION	Oct-2003	May-2007
14	WELLBUTRIN					ANXIETY		
15	XANAX				UNK, qd	DEPRESSION	Oct-2003	May-2007
16	XANAX					SLEEP DISORDER		

Case ID: 6687881

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
17	XANAX					ANXIETY		
18	ZOLOFT				UNK	DEPRESSION	Oct-2003	May-2007
19	ZOLOFT					ANXIETY		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	RESTORIL		NA	Unk				TYCO	
2	CYMBALTA		NA	NA					
3	CYMBALTA		NA	NA					
4	LEXAPRO		Yes	NA					
5	LEXAPRO		Yes	NA					
6	NEURONTIN		Unk	NA					
7	NEURONTIN		Unk	NA					
8	RESTORIL		NA	Unk				TYCO	
9	SEROQUEL		NA	NA					
10	SEROQUEL		NA	NA					
11	TRAZODONE HYDROCHLORIDE		Unk	NA					
12	TRAZODONE HYDROCHLORIDE		Unk	NA					
13	WELLBUTRIN		NA	NA					
14	WELLBUTRIN		NA	NA					
15	XANAX		NA	NA					

Case ID: 6687881

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
16	XANAX		NA	NA					
17	XANAX		NA	NA					
18	ZOLOFT		Unk	NA					
19	ZOLOFT		Unk	NA					

Event Information:

Preferred Term (MedDRA Â Version: 22.1)	ReC
Abnormal behaviour	NA
Amnesia	NA
Anger	Unk
Anxiety	NA
Aphasia	NA
Asbestosis	NA
Attention deficit/hyperactivity disorder	NA
Blood cholesterol abnormal	Unk
Blood pressure increased	Unk
Blood triglycerides abnormal	Unk
Bruxism	NA
Confusional state	Unk
Constipation	NA
Depression	NA
Drug withdrawal headache	Unk
Dyskinesia	NA
Emotional distress	NA

Case ID: 6687881

Feeling abnormal	Unk
Gait disturbance	NA
Hallucination	Unk
Hostility	NA
Hyperhidrosis	NA
Hypothyroidism	NA
Lethargy	NA
Mental disorder	Unk
Mental impairment	Unk
Muscle spasms	NA
Muscle twitching	NA
Night sweats	NA
Nightmare	Unk
Pain	Unk
Pallor	Unk
Pancreatitis	Unk
Panic attack	Unk
Paranoia	NA
Pyrexia	NA
Renal failure	Unk
Restless legs syndrome	NA
Road traffic accident	Unk
Screaming	NA
Seizure	Unk
Sleep apnoea syndrome	Unk
Stress	Unk
Suicidal ideation	Unk

Case ID: 6687881

Suicide attempt	Unk
Tachycardia	NA
Tardive dyskinesia	Unk
Terminal insomnia	NA
Thyroid disorder	Unk
Tremor	NA
Urinary incontinence	NA
Vomiting	Unk
Weight decreased	Unk
Withdrawal syndrome	Unk

Event/Problem Narrative:

This report was received from a consumer and another manufacturer.A male patient was prescribed temazepam (Restoril) in OCT2003 for the treatment of severe depression and anxiety which ensued following a work accident after which the patient was rendered unable to work due to a severe shoulder and arm injury. The patient was also reportedly prescribed alprazolam (Xanax), escitalopram oxalate (Lexapro), quetiapine (Seroquel), bupropion (Wellbutrin) and duloxetine hydrochloride (Cymbalta) concomitantly for the same indications.In OCT2003, almost immediately after taking the prescribed medications, the patient "became a living zombie." The patient stated that he was so medicated that there were times he did not know what day of the week or what month it was. While receiving the medications, the patient was involved in five automobile accidents. In early 2007, the patient claimed to experience tardive dyskinesia, characterized by unusual movements of the mouth, including involuntary movements up and down and side to side in an uncontrolled manner. The patient's lips would also purse up and down, his tongue would move back and forth uncontrollably and his teeth would grind. The patient raised the issue with his psychiatrist, whom he said always changed the subject, and mentioned he felt that the psychiatrist did not want to discuss the condition. Soon afterwards, on 10MAY2007, the patient received a letter of dismissal of care from his psychiatrist, stating that he had missed too many appointments and as per office policy, their professional relationship was to be terminated after 15 days from receipt of the letter. The patient admitted to missing some appointments due to living 50 miles from the office and being "stoned" most of the time. The patient contacted the (b) (6) ((b) (6)) for help in realizing he would effectively be without any medication within a few days. The patient was informed that it would be a lengthy process to change physicians and nothing could be done for him at that time. As the patient could no longer obtain the medications, he discontinued their use abruptly. Within a few days, the patient experienced withdrawal symptoms characterized by profuse sweating and sporadic sleep patterns. The patient also experienced hallucinations, severe headaches, and an inability to function except for bathroom visits. On drifting off to sleep, the patient would wake himself up screaming and hollering. The patient attempted suicide by "swallowing a bunch of pills" and refused his wife's pleas to go to the emergency room (ER) for fear of being institutionalized. For two weeks the patient lay on his couch in this condition. After this period the patient reportedly lost around 12 to 15

pounds and "looked like a ghost." The patient took the medications daily, as prescribed, for almost four years from OCT2003 until MAY2007, with the exception of Lexapro (discontinued in 2006 due to being considered redundant). Since going through the withdrawal process just over a year ago, the patient continued to experience severe headaches, severe depression and anxiety, severe insomnia, sleep apnea, horrifying nightmares, daily physical and mental pain and suicidal thoughts, which were stressful. The patient's thyroid had reportedly "shut down" and his blood pressure was stated as "sky high;" both required medical treatment. The patient's physician told him he was in the "third phase of renal failure" and was close to needing dialysis. The patient's cholesterol and triglycerides were also "out of control." The patient's inability to function resolved after two weeks and the five road traffic accidents occurred between OCT2003 and MAY2007. The outcomes of the events "became a living zombie," hallucinations, confusion, tardive dyskinesia, weight loss, "looked like a ghost," and attempted suicide were not reported. The patient's medical history included severe depression and anxiety, severe shoulder and arm injuries resulting from a work accident, and an inability to work due to the injuries.Follow-up information was received on 01JUL2008 from a consumer via another manufacturer (Pfizer, Inc., Manufacturer Report Number 2008051192).After discontinuing the medications abruptly in 2007, the patient also experienced a couple of seizures. The outcome of the seizures was not reported.Follow-up information was received on 25AUG2008 from a consumer via another manufacturer (Pfizer, Inc., Manufacturer Report Number 2008051192).The patient also initiated the use of trazodone, gabapentin (Neurontin) and sertraline (Zoloft) in OCT2003 for the treatment of severe depression and anxiety.Upon receiving the letter of dismissal from the physician, in a fit of panic, rage and insanity, the patient swallowed a full bottle of some pills and vomited. Additionally, the patient experienced pancreatitis.The outcomes of the events pancreatitis, panic, rage, insanity and vomited were not reported.Follow-up information was received on 15OCT2008 from a healthcare professional (physician) via another manufacturer (Eli Lilly and Co., Reference Number US200806004436).In addition to the previously reported events, the patient reportedly experienced "abestosis," dyskinesia, muscle twitching, bruxism, hyperhidrosis, insomnia, early morning awakening, emotional distress, depression, anxiety, abnormal behavior, hostility, tachycardia, urinary incontinence, lethargy, aphasia, pyrexia, muscle spasms, restless leg syndrome, attention deficit disorder, hypothyroidism, chronic constipation and gait disturbance. The outcomes of the events of "abestosis," dyskinesia, muscle twitching, bruxism, hyperhidrosis, insomnia, early morning awakening, emotional distress, depression, anxiety, abnormal behavior, hostility, tachycardia, urinary incontinence, lethargy, aphasia, pyrexia, muscle spasms, restless leg syndrome, attention deficit disorder, hypothyroidism, chronic constipation and gait disturbance were not reported. Follow-up information was received on 05NOV2008 from a healthcare professional (pharmacist) via another manufacturer (Pfizer, Inc., Manufacturer Report Number 2008051192).The patient initiated the use of Xanax for the additional indication of a sleep disorder. The patient initiated Neurontin for the treatment of memory loss and restless leg syndrome. In addition to the previously reported events, the patient experienced screaming, impairment in activities of daily living and sedation. The outcomes of screaming, impairment in activities of daily living and sedation were not reported. Additional medical history included back pain, sleep disorder, memory loss, restless leg syndrome, abnormal blood pressure, abnormal cholesterol and triglycerides and a thyroid disorder. Concomitant medications included lisinopril, fenofibrate, levothyroxine, zolpidem tartrate (Ambien), hydrochlorothiazide, hydrocodone with acetaminophen and carisoprodol.Follow-up information was received on 26JAN2009, from a consumer, confirmed by healthcare professionals (physician and pharmacist), via another manufacturer (Pfizer) Reference number 2008051192.The patient was 63-years-old at the time of the report.In addition to previously reported events, the patient experienced having no memory due to the effects of the medication, over vast amounts of time during the four-year therapy period. In either late 2006 or early 2007, the patient claimed to experience tardive dyskinesia. The patient stated that the condition exacerbated his tendency to be a recluse as he found it very difficult and embarrassing to attempt interaction with other individuals. The patient reported that after four years of treatment, his physician dismissed him as a patient due to an

Case ID: 6687881

excessive number of missed appointments and gave him two weeks to find another physician. The patient was unable to get the medications through another physician via his company's workers compensation program, and was unable to afford private care. As a result, the patient was forced to stop taking his medications abruptly. Within a couple of days, the patient experienced a severe withdrawal reaction that included fever and cramps. Prior to receiving the medications, the patient reported being in good health other than the depression and anxiety. After a year of abruptly stopping the medications, the patient continued to experience constant thoughts of suicide daily. The patient also experienced paranoia, night sweats, uncontrolled body shaking and aching all over. The patient's wife left him when he became "strange and bizarre" from taking the medications. The patient was charged with a DWI (driving while intoxicated) when he wasn't drinking, but laboratory results showed some of the drugs in his system. The patient was previously treated with Effexor but experienced an adverse reaction of hypertensive blood pressure. The patient was medically treated for the thyroid disorder and "sky-high" blood pressure. Additionally, "abestosis" was clarified as asbestosis.The outcomes of the events of no memory, fever, cramps, paranoia, night sweats, uncontrolled body shaking and aching all over were not reported. The patient had no previous history of DWI.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ACCIDENT AT WORK	02-Aug-2002		YES
AMNESIA			YES
ANXIETY			YES
BACK PAIN			YES
BLOOD CHOLESTEROL ABNORMAL			YES
BLOOD PRESSURE ABNORMAL			YES
BLOOD TRIGLYCERIDES ABNORMAL			YES
DEPRESSION			YES
LOSS OF EMPLOYMENT			YES
RESTLESS LEGS SYNDROME			YES
SLEEP DISORDER			YES
SUICIDAL IDEATION			YES

Case ID: 6687881

Medical History Product(s)	Start Date	End Date	Indications	Events
THYROID DISORDER			YES	

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	AMBIEN				SLEEP DISORDER			
2	CARISOPRODOL				BACK PAIN			
3	FENOFIBRATE				BLOOD CHOLESTEROL ABNORMAL			
4	FENOFIBRATE				BLOOD TRIGLYCERIDES ABNORMAL			
5	HYDROCHLOROTHIAZIDE							
6	HYDROCODONE BITARTRATE				BACK PAIN			
7	LEVOTHYROXINE				THYROID DISORDER			
8	LISINOPRIL				BLOOD PRESSURE ABNORMAL			

Reporter Source:

Study Report?: No

Sender Organization: COVIDIEN

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6691894

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** Y **Country:** USA **Event Date:** 01-Jan-2003 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 03-Aug-2009 **Mfr Rcvd Date:** 30-Jan-2009 **Mfr Control #:** US-ASTRAZENECA-2008UW13210 **Application #:** 020639

Patient Information:

Age: 63 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	SEROQUEL			Oral		DEPRESSION	Oct-2003	2007
2	CYMBALTA					ANXIETY	Oct-2003	2007
3	CYMBALTA					DEPRESSION	Oct-2003	2007
4	EFFEXOR						Oct-2003	
5	LEXAPRO					DEPRESSION	Oct-2003	2006
6	LEXAPRO					ANXIETY	Oct-2003	2006
7	NEURONTIN					AMNESIA	Oct-2003	
8	NEURONTIN					RESTLESS LEGS SYNDROME	Oct-2003	
9	RESTORIL					DEPRESSION	Oct-2003	2007
10	RESTORIL					ANXIETY	Oct-2003	2007
11	SEROQUEL			Oral		ANXIETY	Oct-2003	2007
12	TRAZODONE HYDROCHLORIDE						Oct-2003	
13	WELLBUTRIN					DEPRESSION	Oct-2003	2007
14	WELLBUTRIN					ANXIETY	Oct-2003	2007
15	XANAX					DEPRESSION	Oct-2003	2007
16	XANAX					ANXIETY	Oct-2003	2007

Case ID: 6691894

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
17	XANAX					SLEEP DISORDER	Oct-2003	2007
18	ZOLOFT						Oct-2003	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	SEROQUEL	0 Year	Unk	NA					
2	CYMBALTA	0 Year	Unk	NA					
3	CYMBALTA	0 Year	Unk	NA					
4	EFFEXOR	0 Year	Unk	NA					
5	LEXAPRO	0 Year	Unk	NA					
6	LEXAPRO	0 Year	Unk	NA					
7	NEURONTIN	0 Year	Unk	NA					
8	NEURONTIN	0 Year	Unk	NA					
9	RESTORIL	0 Year	Unk	NA					
10	RESTORIL	0 Year	Unk	NA					
11	SEROQUEL	0 Year	Unk	NA					
12	TRAZODONE HYDROCHLORIDE	0 Year	NA	NA					
13	WELLBUTRIN	0 Year	Unk	NA					
14	WELLBUTRIN	0 Year	Unk	NA					
15	XANAX	0 Year	Unk	NA					
16	XANAX	0 Year	Unk	NA					

Case ID: 6691894

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	**Interval 1st Dose to Event**	**DeC**	**ReC**	**Lot#**	**Exp Date**	**NDC #**	**MFR/Labeler**	**OTC**
17	XANAX	0 Year	Unk	NA					
18	ZOLOFT	0 Year	Unk	NA					

Event Information:

Preferred Term (MedDRA Version: 22.1)	ReC
Amnesia	NA
Anger	NA
Anxiety	NA
Aphasia	NA
Asbestosis	NA
Attention deficit/hyperactivity disorder	NA
Blood cholesterol abnormal	NA
Blood cholesterol increased	NA
Blood triglycerides abnormal	NA
Bruxism	NA
Constipation	NA
Decreased appetite	NA
Depression	NA
Disorientation	NA
Dissociative disorder	NA
Emotional distress	NA
Feeling abnormal	NA
Gait disturbance	NA
Hallucination	NA
Headache	NA

Case ID: 6691894

Hostility	NA
Hyperhidrosis	NA
Hypertension	NA
Hypothyroidism	NA
Insomnia	NA
Lethargy	NA
Loss of personal independence in daily activities	NA
Mental disorder	NA
Muscle spasms	NA
Muscle twitching	NA
Nightmare	NA
Overdose	NA
Pain	NA
Pallor	NA
Pancreatitis	NA
Panic disorder	NA
Paranoia	NA
Pyrexia	NA
Regurgitation	NA
Renal failure	NA
Restless legs syndrome	NA
Road traffic accident	NA
Screaming	NA
Seizure	NA
Sleep apnoea syndrome	NA
Stress	NA
Suicidal ideation	NA

Case ID: 6691894

Suicide attempt	NA
Tachycardia	NA
Tardive dyskinesia	NA
Thyroid disorder	NA
Treatment noncompliance	NA
Urinary incontinence	NA
Vomiting	NA
Weight decreased	NA
Withdrawal syndrome	NA

Event/Problem Narrative:

OVERDOSE, SUICIDE ATTEMPT, SUICIDAL THOUGHTS, THIRD PHASE OF RENAL FAILURE, THYROID SHUT DOWN, BECAME A ZOMBIE LITERALLY STONED, DID NOT KNOW DAY OF WEEK, UNABLE TO FUNCTION}A report was received concerning from 63 year old male consumer via another pharmaceutical company (Pfizer). Follow-up was received from a pharmacist; and a physician via another pharmaceutical company (GlaxoSmithKline).The patient was being treated with SEROQUEL (quetiapine fumarate) oral for depression, XANAX (alprazolam) for depression, anxiety and sleep, WELLBUTRIN (bupropion hydrochloride) for depression and anxiety, LEXAPRO (escitalopram oxalate) for depression and anxiety, RESTORIL (temazepam) for depression and anxiety, CYMBALTA (duloxetine) for depression and anxiety, ZOLOFT (sertraline), Neurontin (gabapentin) for memory loss and restless leg syndrome EFFEXOR (venlafaxine hydrochloride) and trazodone. Concomitant medications included lisinopril for blood pressure, fenofibrate for triglycerides and cholesterol, levothyroxine for thyroid disorder, zolpidem tartrate for sleep disorder, hydrochlorothiazide for fluid loss, hydrocodone with acetaminophen for back pain and carisoprodol for back pain.The patient had a history of multiple shoulder and arm injuries from an accident in Aug-2002, severe depression, suicidal ideation and anxiety. The patient experienced severe headaches which started during 2007, overdose, suicide attempt, suicidal thoughts, third phase of renal failure, thyroid shut down, unable to function, depression overpowering, cholesterol out of control, triglycerides out of control, sleep apnea, blood pressure sky high, stressful, daily physical pain, insanity, daily mental pain, lost 12 - 15 pounds, screaming hollering, insomnia, sweating profusely, hallucinations, teeth grind, treatment noncompliance, seizures, horrifying nightmares, and probable tardive dyskinesia which started during 2007; became a zombie literally stoned, and no memory, which started during 2003; pancreatitis, did not know day of week, five auto accidents, anxiety levels are mind bending, panic, rage, vomited cannot hold food down, severe withdrawal, fever, attention deficit disorder, unable to eat, asbestosis, emotional distress, urinary incontinence, lethargy, aphasia, muscle twitching, cramps, restless leg syndrome, chronic constipation, tachycardia, high cholesterol, and paranoia, hypothyroidism, feeling abnormal, pallor, abnormal cholesterol, inability to hold down solid foods, gait disturbance, insomnia and hostility.Before starting these medications, he was in very good health other than anxiety and depression. He started the medications, dosages unknown, in Oct-2003 for severe depression and anxiety. He immediately became a living zombie. He was so medicated that there were times when he did not know

Case ID: 6691894

what day of the week or what month it was. There are vast amounts of time where he has absolutely no memory. While on these medications, he was in five automobile accidents. In early 2007 he started having unusual movements of his mouth, involuntarily up and down, side to side in an uncontrollable manner. His lips would purse up and down and his tongue would move back and forth uncontrollably. His teeth would grind. He suspected it might be due to some of the medications he was taking. He felt he probably had tardive dyskinesia. The tardive dyskinesia has exacerbated his tendency to be a recluse. After four years of treatment his physician dismissed him as a patient due to excessive missed appointments. Upon receiving the letter of dismissal from his physician, in a fit of panic, rage, and insanity, he swallowed a full bottle of some pills and vomited. He was literally stoned most of the time and there were times he was not cognizant of an existing appointment. He was given two weeks notice to find another physician. He was unable to get the medicines with insurance or finances, and had to stop taking his medication abruptly, in 2007. He experienced a rather severe withdrawal. Within a couple of days he started hallucinating and sweating profusely. He would lie on the couch unable to function except for using the bathroom. He was unable to eat. He had a couple of seizures. He slept sporadically and awoke screaming and hollering from horrifying nightmares. He had fever and cramps. He resolved that he wanted to die and unsuccessfully attempted suicide by swallowing a bunch of pills (not specified). He lost 12 to 15 pounds and looked like a ghost. He suffered from daily physical and mental pain and continued to have suicidal thoughts which are very stressful. His thyroid shut down and he was treated medically. His blood pressure was sky high and was treated medically. He was in the third phase of renal failure and was close to needing dialysis. He had severe insomnia, early morning awakening and sleep apnea. His triglycerides and cholesterol were out of control. He had severe headaches and his depression at times was overpowering. His anxiety levels were mind bending. Since abruptly stopping the medications, he still went through each day with constant thoughts of suicide. On an unknown date he experienced Pancreatitis. The events were considered serious due to medically important. The patient has not yet recovered.Summary of follow-up information received 27-Aug-2008: suspect drugs Zoloft, Neurontin and trazodone, suspect drug dosing regimens updated, event Pancreatitis*, and added sentence and events upon receiving the letter of dismissal from his physician, in a fit of panic, rage, and insanity, he swallowed a full bottle of some pills and vomited.Summary of follow-up information received 31-Oct-2008: The case is now medically confirmed, patient age 63 years old, adverse events no memory, withdrawal, cramps, fever, restless leg syndrome, attention deficit disorder, unable to eat, chronic constipation, asbestosis, muscle twitching, emotional distress, tachycardia, urinary incontinence, lethargy, and aphasia; suspect medication details, and concomitant medications.Summary of follow-up information received by AstraZeneca 30-Jan-2009: Added suspect medication of venlafaxine hydrochloride and added events of paranoia and high cholesterol.Summar of follow-up information: combined case safety date from 2008UW23140 to 2008UW13210 - updated the narrative with nonserious events of hypothyroidism, feeling abnormal, pallor, abnormal cholesterol, inability to hold down food, gait disturbance, insomnia, hostility; medical history of severe depression, suicidal ideation and anxiety.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
MULTIPLE INJURIES	Aug-2002		UNKNOWN
ANXIETY			UNKNOWN

Case ID: 6691894

DEPRESSION	UNKNOWN
SUICIDAL IDEATION	UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Cholesterol					
Triglycerides					

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN\HYDROCODONE BITARTRATE				BACK PAIN			
2	AMBIEN				SLEEP DISORDER			
3	CARISOPRODOL				BACK PAIN			
4	FENOFIBRATE				BLOOD TRIGLYCERIDES			
5	FENOFIBRATE				BLOOD CHOLESTEROL			
6	HYDROCHLOROTHIAZIDE				DEHYDRATION			
7	LEVOTHYROXINE				THYROID DISORDER			
8	LISINOPRIL				BLOOD PRESSURE			

Reporter Source:

Study Report?: No

Sender Organization: ASTRAZENECA

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6899800

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** N **Country:** USA **Event Date:** 01-Oct-2003 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 03-Feb-2009 **Mfr Rcvd Date:** 26-Jan-2009 **Mfr Control #:** US-WYE-H07876809 **Application #:** 020151

Patient Information:

Age: 58 YR **Sex:** Male **Weight:** 90.8 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	EFFEXOR			Oral	unknown	DEPRESSION		
2	CYMBALTA				unknown	DEPRESSION	Oct-2003	May-2007
3	LEXAPRO			Oral	unknown	DEPRESSION	Oct-2003	May-2007
4	LEXAPRO					ANXIETY		
5	NEURONTIN				unknown	AMNESIA	Oct-2003	
6	NEURONTIN					RESTLESS LEGS SYNDROME		
7	RESTORIL				unknown	DEPRESSION	Oct-2003	May-2007
8	SEROQUEL				unknown	DEPRESSION	Oct-2003	May-2007
9	SEROQUEL					ANXIETY		
10	TRAZODONE HYDROCHLORIDE				unknown		Oct-2003	
11	WELLBUTRIN				unknown	DEPRESSION	Oct-2003	May-2007
12	WELLBUTRIN					ANXIETY		
13	XANAX				unknown	ANXIETY	Oct-2003	May-2007
14	XANAX					DEPRESSION		
15	XANAX					SLEEP DISORDER		
16	ZOLOFT				unknown		Oct-2003	

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6899800

#	Product Name	Compounded Drug ? / Interval 1st Dose to Event	Dose/ Frequency / DeC	Route / ReC	Dosage Text / Lot#	Exp Date	NDC #	Indications(s) / MFR/Labeler	Start Date	End Date / OTC
1	EFFEXOR		No	NA				WYETH		
2	CYMBALTA	3 Year	No	NA				ELI LILLY AND CO		
3	LEXAPRO	3 Year	No	NA				LUNDBECK		
4	LEXAPRO		NA	NA				LUNDBECK		
5	NEURONTIN		NA	NA						
6	NEURONTIN	3 Year	No	NA						
7	RESTORIL	3 Year	No	NA						
8	SEROQUEL		NA	NA				UNKNOWN		
9	SEROQUEL	3 Year	No	NA				UNKNOWN		
10	TRAZODONE HYDROCHLORIDE	3 Year	No	NA				UNKNOWN		
11	WELLBUTRIN	3 Year	No	NA				GLAXOSMITHKLINE		
12	WELLBUTRIN		NA	NA				GLAXOSMITHKLINE		
13	XANAX		NA	NA						
14	XANAX		NA	NA						
15	XANAX	3 Year	No	NA						
16	ZOLOFT	3 Year	No	NA				PFIZER		

Event Information:

Preferred Term (MedDRA Â© Version: 22.1)	ReC
Abnormal behaviour	NA

Case ID: 6899800

Amnesia	NA
Anger	NA
Anxiety	NA
Aphasia	NA
Asbestosis	NA
Attention deficit/hyperactivity disorder	NA
Blood cholesterol increased	NA
Blood triglycerides increased	NA
Bruxism	NA
Condition aggravated	NA
Constipation	NA
Decreased appetite	NA
Depression	NA
Disorientation	NA
Drug withdrawal syndrome	NA
Emotional distress	NA
Feeling abnormal	NA
Hallucination	NA
Headache	NA
Hyperhidrosis	NA
Hypertension	NA
Hypothyroidism	NA
Insomnia	NA
Intentional overdose	NA
Lethargy	NA
Loss of personal independence in daily activities	NA
Mental disorder	NA

Case ID: 6899800

Muscle spasms	NA
Muscle twitching	NA
Night sweats	NA
Nightmare	NA
Pancreatitis	NA
Panic reaction	NA
Paranoia	NA
Pyrexia	NA
Renal failure	NA
Restless legs syndrome	NA
Road traffic accident	NA
Screaming	NA
Sedation	NA
Seizure	NA
Sleep apnoea syndrome	NA
Social avoidant behaviour	NA
Suicidal ideation	NA
Suicide attempt	NA
Tachycardia	NA
Tardive dyskinesia	NA
Terminal insomnia	NA
Tremor	NA
Urinary incontinence	NA
Vomiting	NA
Weight decreased	NA

Case ID: 6899800

Event/Problem Narrative:

This case was considered medically important. Information was received from a consumer regarding a 58-year-old male patient who received Effexor (venlafaxine hydrochloride tablet) therapy and experienced becoming a "living zombie", times where he did not know what day of the week or what month it was, reluctant to leave his home and interact with other people, teeth grinding, tardive dyskinesia, mouth moving involuntarily up and down and his tongue moving back and forth uncontrollably, vomited, wanting to die, unsuccessfully attempted suicide, swallowed a full bottle of pills (unspecified) because he wanted to die, insanity, rage, a fit of panic, five auto accidents, horrifying nightmares, weight loss of 12 to 15 pounds, thyroid had "shut down", blood pressure was "sky high", "in the third phase of renal failure and is close to needing dialysis", triglycerides were "out of control", cholesterol was "out of control", high anxiety levels, restless legs syndrome, attention deficit disorder, constipation, sleep apnea, pancreatitis, asbestosis, early morning awakening, muscle twitching, emotional distress, tachycardia, urinary incontinence, lethargy, cramps, impaired daily living activities, would lay on the couch for several days at a time, unable to function except for using the bathroom, aphasia, missing doctor's appointments because he was "literally stoned" most of the time, periods of time where he had no memory at all, and becoming strange/bizarre from the medications. He also experienced the following events after abruptly discontinuing medications: hallucinations, screaming/ hollering, insomnia, fever, sweating, cramps, headaches, inability to eat, night sweats, paranoia, uncontrollable body shaking, and "a couple of seizures." MEDICAL HISTORY: The patient's concurrent illnesses include hypertension, blood triglycerides increased, blood cholesterol increased, thyroid disorder, amnesia, and back pain with a past history of accident (resulting in severe shoulder and arm injuries on 02-AUG-2002). PRODUCT DETAILS: Indication for Effexor was depression. Duration of therapy was not provided. Dose regimen was not provided. Additional suspect medication included Lexapro (escitalopram oxalate), Xanax (alprazolam), Zoloft (sertraline), Neurontin (gabapentin), Trazodone, Seroquel (quetiapine), Wellbutrin (bupropion hydrochloride), Restoril (temazepam) and Cymbalta (duloxetine). CONCOMITANT THERAPY: Concomitant therapy included Fenofibrate, Levothyroxine, Ambien (zolpidem tartrate), Hydrochlorothiazide, Hydrocodone W/Acetaminophen (hydrocodone bitartrate/paracetamol), Carisoprodol and Lisinopril. EVENT DETAILS: The patient experienced becoming a "living zombie" (feeling abnormal) and times where he was so medicated he did not know what day of the week or what month it was (disorientation) in Oct-2003. He also experienced periods of time where he had no memory at all (amnesia)(condition aggravated), becoming strange/bizarre from the medications (abnormal behaviour) causing his wife to leave him, and being in five auto accidents (road traffic accident). Sometime in late 2006 or early 2007, he began experiencing his mouth moving involuntarily up and down, his tongue moving back and forth uncontrollably and teeth grinding (bruxism). After the patient did some "researching", he concluded that he "probably had tardive dyskinesia" (tardive dyskinesia) which he defined as "uncontrollable mouth movements." The dyskinesia caused the patient embarrassment and he became reluctant to leave his home and interact with other people (social avoidant behaviour). Venlafaxine, trazodone, gabapentin, and sertraline therapies were discontinued on unknown dates. Additionally, the patient reported that his physician dismissed him as a patient due to excessive missed appointments. He stated that he was "literally stoned" most of the time (sedation), and that there was a time or two that he was not cognizant of an existing appointment. He received a letter of dismissal on 10-May-2007 giving him two weeks notice to find a new physician. Upon receiving the letter, in a fit of panic (panic reaction), rage (anger), and insanity (mental disorder), the patient swallowed a full bottle of unspecified pills (intentional overdose) and then vomited (vomiting). He reported that he wanted to die (suicidal ideation) and that swallowing a bunch of pills was an unsuccessful suicide attempt (suicide attempt). Because he was unable to get medications through another physician, he was forced to abruptly discontinue the medications he was taking at the time which included escitalopram, alprazolam, duloxetine, quetiapine, bupropion, and temazepam in May-2007. Shortly after running out of the medications, he experienced severe withdrawal (drug withdrawal syndrome) and was experiencing hallucinations (hallucination), screaming and hollering (screaming), insomnia (insomnia), fever (pyrexia), profuse

Case ID: 6899800

sweating (hyperhidrosis), cramps (muscle spasms), severe headaches (headache), inability to eat and hold down solid foods (anorexia)(vomiting), night sweats (night sweats), paranoia (paranoia), uncontrollable body shaking (tremor) and "a couple of seizures" (convulsion). Dates of Effexor therapy were not provided and it is unclear if therapy had been discontinued previously. Additionally, he experienced impaired daily living activities [would lay on the couch for several days at a time, unable to function except for using the bathroom] (activities of daily living impaired), only able to sleep sporadically and when he would drift off to sleep, he would wake screaming and hollering, horrifying nightmares (nightmare), and weight loss of 12 to 15 pounds (weight decreased). He was also reportedly told by his physician that he "was in the third phase of renal failure and is close to needing dialysis" (renal failure). The patient also experienced attention deficit disorder (attention deficit/hyperactivity disorder), constipation (constipation), sleep apnea (sleep apnoea syndrome), pancreatitis (pancreatitis), asbestosis (asbestosis), early morning awakening (early morning awakening), muscle twitching (muscle twitching), emotional distress (emotional distress), tachycardia (tachycardia), urinary incontinence (urinary incontinence), lethargy (lethargy), aphasia (aphasia). He also experienced worsening of the following pre-existing events (condition aggravated): periods of time where he had no memory at all (amnesia), blood pressure was "sky high" (hypertension), thyroid had "shut down" (hypothyroidism), triglyceride and cholesterol levels were "out of control" (blood triglycerides increased)(blood cholesterol increased), high anxiety levels (anxiety), restless legs syndrome (restless legs syndrome). As of 15-Jan-2009, venlafaxine, escitalopram, alprazolam, sertraline, gabapentin, trazodone, quetiapine, bupropion, temazepam, and duloxetine remained discontinued. The outcome of events of suicidal ideation, renal failure, hypertension, tardive dyskinesia, amnesia, insomnia, screaming, nightmare, night sweats, paranoia, tremor, depression and anxiety were not recovered. The outcomes of all other events were unknown. This case was considered medically important for the following events: suicide attempt, suicidal ideation, intentional overdose, panic, anger, mental disorder, pancreatitis, convulsion, renal failure, drug withdrawal syndrome and activities of daily living impaired. The report of these events remained medically unconfirmed and further details were not provided.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ACCIDENT			NO
AMNESIA			YES
BACK PAIN			YES
BLOOD CHOLESTEROL INCREASED			YES
BLOOD TRIGLYCERIDES INCREASED			YES
HYPERTENSION			YES
THYROID DISORDER			YES

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 6899800

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN\HYDROCODONE BITARTRATE				BACK PAIN			
2	AMBIEN				SLEEP DISORDER			
3	CARISOPRODOL				BACK PAIN			
4	FENOFIBRATE				BLOOD TRIGLYCERIDES INCREASED			
5	FENOFIBRATE				BLOOD CHOLESTEROL INCREASED			
6	HYDROCHLOROTHIAZIDE							
7	LEVOTHYROXINE				THYROID DISORDER			
8	LISINOPRIL				HYPERTENSION			

Reporter Source:

Study Report?: No

Sender Organization: WYETH

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15545805

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** HO,OT, **Application Type:** NDA

FDA Rcvd Date: 10-Dec-2019 **Mfr Rcvd Date:** 05-Dec-2019 **Mfr Control #:** CA-PFIZER INC-2018433138 **Application #:** 020987

Patient Information:

Age: 74 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PANTOPRAZOLE			Unknown	UNK			
2	AMLODIPINE BESILATE		10 MG/QD	Unknown	10 mg, 1x/day		2018	2018
3	CALCIUM CARBONATE			Oral	UNK			
4	ERGOCALCIFEROL			Oral	UNK			
5	ESCITALOPRAM			Unknown	UNK			
6	HYDROMORPHONE HYDROCHLORIDE			Oral	UNK			
7	SANDOSTATIN		30 MG//month	Intramuscular	30 mg, monthly		21-Nov-2012	
8	SANDOSTATIN		20 MG//month	Intramuscular	20 mg, monthly			
9	SANDOSTATIN		20 MG//month	Intramuscular	20 mg, monthly	Neuroendocrine tumour		
10	SANDOSTATIN		20 MG/	Subcutaneous	20 mg, UNK			
11	SANDOSTATIN		BID	Subcutaneous	UNK, 2x/day	Neuroendocrine tumour	11-Jul-2011	24-Jul-2011

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	PANTOPRAZOLE		Unk	NA				PFIZER	
2	AMLODIPINE BESILATE		Unk	NA				PFIZER	
3	CALCIUM CARBONATE		Unk	NA				PFIZER	

Case ID: 15545805

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
4	ERGOCALCIFEROL		Unk	NA					
5	ESCITALOPRAM		Unk	NA					
6	HYDROMORPHONE HYDROCHLORIDE		Unk	NA				UNKNOWN	
7	SANDOSTATIN		Unk	NA					
8	SANDOSTATIN		Unk	NA					
9	SANDOSTATIN		Unk	NA					
10	SANDOSTATIN		Unk	NA					
11	SANDOSTATIN		Unk	NA					

Event Information:

Preferred Term (MedDRA Â Version: 22.1)	ReC
Abdominal discomfort	NA
Anger	NA
Anxiety	NA
Arthropod bite	NA
Blood pressure increased	NA
Blood pressure systolic increased	NA
Bronchitis	NA
Cerebrovascular accident	NA
Contusion	NA
Cough	NA
Crying	NA
Depressed mood	NA

Case ID: 15545805

Depression	NA
Diarrhoea	NA
Drug hypersensitivity	NA
Emotional distress	NA
Erythema	NA
Fall	NA
Fatigue	NA
Feeling abnormal	NA
Feeling jittery	NA
Gait disturbance	NA
Head banging	NA
Headache	NA
Hypertension	NA
Hypoacusis	NA
Inappropriate schedule of product administration	NA
Joint swelling	NA
Malaise	NA
Malignant neoplasm progression	NA
Mental disorder	NA
Muscular weakness	NA
Nasopharyngitis	NA
Nausea	NA
Nervousness	NA
Pain in extremity	NA
Peripheral swelling	NA
Pneumonia	NA
Pollakiuria	NA

Case ID: 15545805

Productive cough	NA
Psychiatric symptom	NA
Rash	NA
Rib fracture	NA
Screaming	NA
Suicidal ideation	NA
Suicide attempt	NA
Tremor	NA
Unresponsive to stimuli	NA
Vasculitis	NA
Wound	NA
Wrist fracture	NA

Event/Problem Narrative:

This is a spontaneous report from a contactable healthcare professional, physician and a consumer via the Health Canada (regulatory authority report number: E2B_01898138 and 00392401), based on information received by Pfizer from Takeda (manufacturer control number: CA-TAKEDA-2018TUS030458), license party for pantoprazole.
This case was received by Takeda on 16-Oct-2018 via the Health Canada (reference number: CA-11998 (local case number), E2B_01898138 / 000392401 (Regulatory authority number)).The Market Authorization Holder AER Number was 2018433138, CA2018GSK214937, CRLMS05180204190089, PHHY2011CA64556, 2019-CA-000895, 2019-CA-000939, 2019-CA-000954.This spontaneous case concerned a 74-year-old female patient of an unknown ethnicity. Concurrent condition included neuroendocrine tumour, Sweating, Spot pigmented, allergic to amoxicillin/ tetracycline, allergic to dye and allergic to sulfa. On an unspecified date, the patient began therapy with pantoprazole of an unknown dose and frequency at an unknown formulation for an unknown indication. On an unspecified date, the patient began oral therapy with hydromorphone at an unknown dose and frequency for an unknown indication. On an unspecified date, the patient began therapy with escitalopram at an unknown dose, frequency and route of administration for an unknown indication. On an unspecified date in 2018, the patient began therapy with Amlodipine (amlodipine besilate) tablet, at a dose of 10 milligram daily, for an unknown indication. On an unknown date, the patient also began intramuscular therapy with Sandostatin (octreotide acetate) 20 mg monthly, for neuroendocrine tumour then on 11-Jul-2011 switched twice daily with unknown dose and discontinued on 24-Jul-2011. On 21-Nov-2012 increased the dose to 30 mg monthly then decreased the dose at 20 mg monthly and 20 mg at unknown frequency via subcutaneous route. On an unknown date, the patient also began oral therapy with calcium carbonate of an unknown dose, frequency at an unknown route of administration for an unknown indication. On an unknown date, the patient also began oral therapy with ergocalciferol of an unknown dose, frequency at an unknown route of administration for an unknown indication. On an unknown date, the patient measured the blood pressure which resulted 140/90 mmHg,

Case ID: 15545805

142/78 and 156/76, on 19Oct2012, resulted 142/68 mmHg, on 14Dec2012, resulted 140/80 mmHg, on 17Nov2014, resulted 122/80 mmHg, on 20Jan2015, resulted 122/70 mmHg, on 21Sep2015, resulted 140/90 mmHg, on 22Feb2016, resulted 140/68 mmHg, on 21-Sep-2015, resulted 140/90 mmHg, on 22-Feb-2016, resulted 140/68 mmHg, on 17-Nov-2016, resulted 145/70 mmHg, on 07Jun2017, resulted 151/81 mmHg, on 05Sep2017, resulted 150/88 mmHg, on 04Oct2017, resulted 143/76 mmHg and body temperature which resulted 36 degree Celsius. On 01Nov2017, laboratory test blood pressure, resulted 142/70 mmHg, and body temperature 36 degree Celsius. On 04Jan2018, resulted 151/88 mmHg, body temperature which resulted 36.4 degree Celsius, pulse rate resulted 78 beats per minute, respiratory rate resulted 18 rpm and vital signs measurement resulted slightly elevated. On an unknown date, after an unknown duration of therapy, the patient experienced abdominal discomfort, anger, anxiety, arthropod bite, blood pressure increased, blood pressure systolic increased, bronchitis, cerebrovascular accident, contusion, cough, crying, depressed mood, depression, diarrhoea, drug hypersensitivity, emotional distress, erythema, fall, fatigue, feeling jittery, gait disturbance, head banging, headache, hypoacusis, inappropriate schedule of drug administration, joint swelling, malaise, malignant neoplasm progression, mental disorder, muscular weakness, nasopharyngitis, nausea, nervousness, pain in extremity, peripheral swelling, pneumonia, pollakiuria, productive cough, psychiatric symptom, rash, rib fracture, screaming, suicidal ideation, suicide attempt, tremor, unresponsive to stimuli, vasculitis, wound and wrist fracture. On an unknown date, the patient was hospitalized due to the events Suicide attempt, fall, Cerebrovascular accident, pneumonia, diarrhea, malaise, fatigue, nausea, arthropod bite, joint swelling, erythema and peripheral swelling. The events suicidal ideation, unresponsive to stimuli, malignant neoplasm progression, depression, vasculitis, rib fracture, wrist fracture, head banging, bronchitis and productive cough were considered to be medically significant and rest of the events (except events for hospitalization) were considered to be non-serious. The action taken with pantoprazole and other co-suspect therapy was unknown. On an unknown date, the events bronchitis, pollakiuria, nausea, productive cough, tremor, nervousness, abdominal discomfort and depression was recovered and rest of the events were not recovered. No further follow-up information was expected on this case. The above is a revised narrative incorporating additional information received on 20Nov2019 from an other heath professional via Health Canada (Health Canada reference number: E2B_01898138 Local case number: CA-11998). The following information was added: suspect drug information, events coding, outcome of the events, concomitant drug dose, medical history of the patient, laboratory test, event seriousness and narrative were updated.

Follow-up (04Apr2019): This is a follow up report form contactable healthcare professional via Health Canada Vigilance (regulatory authority number: E2B_01898138). New information updated: dose, frequency and route of administration were added for amlodipine besilate and perindopril, dose was updated for prednisone and therapy duration was updated for octreotide acetate. Suspect Products included: amlodipine tablet, 10mg, Frequency: 1 every 1Day; calcium carbonate; ergocalciferol; escitalopram tablet; hydromorphone; pantoprazole; octreotide acetate (SANDOSTATIN) Intramuscular, 30mg, Frequency: 1 every 1Month for Neuroendocrine tumour, Intramuscular 20mg Frequency: 1 every 1 Month, for Neuroendocrine tumour, Subcutaneous, Frequency: 2 every 1Day, Therapy Duration: 14.0 Days, for Neuroendocrine tumour, Intramuscular, 20mg Frequency: 1 every 1 Month for Neuroendocrine tumour.

Follow-up (29Mar2019): This is a follow-up spontaneous report from a contactable healthcare professional via the Health Canada (regulatory authority report number: E2B_02189082) and from physician via the Health Canada (regulatory authority report number: E2B_02257939), based on information received by Pfizer from Takeda (manufacturer control number: CA-TAKEDA-2018TUS030458), license party for pantoprazole. New information includes reporter information, suspect drug SANDOSTATIN formulation and dosing regimen, and causality

assessment. This case was received by Takeda on 16Oct2018 via the Health Canada (reference number: CA-11998 (local case number), E2B_01898138 / 000392401 (Regulatory authority number)). The Market Authorization Holder AER Number was 2018433138 and CA2018GSK214937. This spontaneous case concerned a 74-year-old female patient of an unknown ethnicity. Concurrent condition included neuroendocrine tumour. Concomitant medications included acetaminophen, escitalopram, gabapentin, hydromorphone, olanzapine and prucalopride succinate. On an unspecified date, the patient began therapy with pantoprazole of an unknown dose and frequency at an unknown formulation for an unknown indication. On an unknown date, the patient also began intramuscular therapy with Sandostatin (octreotide acetate) 20 mg monthly, for neuroendocrine tumour then increased the dose to 30 mg monthly then decreased the dose at 20 mg monthly then switched at the dose with twice daily and 20 mg at unknown frequency via subcutaneous route. On an unknown date, the patient also began intramuscular therapy with Sandostatin (octreotide acetate) solution for injection at a dose of 30 mg with unknown frequency, for neuroendocrine tumour. On an unknown date, the patient also began therapy with calcium carbonate of an unknown dose, frequency at an unknown route of administration for an unknown indication. On an unknown date, the patient also began therapy with ergocalciferol of an unknown dose, frequency at an unknown route of administration for an unknown indication. On an unknown date, after an unknown duration of therapy, the patient experienced abdominal discomfort, anger, anxiety, arthropod bite, blood pressure increased, blood pressure systolic increased, bronchitis, cerebrovascular accident, contusion, cough, crying, depressed mood, depression, diarrhoea, drug hypersensitivity, emotional distress, erythema, fall, fatigue, feeling jittery, gait disturbance, head banging, headache, hypoacusis, inappropriate schedule of drug administration, joint swelling, malaise, malignant neoplasm progression, mental disorder, muscular weakness, nasopharyngitis, nausea, nervousness, pain in extremity, peripheral swelling, pneumonia, pollakiuria, productive cough, psychiatric symptom, rash, rib fracture, screaming, suicidal ideation, suicide attempt, tremor, unresponsive to stimuli, vasculitis, wound and wrist fracture. The events were considered to be medically significant which also led to hospitalization. The action taken with pantoprazole, calcium carbonate, ergocalciferol and sandostatin therapy was unknown. Outcome of the events was not recovered. No further follow-up information was expected on this case. The above is a revised narrative incorporating additional information received on 29-Mar-2019, from other health care professional via the Health Canada (reference number E2B_02189082 (Regulatory Authority number), CA-13047 (local case number)) and from a physician via the Health Canada Canada (reference number E2B_02257939 (Regulatory Authority number), CA-13098 (local case number)) were merge together in this case. The following information was updated: coding of the suspect drug (Sandostatin) with updated dosage form (solution for injection), dose of the suspect drug (Sandostatin (unknown formulation)), reporter and case narrative was updated.

Follow-up (09May2019): New information from contactable health care professional via Health Canada Vigilance (regulatory authority numbers: 000392401 and E2B_01898138). Information was reported as follows. The events were reported to be serious (seriousness criteria of Hospitalization and Other medically important conditions) and medically confirmed. The reported events with current report are: Abdominal discomfort, Anger, Anxiety, Arthropod bite, Blood pressure increased, Bronchitis, Cerebrovascular accident, Contusion, Cough, Crying, Depressed mood, Depression, Diarrhoea, Emotional distress, Erythema, Fall, Fatigue, Feeling abnormal, Feeling jittery, Gait disturbance, Head banging, Headache, Hypertension, Hypoacusis, Inappropriate schedule of product administration, Joint swelling, Malaise, Malignant neoplasm progression, Mental disorder, Muscular weakness, Nasopharyngitis, Nausea, Nervousness, Pain in extremity, Peripheral swelling, Pneumonia, Pollakiuria, Productive cough, Psychiatric symptom, Rash, Rib fracture, Screaming, Suicidal ideation, Suicide attempt, Tremor, Unresponsive to stimuli, Vasculitis, Wound, and Wrist fracture. The patient was reported to have not recovered from all the events. Suspect drug details were reported as follows: AMLODIPINE tablet route unknown 10 mg 1 every 1 day; CALCIUM CARBONATE route unknown;

Case ID: 15545805

ERGOCALCIFEROL route unknown; ESCITALOPRAM tablet route unknown; HYDROMORPHONE route unknown; PANTOPRAZOLE route unknown; SANDOSTATIN intramuscular route 30 mg 1 every 1 month, 20 mg 1 every 1 month, for neuroendocrine tumour; SANDOSTATIN subcutaneous route 2 every 1 day for 14 day, 2 every 1 day, for neuroendocrine tumour.

Follow-up (05Nov2019): This is a follow-up spontaneous report from a contactable consumer, healthcare professional and physician via Health Canada (regulatory authority number: 000726961, 000725546, 000725852, 000 72571), based on information received by Pfizer from Takeda (manufacturer control number CA-TAKEDA-2018TUS030458), license party for pantoprazole. This case was received by Takeda on 16-Oct-2018 via the Health Canada (reference number: CA-11998 (local case number), E2B_01898138 / 000392401 (Regulatory authority number)).The Market Authorization Holder AER Number was 2018433138, CA2018GSK214937, CRLMS05180204190089, PHHY2011CA64556, 2019-CA-000895, 2019-CA-000939, 2019-CA-000954.This spontaneous case concerned a 74-year-old female patient of an unknown ethnicity.Concurrent condition included neuroendocrine tumour.Concomitant medications included acetaminophen, gabapentin, olanzapine, perindopril and prucalopride succinate.On an unspecified date, the patient began therapy with pantoprazole of an unknown dose and frequency at an unknown formulation for an unknown indication.On an unspecified date, the patient began oral therapy with hydromorphone at an unknown dose and frequency for an unknown indication.On an unspecified date, the patient began therapy with escitalopram at an unknown dose, frequency and route of administration for an unknown indication.On an unspecified date, the patient began therapy with Amlodipine (amlodipine besilate) tablet, at a dose of 10 milligram daily, for an unknown indication.On an unknown date, the patient also began intramuscular therapy with Sandostatin (octreotide acetate) 20 mg monthly, for neuroendocrine tumour then increased the dose to 30 mg monthly then decreased the dose at 20 mg monthly then switched at the dose with twice daily and 20 mg at unknown frequency via subcutaneous route.On an unknown date, the patient also began oral therapy with calcium carbonate of an unknown dose, frequency at an unknown route of administration for an unknown indication.On an unknown date, the patient also began oral therapy with ergocalciferol of an unknown dose, frequency at an unknown route of administration for an unknown indication.On an unknown date, after an unknown duration of therapy, the patient experienced abdominal discomfort, anger, anxiety, arthropod bite, blood pressure increased, blood pressure systolic increased, bronchitis, cerebrovascular accident, contusion, cough, crying, depressed mood, depression, diarrhoea, drug hypersensitivity, emotional distress, erythema, fall, fatigue, feeling jittery, gait disturbance, head banging, headache, hypoacusis, inappropriate schedule of drug administration, joint swelling, malaise, malignant neoplasm progression, mental disorder, muscular weakness, nasopharyngitis, nausea, nervousness, pain in extremity, peripheral swelling, pneumonia, pollakiuria, productive cough, psychiatric symptom, rash, rib fracture, screaming, suicidal ideation, suicide attempt, tremor, unresponsive to stimuli, vasculitis, wound and wrist fracture.The events were considered to be medically significant which also led to hospitalization.The action taken with pantoprazole and other co-suspect therapy was unknown.Outcome of the events was not recovered.No further follow-up information was expected on this case.The above is a revised narrative incorporating additional information received on 05-Nov-2019, from a consumer via the Health Canada (reference number 000726961 (Regulatory Authority number), CA-14475 (local case number)), from regulatory authority via the Health Canada (reference number 000725546 (Regulatory Authority number), CA-14453 (local case number)), from a physician via the Health Canada (reference number 000725852 (Regulatory Authority number), CA-14464 (local case number)), from an other healthcare professional via the Health Canada (reference number 000 725715 (Regulatory Authority number), CA-14458 (local case number)) were merge together in this case. The following information was updated: coding of the suspect drug (Sandostatin, hydromorphone, escitalopram, Amlodipine) with updated dosage form, route of calcium carbonate, ergocalciferol, hydromorphone and case narrative was updated.

Case ID: 15545805

Follow-up (20Nov2019): This is a follow-up spontaneous report from a contactable healthcare professional via Canada regulatory authority (regulatory authority number: E2B_01898138), based on information received by Pfizer from Takeda (manufacturer control number CA-TAKEDA-2018TUS030458), license party for pantoprazole.
The above is a revised narrative incorporating additional information received on 20Nov2019 from an other heath professional via Health Canada (Health Canada reference number: E2B_01898138 Local case number: CA-11998). The following information was added: suspect drug information, events coding, outcome of the events, concomitant drug dose, medical history of the patient, laboratory test, event seriousness and narrative were updated.
Reporter comment: The reporter's causality assessment was not reported for the events with pantoprazole and other co-suspect therapy.
TAKEDA Comment: Based on available information, a possible causal relationship between administration of Pantoprazole, Calcium carbonate and the reported serious events arthropod bite, bronchitis, cerebrovascular accident, depression, diarrhoea, erythema, fall, fatigue, head banging, joint swelling, malaise, malignant neoplasm progression, nausea, peripheral swelling, pneumonia, productive cough, rib fracture, suicidal ideation, suicide attempt, unresponsive to stimuli, vasculitis, wound and wrist fracture cannot be completely excluded at this point. Causality is confounded by multiple co-suspect drugs and underlying neuroendocrine tumour. The rest of the events are considered as non-serious.
Pfizer is a marketing authorization holder of calcium carbonate, amlodipine besilate, hydromorphone in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of calcium carbonate, amlodipine besilate, hydromorphone has submitted the same report to the regulatory authorities.

Follow-up (05Dec2019): The following information was received from Takeda: Vomiting has been updated in narrative as concurrent condition. Laboratory data which was captured twice in narrative has been removed and concomitant medication details has been updated in narrative.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Allergic reaction to antibiotics			YES
Allergy to chemicals			YES
Neuroendocrine tumour			YES
Spot pigmented			YES
Sulfonamide allergy			YES
Sweating			YES

Case ID: 15545805

Vomiting			YES	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**
AMOXICILLIN				Drug allergy
TETRACYCLINE				Drug allergy

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood pressure	increased				N
Blood pressure	150/88	mmHg			N
Blood pressure	156/76	mmHg			N
Blood pressure	151/81	mmHg			N
Body temperature	36	Centigrade			N
Blood pressure	143/76	mmHg			N
Body temperature	36.4	Centigrade			N
Blood pressure	140/80	mmHg			N
Blood pressure	140/68	mmHg			N
Blood pressure systolic	increased				N
Blood pressure	122/80	mmHg			N
Blood pressure	151/88	mmHg			N
Pulse rate	78				N
Blood pressure	142/78	mmHg			N
Vital signs measurement	slightly elevated				N
Blood pressure	122/70	mmHg			N
Blood pressure	145/70	mmHg			N
Respiratory rate	18				N
Blood pressure	140/90	mmHg			N
Blood pressure	142/68	mmHg			N
Blood pressure	140/90	mmHg			N
Blood pressure	142/70	mmHg			N
Body temperature	36	Centigrade			N

Case ID: 15545805

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN		Unknown	UNK				
2	GABAPENTIN		Unknown	UNK				
3	OLANZAPINE		Unknown	UNK				
4	PERINDOPRIL	4 MG/QD	Unknown	4 mg, 1x/day				
5	PERINDOPRIL		Unknown	UNK				
6	PREDNISONE	35 MG/		35 mg, UNK				
7	PREDNISONE		Unknown	UNK				
8	PRUCALOPRIDE SUCCINATE		Unknown	UNK				

Reporter Source:

Study Report?: No

Sender Organization: PFIZER

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16469566

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** HO,OT, **Application Type:** ANDA

FDA Rcvd Date: 24-Jun-2019 **Mfr Rcvd Date:** 12-Jun-2019 **Mfr Control #:** CA-APOTEX-2019AP016757 **Application #:** 078777

Patient Information:

Age: 74 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ESCITALOPRAM			Unknown	UNK	Product used for unknown indication		
2	AMLODIPINE		10 MG/	Unknown	10 mg, qd	Product used for unknown indication		
3	CALCIUM CARBONATE			Unknown	UNK	Product used for unknown indication		
4	ERGOCALCIFEROL			Unknown	UNK	Product used for unknown indication		
5	HYDROMORPHONE			Unknown	UNK	Product used for unknown indication		
6	PANTOPRAZOLE			Unknown	UNK	Product used for unknown indication		
7	SANDOSTATIN		20 MG//month	Intramuscular	20 mg, q.m.t.	Neuroendocrine tumour		
8	SANDOSTATIN		30 MG//month	Intramuscular	30 mg, q.m.t.			
9	SANDOSTATIN		BID	Subcutaneous	UNK UNK, bid			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ESCITALOPRAM		Unk	NA				APOTEX	
2	AMLODIPINE		Unk	NA				APOTEX	
3	CALCIUM CARBONATE		Unk	NA					
4	ERGOCALCIFEROL		Unk	NA					

Case ID: 16469566

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
5	HYDROMORPHONE		Unk	NA					
6	PANTOPRAZOLE		Unk	NA				APOTEX	
7	SANDOSTATIN		Unk	NA					
8	SANDOSTATIN		Unk	NA					
9	SANDOSTATIN		Unk	NA					

Event Information:

Preferred Term (MedDRA Â Version: 22.1)	ReC
Abdominal discomfort	NA
Anger	NA
Anxiety	NA
Arthropod bite	NA
Blood pressure increased	NA
Bronchitis	NA
Cerebrovascular accident	NA
Contusion	NA
Cough	NA
Crying	NA
Depressed mood	NA
Depression	NA
Diarrhoea	NA
Emotional distress	NA
Erythema	NA
Fall	NA

Case ID: 16469566

Fatigue	NA
Feeling abnormal	NA
Feeling jittery	NA
Gait disturbance	NA
Head banging	NA
Headache	NA
Hypertension	NA
Hypoacusis	NA
Inappropriate schedule of product administration	NA
Joint swelling	NA
Malaise	NA
Malignant neoplasm progression	NA
Mental disorder	NA
Muscular weakness	NA
Nasopharyngitis	NA
Nausea	NA
Nervousness	NA
Pain in extremity	NA
Peripheral swelling	NA
Pneumonia	NA
Pollakiuria	NA
Productive cough	NA
Psychiatric symptom	NA
Rash	NA
Rib fracture	NA
Screaming	NA
Suicidal ideation	NA

Case ID: 16469566

Suicide attempt	NA
Tremor	NA
Unresponsive to stimuli	NA
Vasculitis	NA
Wound	NA
Wrist fracture	NA

Event/Problem Narrative:

Reference number 2019AP016757 is an initial spontaneous case, reported on 12-Jun-2019 by an other health professional via The Health Canadian Regulatory Authority (Adverse reaction report number: E2B_01898138) and pertaining to a 74-year-old female patient.

The patientÂs medical history was not reported. Concomitant medications included Acetaminophen (paracetamol), gabapentin, olanzapine, prucalopride succinate (dose and route unknown for all), perindopril 4 mg once a day, prednisone 35 mg (route unknown for both) and all were used for unknown indication.

On an unknown date, the patient started taking Escitalopram (escitalopram oxalate) tablet (dose, route, therapy duration and frequency were unknown), Amlodipine (amlodipine besilate) tablet 10 mg once a day (route unknown), calcium carbonate (dose, route, therapy duration and frequency were unknown), Hydromorphone (hydromorphone hydrochloride) (dose, route, therapy duration and frequency were unknown), Pantoprazole (pantoprazole sodium) (dose, route, therapy duration and frequency were unknown), ergocalciferol (dose, route, therapy duration and frequency were unknown) all used for unknown indication and Sandostatin (octreotide acetate) 20 mg every month via intramuscular route and twice a day via subcutaneous route for therapy duration of 14 days and 30 mg every month via intramuscular route for neuroendocrine tumour. On an unknown date, the patient experienced abdominal discomfort (ABDOMINAL DISCOMFORT), anger (ANGER), anxiety (ANXIETY), arthropod bite (ARTHROPOD BITE), blood pressure increased (BLOOD PRESSURE INCREASED), bronchitis (BRONCHITIS), cerebrovascular accident (CEREBROVASCULAR ACCIDENT), contusion (CONTUSION), cough (COUGH), crying (CRYING), depressed mood (DEPRESSED MOOD), depression (DEPRESSION), diarrhoea (DIARRHOEA), emotional distress (EMOTIONAL DISTRESS), erythema (ERYTHEMA), fall (FALL), fatigue (FATIGUE), feeling abnormal (FEELING ABNORMAL), feeling jittery (FEELING JITTERY), gait disturbance (GAIT DISTURBANCE), head banging (HEAD BANGING), headache (HEADACHE), hypertension (HYPERTENSION) for 2210 days, hypoacusis (HYPOACUSIS), joint swelling (JOINT SWELLING), malaise (MALAISE), malignant neoplasm progression (MALIGNANT NEOPLASM PROGRESSION), mental disorder (MENTAL DISORDER), muscular weakness (MUSCULAR WEAKNESS), nasopharyngitis (NASOPHARYNGITIS), nausea (NAUSEA), nervousness (NERVOUSNESS), pain in extremity (PAIN IN EXTREMITY), peripheral swelling (PERIPHERAL SWELLING), pneumonia (PNEUMONIA), pollakiuria (POLLAKIURIA), productive cough (PRODUCTIVE COUGH), psychiatric symptom (PSYCHIATRIC SYMPTOM), rash (RASH), rib fracture (RIB FRACTURE), suicidal ideation (SUICIDAL IDEATION), suicide attempt (SUICIDE ATTEMPT), tremor (TREMOR), unresponsive to stimuli (UNRESPONSIVE TO STIMULI),

Case ID: 16469566

vasculitis (VASCULITIS), wound (WOUND), screaming (SCREAMING) and events wrist fracture (WRIST FRACTURE) and inappropriate schedule of product administration (INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION) were reported.

Action taken with suspect drugs escitalopram, amlodipine, calcium carbonate, hydromorphone and pantoprazole was unknown. The outcome of the events was not recovered. Dechallenge was unknown and rechallenge was not applicable. The seriousness criteria for the events were hospitalization and medically significant.

The manufacturer of the escitalopram oxalate, amlodipine besilate, calcium carbonate, hydromorphone hydrochloride and pantoprazole sodium was unidentified; however, the Apotex or its affiliates brand of product cannot be excluded from consideration.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN		Unknown	UNK	Product used for unknown indication			
2	GABAPENTIN		Unknown	UNK	Product used for unknown indication			
3	OLANZAPINE		Unknown	UNK	Product used for unknown indication			
4	PERINDOPRIL	4 MG/	Unknown	4 mg, qd	Product used for unknown indication			

Case ID: 16469566

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
5	PREDNISONE	35 MG/	Unknown	35 mg, UNK	Product used for unknown indication			
6	PRUCALOPRIDE SUCCINATE		Unknown	UNK	Product used for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: APOTEX

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16477295

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** HO,OT, **Application Type:** ANDA

FDA Rcvd Date: 20-Sep-2019 **Mfr Rcvd Date:** 05-Sep-2019 **Mfr Control #:** CA-AUROBINDO-AUR-APL-2019-035133 **Application #:** 078021

Patient Information:

Age: 74 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Amlodipine Tablets		10 MG/QD	Unknown	10 milligram, Once a Day	Product used for unknown indication		
2	Calcium carbonate			Oral	UNK	Product used for unknown indication		
3	Ergocalciferol			Oral	UNK	Product used for unknown indication		
4	Escitalopram Tablets			Unknown	UNK	Product used for unknown indication		
5	Hydromorphone			Oral	UNK	Product used for unknown indication		
6	Pantoprazole			Unknown	UNK	Product used for unknown indication		
7	Sandostatin		20 MG/	Intramuscular	20 milligram	Neuroendocrine tumour		
8	Sandostatin		20 MG/	Intramuscular	20 milligram, once a month			
9	Sandostatin		30 MG/	Intramuscular	30 milligram, once a month			
10	Sandostatin		BID	Subcutaneous	UNK UNK, Two Times a Day	Neuroendocrine tumour		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Amlodipine Tablets		Unk	Unk				AUROBINDO	
2	Calcium carbonate		Unk	Unk					
3	Ergocalciferol		Unk	Unk					

Case ID: 16477295

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
4	Escitalopram Tablets		Unk	Unk				AUROBINDO	
5	Hydromorphone		Unk	Unk					
6	Pantoprazole		Unk	Unk				AUROBINDO	
7	Sandostatin		Unk	Unk					
8	Sandostatin		Unk	Unk					
9	Sandostatin		Unk	Unk					
10	Sandostatin		Unk	Unk					

Event Information:

Preferred Term (MedDRA Version: 22.1)	ReC
Abdominal discomfort	NA
Anger	NA
Anxiety	NA
Arthropod bite	NA
Blood pressure increased	NA
Blood pressure systolic increased	NA
Bronchitis	NA
Cerebrovascular accident	NA
Contusion	NA
Cough	NA
Crying	NA
Depressed mood	NA
Depression	NA

Case ID: 16477295

Diarrhoea	NA
Emotional distress	NA
Erythema	NA
Fall	NA
Fatigue	NA
Feeling abnormal	NA
Feeling jittery	NA
Gait disturbance	NA
Head banging	NA
Headache	NA
Hypertension	NA
Hypoacusis	NA
Inappropriate schedule of product administration	NA
Joint swelling	NA
Malaise	NA
Malignant neoplasm progression	NA
Mental disorder	NA
Muscular weakness	NA
Nasopharyngitis	NA
Nausea	NA
Nervousness	NA
Pain in extremity	NA
Peripheral swelling	NA
Pneumonia	NA
Pollakiuria	NA
Productive cough	NA
Psychiatric symptom	NA

Case ID: 16477295

Rash	NA
Rib fracture	NA
Screaming	NA
Suicidal ideation	NA
Suicide attempt	NA
Tremor	NA
Unresponsive to stimuli	NA
Vasculitis	NA
Wound	NA
Wrist fracture	NA

Event/Problem Narrative:

This is an initial spontaneous report received on 11-Jun-2019 by Aurobindo Pharma Ltd from Canada vigilance database with reference number 01898138, by other health professional.

This report concerned about 74-year-old elderly female patient.

Medical history and historical drugs of the patient were not reported.

Concomitant medications of the patient included acetaminophene, gabapentin, olanzapine, prucalopride succinate all with unknown formulation at unknown dose and frequency via unknown route for unknown indication on unknown date, perindopril with unknown formulation at a dose of 4 milligram once a day via unknown route for unknown indication on unknown date, prednisone with unknown formulation at a dose of 35 milligram at unknown frequency via unknown route for unknown indication and Resotran (prucalopride succinate) film coated tablet of unknown strength, dose and frequency via unknown route and indication on an unknown date.

On an unknown date, the patient received amlodipine tablets at a dose of 10 milligram once a day via unknown route for unknown indication, Sandostatin (octreotide acetate) with unknown formulation at a dose of 20 milligram once a month and 30 milligram once a month via intramuscular route and at unknown dose twice a day (for 14 days) via subcutaneous route for neuroendocrine tumour, escitalopram tablets and pantoprazole with unknown formulation at unknown dose and frequency via unknown route for unknown indication, calcium carbonate, ergocalciferol and hydromorphone with unknown formulation at unknown dose and frequency via oral route for unknown indication.

On an unknown date, the patient experienced abdominal discomfort, anger, anxiety, arthropod bite, blood pressure increased, bronchitis,

Case ID: 16477295

cerebrovascular accident, contusion, cough, crying, depressed mood, depression, diarrhoea, emotional distress, erythema, fall, fatigue, feeling abnormal, feeling jittery, gait disturbance, head banging, headache, hypertension, hypoacusis, inappropriate schedule of product administration, joint swelling, malaise, malignant neoplasm progression, mental disorder, muscular weakness, nasopharyngitis, nausea, nervousness, pain in extremity, peripheral swelling, pneumonia, pollakiuria, productive cough, psychiatric symptom, rash, rib fracture, screaming, suicidal ideation, suicide attempt, tremor, unresponsive to stimuli, vasculitis, wound, wrist fracture and blood pressure systolic increased.

Laboratorial examination included blood pressure had increased and blood pressure systolic was increased on unknown date.

Treatment medications were not reported.

Action taken with the suspect products amlodipine tablets, escitalopram tablets, pantoprazole were unknown.

The outcome of the events was not recovered/not resolved.

The case was assessed as serious (hospitalization and medically significant).

Follow up information (05-Jul-2019): Follow up information received by Aurobindo Pharma Ltd from Canada vigilance database with reference number 000725546, by consumer.

Reporter details were added.

Laboratorial data blood pressure systolic increased was added.

Concomitant drug Resotran (prucalopride succinate) film coated tablet was newly added.

Event blood pressure systolic increased was newly added.

Additional information received on (08-Jul-2019): Follow up information received by Aurobindo Pharma Ltd from Canada vigilance database with reference number 000725546, by consumer.

No New significant information was received.

Additional information received on (09-Jul-2019): Follow up information received by Aurobindo Pharma Ltd from Canada vigilance database with reference number 000725546, by consumer.

Case ID: 16477295

No New significant information was received.

Follow-up (05-Sep-2019): This follow-up report received on 05-Sep-2019 by Aurobindo Pharma Ltd from Canada vigilance database with reference number 000726961, by a consumer.
Suspect products calcium carbonate, ergocalciferol and hydromorphone route of administration was added.

Additional information received on 09-Sep-2019 by Aurobindo Pharma Ltd from Canada vigilance database with reference number 000726961, by consumer.
No new information was updated.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood pressure systolic	increased	N/A			N
Blood pressure measurement	increased	N/A			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Acetaminophene		Unknown	UNK	Product used for unknown indication			
2	Gabapentin		Unknown	UNK	Product used for unknown indication			
3	Olanzapine		Unknown	UNK	Product used for unknown indication			
4	Perindopril	4 MG/QD	Unknown	4 milligram, Once a Day	Product used for unknown indication			

Case ID: 16477295

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
5	Prednisone		Unknown	UNK				
6	Prednisone	35 MG/	Unknown	35 milligram	Product used for unknown indication			
7	Prucalopride succinate		Unknown	UNK	Product used for unknown indication			
8	Resotran		Unknown	UNK	Product used for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: AUROBINDO

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16656595

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** HO,OT **Application Type:** ANDA

FDA Rcvd Date: 18-Sep-2019 **Mfr Rcvd Date:** 15-Sep-2019 **Mfr Control #:** CA-TEVA-2019-CA-1084342 **Application #:** 077056

Patient Information:

Age: 74 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PANTOPRAZOLE			Unknown		Product used for unknown indication		
2	AMLODIPINE		10 MG/QD	Unknown	10 Milligram Daily;	Product used for unknown indication		
3	CALCIUM CARBONATE			Unknown		Product used for unknown indication		
4	ERGOCALCIFEROL			Unknown		Product used for unknown indication		
5	ESCITALOPRAM			Unknown		Product used for unknown indication		
6	HYDROMORPHONE			Oral		Product used for unknown indication		
7	SANDOSTATIN		20 MG//month	Intramuscular		Neuroendocrine tumour		
8	SANDOSTATIN		20 MG/	Intramuscular				
9	SANDOSTATIN		30 MG//month	Intramuscular				
10	SANDOSTATIN		BID	Subcutaneous				

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	PANTOPRAZOLE		Unk	NA				TEVA	
2	AMLODIPINE		Unk	NA				TEVA	
3	CALCIUM CARBONATE		Unk	NA					

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16656595

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
4	ERGOCALCIFEROL		Unk	NA					
5	ESCITALOPRAM		Unk	NA				IVAX	
6	HYDROMORPHONE		Unk	NA				ACTAVIS	
7	SANDOSTATIN		Unk	NA					
8	SANDOSTATIN		Unk	NA					
9	SANDOSTATIN		Unk	NA					
10	SANDOSTATIN		Unk	NA					

Event Information:

Preferred Term (MedDRA Â Version: 22.1)	ReC
Abdominal discomfort	NA
Anger	NA
Anxiety	NA
Arthropod bite	NA
Blood pressure increased	NA
Blood pressure systolic increased	NA
Bronchitis	NA
Cerebrovascular accident	NA
Contusion	NA
Cough	NA
Crying	NA
Depressed mood	NA
Depression	NA

Case ID: 16656595

Diarrhoea	NA
Drug hypersensitivity	NA
Emotional distress	NA
Erythema	NA
Fall	NA
Fatigue	NA
Feeling jittery	NA
Gait disturbance	NA
Head banging	NA
Headache	NA
Hypoacusis	NA
Inappropriate schedule of product administration	NA
Joint swelling	NA
Malaise	NA
Malignant neoplasm progression	NA
Mental disorder	NA
Muscular weakness	NA
Nasopharyngitis	NA
Nausea	NA
Nervousness	NA
Pain in extremity	NA
Peripheral swelling	NA
Pneumonia	NA
Pollakiuria	NA
Productive cough	NA
Psychiatric symptom	NA
Rash	NA

Case ID: 16656595

Rib fracture	NA
Screaming	NA
Suicidal ideation	NA
Suicide attempt	NA
Tremor	NA
Unresponsive to stimuli	NA
Vasculitis	NA
Wound	NA
Wrist fracture	NA

Event/Problem Narrative:

23-Jul-2019, Spontaneous, Health authority Serious report ((HEALTH AUTHORITY;MARKET AUTHORIZATION HOLDER AER NUMBER; E2B_02189082;2018433138)
This is a Health authority case downloaded from the Canada Vigilance Adverse Reaction Online database and will be submitted to MHPD via the Canada Vigilance Program as per the regulations.
Health Authority Initial received date 24-Oct-2018
A Other health professional reported the case of a 74-Years-old Female patient who received CALCIUM CARBONATE (Product cannot be excluded as a Teva product), PANTOPRAZOLE (Product cannot be excluded as a Teva product), ERGOCALCIFEROL (not Teva's product), SANDOSTATIN (OCTREOTIDE, not Teva's product).
The patient took CALCIUM CARBONATE for PRODUCT USED FOR UNKNOWN INDICATION (Unknown), PANTOPRAZOLE for PRODUCT USED FOR UNKNOWN INDICATION (Unknown), ERGOCALCIFEROL for PRODUCT USED FOR UNKNOWN INDICATION (Unknown), SANDOSTATIN for NEUROENDOCRINE TUMOUR (OCTREOTIDE, dosing regimen 1: Intramuscular; dosing regimen 2: Subcutaneous).
While on the suspect medication(s), the patient experienced ABDOMINAL DISCOMFORT(Serious); ANGER(Serious); ANXIETY(Serious); ARTHROPOD BITE(Serious); BLOOD PRESSURE INCREASED(Serious); BLOOD PRESSURE SYSTOLIC INCREASED(Serious); BRONCHITIS(Serious); CEREBROVASCULAR ACCIDENT(Serious); CONTUSION(Serious); COUGH(Serious); CRYING(Serious); DEPRESSED MOOD(Serious); DEPRESSION(Serious); DIARRHOEA(Serious); DRUG HYPERSENSITIVITY(Serious); EMOTIONAL DISTRESS(Serious); ERYTHEMA(Serious); FALL(Serious); FATIGUE(Serious); FEELING JITTERY(Serious); GAIT DISTURBANCE(Serious); HEAD BANGING(Serious); HEADACHE(Serious); HYPOACUSIS(Serious); INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION(Serious); JOINT SWELLING(Serious); MALAISE(Serious); MALIGNANT NEOPLASM PROGRESSION(Serious); MENTAL DISORDER(Serious); MUSCULAR WEAKNESS(Serious); NASOPHARYNGITIS(Serious); NAUSEA(Serious); NERVOUSNESS(Serious); PAIN IN EXTREMITY(Serious); PERIPHERAL SWELLING(Serious); PNEUMONIA(Serious); POLLAKIURIA(Serious); PRODUCTIVE COUGH(Serious); PSYCHIATRIC SYMPTOM(Serious); RASH(Serious); RIB

Case ID: 16656595

FRACTURE(Serious); SCREAMING(Serious); SUICIDAL IDEATION(Serious); SUICIDE ATTEMPT(Serious); TREMOR(Serious); UNRESPONSIVE TO STIMULI(Serious); VASCULITIS(Serious); WOUND(Serious); WRIST FRACTURE(Serious) .
At the time of the report the outcome of the AEs was: ABDOMINAL DISCOMFORT, ANGER, ANXIETY, ARTHROPOD BITE, BLOOD PRESSURE INCREASED, BLOOD PRESSURE SYSTOLIC INCREASED, BRONCHITIS, CEREBROVASCULAR ACCIDENT:, CONTUSION, COUGH, CRYING, DEPRESSED MOOD, DEPRESSION, DIARRHOEA:, DRUG HYPERSENSITIVITY, EMOTIONAL DISTRESS:, ERYTHEMA, FALL, FATIGUE, FEELING JITTERY, GAIT DISTURBANCE, HEAD BANGING:, HEADACHE:, HYPOACUSIS, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION:, JOINT SWELLING:, MALAISE, MALIGNANT NEOPLASM PROGRESSION, MENTAL DISORDER, MUSCULAR WEAKNESS, NASOPHARYNGITIS, NAUSEA, NERVOUSNESS, PAIN IN EXTREMITY, PERIPHERAL SWELLING:, PNEUMONIA, POLLAKIURIA:, PRODUCTIVE COUGH, PSYCHIATRIC SYMPTOM, RASH, RIB FRACTURE:, SCREAMING, SUICIDAL IDEATION, SUICIDE ATTEMPT, TREMOR:, UNRESPONSIVE TO STIMULI, VASCULITIS, WOUND, WRIST FRACTURE- Not recovered/not resolved.
Action taken with suspect drug: CALCIUM CARBONATE - Unknown.
The patient's medical history was not reported.
The patient's concomitant medication included ACETAMINOPHEN(PARACETAMOL; Unknown); ESCITALOPRAM(Tablet, Unknown); GABAPENTIN(Unknown); HYDROMORPHONE(Unknown); OLANZAPINE(Unknown); PRUCALOPRIDE SUCCINATE(Unknown).
The patient's past medication were unspecified.
Lab tests-
BLOOD PRESSURE: increased Not Applicable
BLOOD PRESSURE SYSTOLIC: increased Not Applicable
This case was considered serious based on the following criteria: (Hospitalization Required, Other Serious (Important Medical Events))
Because this is a spontaneous case, regulatory distribution will be handled as though it is a related case.

15-Sep-2019:
Additional information were received from Canada health authority and added into this FU.
Report duplicates were added as Health authority:E2B_01898138,000392401,000726961,000725546 Market Authorization Holder AER Number: CRLMS05180204190089
Additional new teva suspects were added as AMLODIPINE For Product used for unknown indication (Tablet, unknown 10 mg, per day),ESCITALOPRAM For Product used for unknown indication (Tablet, unknown) and
HYDROMORPHONE For Product used for unknown indication (Oral)

15-Sep-2019:Duplicate cases 2018-CA-989301 was identified and all the information from the duplicate was merged into this Case.

Relevant Medical History:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16656595

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
BLOOD PRESSURE SYSTOLIC	increased	Not Applicable			N
BLOOD PRESSURE	increased	Not Applicable			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN		Unknown					
2	GABAPENTIN		Unknown					
3	OLANZAPINE		Unknown					
4	PERINDOPRIL							
5	PREDNISONE							
6	RESOTRAN FILM-COATED		Unknown					

Reporter Source:

Study Report?: No **Sender Organization:** TEVA **503B Compounding Outsourcing Facility?:**

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16717259

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** **Outcomes:** HO,OT, **Application Type:** NDA

FDA Rcvd Date: 19-Aug-2019 **Mfr Rcvd Date:** 05-Aug-2019 **Mfr Control #:** CA-ALLERGAN-1933430US **Application #:** 021323

Patient Information:

Age: **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ESCITALOPRAM OXALATE - BP			Unknown		Drug use for unknown indication		
2	AMLODIPINE		10 MG/QD	Unknown		Drug use for unknown indication		
3	CALCIUM CARBONATE			Unknown		Drug use for unknown indication		
4	ERGOCALCIFEROL			Unknown		Drug use for unknown indication		
5	HYDROMORPHONE			Unknown		Drug use for unknown indication		
6	PANTOPRAZOLE			Unknown		Drug use for unknown indication		
7	SANDOSTATIN		1 DF/BID	Subcutaneous	1 DF, bid	Neuroendocrine tumour		
8	SANDOSTATIN		20 MG//month	Intramuscular	20 mg, q month			
9	SANDOSTATIN		30 MG//month	Unknown	30 mg, q month			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ESCITALOPRAM OXALATE - BP		Unk	NA				ALLERGAN	
2	AMLODIPINE		Unk	NA					
3	CALCIUM CARBONATE		Unk	NA					
4	ERGOCALCIFEROL		Unk	NA					

Case ID: 16717259

	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date
	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
5	HYDROMORPHONE		Unk	NA					
6	PANTOPRAZOLE		Unk	NA					
7	SANDOSTATIN		Unk	NA					
8	SANDOSTATIN		Unk	NA					
9	SANDOSTATIN		Unk	NA					

Event Information:

Preferred Term (MedDRA Â Version: 22.1)	ReC
Abdominal discomfort	NA
Anger	NA
Anxiety	NA
Arthropod bite	NA
Blood pressure increased	NA
Blood pressure systolic increased	NA
Bronchitis	NA
Cerebrovascular accident	NA
Contusion	NA
Cough	NA
Crying	NA
Depressed mood	NA
Depression	NA
Diarrhoea	NA
Emotional distress	NA
Erythema	NA

Case ID: 16717259

Fall	NA
Fatigue	NA
Feeling jittery	NA
Gait disturbance	NA
Head banging	NA
Headache	NA
Hypoacusis	NA
Inappropriate schedule of product administration	NA
Joint swelling	NA
Malaise	NA
Malignant neoplasm progression	NA
Mental disorder	NA
Muscular weakness	NA
Nasopharyngitis	NA
Nausea	NA
Nervousness	NA
Pain in extremity	NA
Peripheral swelling	NA
Pneumonia	NA
Pollakiuria	NA
Productive cough	NA
Psychiatric symptom	NA
Rash	NA
Rib fracture	NA
Screaming	NA
Suicidal ideation	NA
Suicide attempt	NA

Tremor	NA
Unresponsive to stimuli	NA
Vasculitis	NA
Wound	NA
Wrist fracture	NA

Event/Problem Narrative:

An initial Regulatory Authority report (Regulatory No: CA-HEALTH CANADA-000725546) from Canada was received via H. Lundbeck (DKLU3002384) originating from an Other Health Professional on 05-AUG-2019 regarding a 74-year-old female patient who experienced abdominal discomfort, arthropod bite, contusion, crying, emotional distress, erythema, head banging, hypoacusis, joint swelling, malignant neoplasm progression, nasopharyngitis, peripheral swelling, pneumonia, unresponsive to stimuli, pollakiuria, productive cough, wrist fracture, psychiatric symptom, inappropriate schedule of product administration, wound, rib fracture, vasculitis, screaming, gait disturbance, depression, diarrhoea, cerebrovascular accident, depressed mood, pain in extremity, feeling jittery, blood pressure increased, blood pressure systolic increased, anxiety, fatigue, fall, bronchitis, nausea, cough, headache, muscular weakness, malaise, mental disorder, nervousness, tremor, rash, suicidal ideation, suicide attempt, and anger following the administration of ESCITALOPRAM OXALATE for "drug used for unapproved indication". Co-suspect drugs included: Sandostatin (octreotide acetate) for "neuroendocrine tumour"; Amlodipine, Ergocalciferol, Calcium Carbonate, Hydromorphone, and Pantoprazole for "product used for unknown indication". Allergan received the report on 14-AUG-2019.

The patient's medical history included "Neuroendocrine tumour" (Neuroendocrine tumour) which occurred on unknown dates.

The patient's concomitant medications included: Acetaminophen (paracetamol) on unknown therapy dates; Gabapentin on unknown therapy dates; Perindopril on unknown therapy dates; Prednisone on unknown therapy dates; Resotran (prucalopride succinate) on unknown therapy dates; Olanzapine on unknown therapy dates.

No dosage information was reported for ESCITALOPRAM OXALATE. The lot number was reported as: unknown. Amlodipine (Tablet) 10 mg via an unknown route qd was initiated on an unknown date for "product used for unknown indication". No dosage information was reported for Ergocalciferol. No dosage information was reported for Calcium Carbonate. No dosage information was reported for Hydromorphone. No dosage information was reported for Pantoprazole. A first dose of Sandostatin (octreotide acetate) 20 mg intramuscular q month was initiated on an unknown date for "neuroendocrine tumour". A second dose of SANDOSTATIN 30 mg via an unknown route q month was initiated on an unknown date. A third dose of SANDOSTATIN 1 DF subcutaneous bid was initiated on an unknown date.

On an unknown date, the patient experienced "Abdominal discomfort" (Abdominal discomfort), "Anger" (Anger), "Anxiety" (Anxiety), "Arthropod bite" (Arthropod bite), "Blood pressure increased" (Blood pressure increased), "Blood pressure systolic increased" (Blood pressure

systolic increased), "Bronchitis" (Bronchitis), "Cerebrovascular accident" (Cerebrovascular accident), "Contusion" (Contusion), "Cough" (Cough), "Crying" (Crying), "Depressed mood" (Depressed mood), "Depression" (Depression), "Diarrhoea" (Diarrhoea), "Emotional distress" (Emotional distress), "Erythema" (Erythema), "Fall" (Fall), "Fatigue" (Fatigue), "Feeling jittery" (Feeling jittery), "Gait disturbance" (Gait disturbance), "Head banging" (Head banging), "Headache" (Headache), "Hypoacusis" (Hypoacusis), "Inappropriate schedule of product administration" (Inappropriate schedule of product administration), "Joint swelling" (Joint swelling), "Malaise" (Malaise), "Malignant neoplasm progression" (Malignant neoplasm progression), "Mental disorder" (Mental disorder), "Muscular weakness" (Muscular weakness), "Nasopharyngitis" (Nasopharyngitis), "Nausea" (Nausea), "Nervousness" (Nervousness), "Pain in extremity" (Pain in extremity), "Peripheral swelling" (Peripheral swelling), "Pneumonia" (Pneumonia), "Pollakiuria" (Pollakiuria), "Productive cough" (Productive cough), "Psychiatric symptom" (Psychiatric symptom), "Rash" (Rash), "Rib fracture" (Rib fracture), "Screaming" (Screaming), "Suicidal ideation" (Suicidal ideation), "Suicide attempt" (Suicide attempt), "Tremor" (Tremor), "Unresponsive to stimuli" (Unresponsive to stimuli), "Vasculitis" (Vasculitis), "Wound" (Wound), and "Wrist fracture" (Wrist fracture). This case was considered serious due to the following seriousness criteria: hospitalization, medically significant. The patient was hospitalized due to abdominal discomfort, arthropod bite, contusion, crying, emotional distress, erythema, head banging, hypoacusis, joint swelling, malignant neoplasm progression, nasopharyngitis, peripheral swelling, pneumonia, unresponsive to stimuli, pollakiuria, productive cough, wrist fracture, psychiatric symptom, inappropriate schedule of product administration, wound, rib fracture, vasculitis, screaming, gait disturbance, depression, diarrhoea, cerebrovascular accident, depressed mood, pain in extremity, feeling jittery, blood pressure increased, blood pressure systolic increased, anxiety, fatigue, fall, bronchitis, nausea, cough, headache, muscular weakness, malaise, mental disorder, nervousness, tremor, rash, suicidal ideation, suicide attempt, and anger on unknown dates.

Laboratory tests were not reported.

Action taken with the suspect drug ESCITALOPRAM OXALATE, Amlodipine, Ergocalciferol, Calcium Carbonate, Hydromorphone, Pantoprazole, and Sandostatin was unknown.
Treatment information was not provided.
At the time of the report, the outcomes of abdominal discomfort, arthropod bite, contusion, crying, emotional distress, erythema, head banging, hypoacusis, joint swelling, malignant neoplasm progression, nasopharyngitis, peripheral swelling, pneumonia, unresponsive to stimuli, pollakiuria, productive cough, wrist fracture, psychiatric symptom, wound, rib fracture, vasculitis, screaming, gait disturbance, depression, diarrhoea, cerebrovascular accident, depressed mood, pain in extremity, feeling jittery, blood pressure increased, blood pressure systolic increased, anxiety, fatigue, fall, bronchitis, nausea, cough, headache, muscular weakness, malaise, mental disorder, nervousness, tremor, rash, suicidal ideation, suicide attempt, and anger were reported as ongoing.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 16717259

Neuroendocrine tumour

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN		Unknown		Drug use for unknown indication			
2	GABAPENTIN		Unknown		Drug use for unknown indication			
3	OLANZAPINE		Unknown		Drug use for unknown indication			
4	PERINDOPRIL		Unknown		Drug use for unknown indication			
5	PREDNISONE		Unknown		Drug use for unknown indication			
6	RESOTRAN		Unknown	28	Drug use for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: ALLERGAN

503B Compounding Outsourcing Facility?:

Literature Text:

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 22-Jan-2020 12:59 PM
Total Number of Cases (Non-Esub): 2
Total Number of Pages: 21
Print Job Number: 21349

Disclaimers:
Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

Processed Case Id's for Images:
5784479 6821501

Failed Case Id's for Images:

Total Failed Cases: 0

U.S. Department of Health and Human S... | MedWatch The FDA Safety Information and Adverse Event Reporting Program | Individual Safety Report | 4641686-6-00-01 | ...es Inc.

Form Approved: OMB No. 0910-0230 Expires: 09/30/05
Please Forward Facsimile | FDA Facsimile Approval on 03/05/2003

Mfr report # S05-USA-01868-01
I/F/Dist report #
FDA Use Only

A. Patient Information

1. Patient identifier: (b) (6) in confidence
2. Age at time of event: 31 yrs or Date of birth: (b) (6)
3. Sex: ☐ female ☒ male
4. Weight: UNK lbs or UNK kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death ..... (mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☒ other: *

3. Date of event (mo/day/yr): ??/??/2005
4. Date of this report (mo/day/yr): 04/19/2005

5. Describe event or problem

This U.S. spontaneous report from a wife describes the occurrence of violence in her 31-year-old husband taking Lexapro (escitalopram) for anxiety and while drinking alcohol (co-suspect). Concomitant medications included Klonopin (clonazepam). There was no past medical history. The patient was always "laid back and quiet." Escitalopram, taken every other day (dose unknown), commenced on an unknown date. In February 2005 the patient saw his physician who told him the escitalopram needed to be taken everyday, so the patient increased the dose to daily use (dose unknown). Subsequent to the increase to daily dosing the patient began to act violent described as acting angry, yelling and threatening his wife. *

6. Relevant tests/laboratory data, including dates

Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Laid back and quiet
Drank same amount of alcohol prior to taking Lexapro everyday

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 LEXAPRO (ESCITALOPRAM)
#2 LEXAPRO (ESCITALOPRAM)

2. Dose, frequency & route used
#1 UNK
#2 UNK

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 Unknown to 02/22/05
#2 02/23/05 to Continuing

4. Diagnosis for use (indication)
#1 Anxiety
#2 Anxiety

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)
#1 UNKNOWN
#2 UNKNOWN

7. Exp. date (if known)
#1 Unknown
#2 Unknown

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)
#1 #2

10. Concomitant medical products and therapy dates (exclude treatment of event)
1. KLONOPIN (CLONAZEPAM) Dates:Unknown to Continuing

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
Forest Laboratories Inc.
Harborside Financial Ctr
Plaza 3 Suite 602
Jersey City, NJ 07311 USA

2. Phone number: 1 201 386-2000

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☒ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other:

4. Date received by manufacturer (mo/day/yr): 04/06/2005

5. (A)NDA # 21-323
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☒ Initial ☐ follow-up #

8. Adverse event term(s)
Aggression

9. Mfr. report number
S05-USA-01868-01

E. Initial reporter

1. Name & address: (b) (6)
phone #: (b) (6)

2. Health professional? ☒ yes ☐ no
3. Occupation: *
4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

FDA 3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

DSS

APR 20 2005

APR 21 2005

U.S. Department of Health a

MEDWA

The FDA Safety Infromation and Adverse Event Reporting Program

Individual Safety Report

4641686-6-00-02

orm Approved: OMB No. 0910-0230 Expires: 08/30/05
hase Forward Facsimile FDA Facsimile Approval on 03/05/2003

fr report # S05-USA-01868-01

F/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
(b) (6) in confidence	or Date of birth:	female / male	lbs or kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- death (mo/day/yr)
- life-threatening
- hospitalization - initial or prolonged
- disability
- congenital anomaly
- required intervention to prevent permanent impairment/damage
- other:

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#3 ALCOHOL
#4

2. Dose, frequency & route used
#3 UNK
#4

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#3 04/04/05 to 04/04/05
#4

4. Diagnosis for use (indication)
#3 Unknown
#4

5. Event abated after use stopped or dose reduced
#3 ☐ yes ☐ no ☒ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#3 UNKNOWN
#4

7. Exp. date (if known)
#3 Unknown
#4

8. Event reappeared after reintroduction
#3 ☐ yes ☐ no ☒ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
#3 NI #4

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

2. Phone number

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☐ 15-day
- ☐ 10-day ☐ periodic
- ☐ Initial ☐ follow-up #____

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name & address

phone #

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

FDA

3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

DSS

APR 20 2005

APR 21 2005

Individual Safety Report
4641686-6-00-03

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 3 of 3
	(b) (6)	S05-USA-01868-01	

B.2. Other outcome

Medically significant

B.5. Describe event or problem

[continuation:] On 04-APR-2005 the patient drank more then 10 beers and (b) (6) (b) (6) He was arrested and taken to jail for domestic violence. The wife moved out of the house with his children. She stated she and the patient had been together for 9 years and he drank the same amount of alcohol prior to taking escitalopram every day and had never acted that way. The physician's nurse reported, via phone, that the patient's last visit was 23-FEB-2005. At that visit the physician stressed the clonazepam was an as needed medication and the escitalopram needed to be taken daily. They were unaware of any of the events as they had not seen or heard from the patient since 23-FEB-2005. As of 07-APR-2005 no other information was available. Further information was requested. This case was deemed serious due to its medical significance.

FPI 051210

E.3. Occupation

PRIMARY CARE PHYSICIAN

CaseID: 6821501

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

Individual Safety Report

6050040-4-00-01

U.S. Depart
Food and D

MEDWATCH

FORM FDA 3500A (10/05)

:nc.

acilities,
and manufacturers
for MANDATORY reporting

Page 1 of 18

Mfr Report # 1000001582

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)
In confidence

2. Age at Time of Event: 58 Y
or
Date of Birth: (b) (6)

3. Sex: [ ] Female [X] Male

4. Weight: 200 lbs
or
kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: (mm/dd/yyyy)
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [X] Other serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/ /2007

4. Date of This Report (mm/dd/yyyy): 01/19/2009

5. Describe Event or Problem

This USA spontaneous report was originally received by Pfizer Pharmaceuticals (Mfr. report# 2008051192) and was forwarded to Forest Pharmaceuticals. This report describes the occurrence of SUICIDE ATTEMPT, SUICIDAL IDEATION, TARDIVE DYSKINESIA, RENAL FAILURE, HALLUCINATING, SEIZURES, ANXIETY AGGRAVATED, BLOOD PRESSURE HIGH, PANCREATITIS, CHOLESTEROL HIGH, TRIGLYCERIDES ABNORMAL, ATTENTION DEFICIT DISORDER, RESTLESS LEG SYNDROME, WITHDRAWAL REACTION, LOST WEIGHT, HYPOTHYROIDISM, ACCIDENT AUTOMOBILE, SEDATION, FEELING ABNORMAL, TEETH GRINDING, EXCESS SWEATING, HEADACHE, INSOMNIA, SCREAMING, PAIN, SLEEP APNEA, NIGHTMARES, DEPRESSION AGGRAVATED, PANIC ATTACK, RAGE, MENTAL DISORDER, VOMITED, MEMORY LOSS, BACK PAIN, CONSTIPATION, ANOREXIA, ASBESTOSIS, PALLOR, ACTIVITIES OF DAILY LIVING IMPAIRED, TACHYCARDIA, URINARY INCONTINENCE, LETHARGY, APHASIA, PYREXIA, NIGHT SWEATS, PARANOIA, UNCONTROLLABLE BODY SHAKING AND BECOMING STRANGE/BIZARRE in a 58 Years old Male patient. Suspect Medication LEXAPRO, (ESCITALOPRAM OXALATE) was initiated in October 2003 at an unknown dose for

Continued

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Concurrent Disease:
MULTIPLE INJURIES (08/02/2002 -)
(Continuing: Yes): shoulder and left arm
DEPRESSION (Continuing: Yes)
ANXIETY (Continuing: Yes)
ACCIDENT (08/02/2002 -) (Continuing: Unknown)

JAN 2 1 2009

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 LEXAPRO(ESCITALOPRAM OXALATE)
#2 XANAX

Continued

2. Dose, Frequency & Route Used
#1 Unknown, Oral
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 10/ /2003 - 05/ /2007
#2 10/ /2003 - 05/ /2007

4. Diagnosis for Use (Indication)
#1 DEPRESSION
#2 ANXIETY

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [X] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [X] Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
1) FENOFIBRATE
2) LEVOTHYROXINE
3) AMBIEN
4) HYDROCHLOROTHIAZIDE
5) HYDROCODONE

Continued

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
Forest Laboratories, Inc.
Harborside Financial Ctr
Plaza 3 Suite 602
Jersey City,NJ 07311
USA
(Initial Unit)

2. Phone Number: 201 386-2000

3. Report Source (Check all that apply)
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [X] Consumer
- [X] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 01/15/2009

5. (A)NDA # 21-323
IND #
STN #
PMA/510(k) #
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [ ] Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
- [ ] 5-day [ ] 30-day
- [ ] 7-day [ ] Periodic
- [ ] 10-day [ ] Initial
- [X] 15-day [X] Follow-up # 1

9. Manufacturer Report Number: 1000001582

8. Adverse Event Term(s)
1) Suicide attempt

Continued

E. INITIAL REPORTER

1. Name and Address
(b) (6)
USA

Phone #

DSS
JAN 28 2009

2. Health Professional? [ ] Yes [X] No

3. Occupation: Consumer

4. Initial Reporter Also Sent Report to FDA? [ ] Yes [ ] No [X] Unk.

CaseID: 6821501

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Individual Safety Report

MED 6050040-4-00-02

, Inc.

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, distributors and manufacturers
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Page 2 of 18

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

Mfr Report # 1000001582

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION

1. Patient Identifier
In confidence

2. Age at Time of Event:
or
Date of Birth:

3. Sex
☐ Female
☐ Male

4. Weight
_____ lbs
or
_____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*

4. Date of This Report *(mm/dd/yyyy)*

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

JAN 2 1 2009

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#3 ZOLOFT
#4 NEURONTIN
Continued

2. Dose, Frequency & Route Used
#3
#4

3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#3 10/ /2003 - Unknown
#4 10/ /2003 - Unknown

4. Diagnosis for Use *(Indication)*
#3
#4 MEMORY LOSS

5. Event Abated After Use Stopped or Dose Reduced?
#3 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#4 ☐ Yes ☐ No ☐ Doesn't Apply UNK

6. Lot #
#3
#4

7. Exp. Date
#3
#4

8. Event Reappeared After Reintroduction?
#3 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#4 ☐ Yes ☐ No ☐ Doesn't Apply UNK

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

2. Phone Number

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

5. (A)NDA # _____
IND # _____
STN # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # _____

9. Manufacturer Report Number

8. Adverse Event Term(s)

E. INITIAL REPORTER

1. Name and Address

Phone #

JAN 23 2009

2. Health Professional?
☐ Yes ☐ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No ☐ Unk.

Individual Safety Report

CaseID: 6821501

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

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FORM FDA 3500A (10/05)

Page 3 **of** 18

Mfr Report # 1000001582

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

JAN 2 1 2009

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3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#5 TRAZODONE HYDROCHLORIDE
#6 SEROQUEL
Continued

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#5	#5 10/ /2003 - Unknown
#6	#6 10/ /2003 - 05/ /2007

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#5	#5 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#6 DEPRESSION	#6 ☐ Yes ☐ No ☒ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#5	#5	#5 ☐ Yes ☐ No ☐ Doesn't Apply UNK
#6	#6	#6 ☐ Yes ☐ No ☒ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
- ☐ Foreign
- ☐ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*

5. (A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

9. **Manufacturer Report Number**

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

OSS
JAN 23 2009

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

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...tributors and manufacturers
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Page 4 of 18

Mfr Report # 1000001582

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

JAN 2 1 2009

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C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#7 WELLBUTRIN

#8 RESTORIL

Continued

2. **Dose, Frequency & Route Used**

#7

#8

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*

#7 10/ /2003 - 05/ /2007

#8 10/ /2003 - 05/ /2007

4. **Diagnosis for Use** *(Indication)*

#7 DEPRESSION

#8 DEPRESSION

5. **Event Abated After Use Stopped or Dose Reduced?**

#7 ☐ Yes ☐ No ☒ Doesn't Apply

#8 ☐ Yes ☐ No ☒ Doesn't Apply

6. **Lot #**

#7

#8

7. **Exp. Date**

#7

#8

8. **Event Reappeared After Reintroduction?**

#7 ☐ Yes ☐ No ☒ Doesn't Apply

#8 ☐ Yes ☐ No ☒ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☐ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____

Combination Product ☐ Yes

Pre-1938 ☐ Yes

OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

9. **Manufacturer Report Number**

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

DSS

JAN 28 2009

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

CaseID: 6821501

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

Individual Safety Report

6050040-4-00-05

U.S. Food ... MEDWATCH

FORM FDA 3500A (10/05)

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/ user-facilities, butors and manufacturers for MANDATORY reporting

Mfr Report # 1000001582

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex: ☐ Female ☐ Male
4. Weight: ... lbs or ... kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ... *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*

4. Date of This Report *(mm/dd/yyyy)*

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

JAN 2 1 2009

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#9 CYMBALTA
#10 EFFEXOR

2. Dose, Frequency & Route Used
#9
#10 Unknown

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#9 10/ /2003 - 05/ /2007
#10 Unknown - Unknown

4. Diagnosis for Use *(Indication)*
#9 DEPRESSION
#10 DEPRESSION

5. Event Abated After Use Stopped or Dose Reduced?
#9 ☐ Yes ☐ No ☐ Doesn't Apply
#10 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#9
#10

7. Exp. Date
#9
#10

8. Event Reappeared After Reintroduction?
#9 ☐ Yes ☐ No ☐ Doesn't Apply
#10 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

2. Phone Number

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

5. (A)NDA #
IND #
STN #
PMA/510(k) #
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ...

9. Manufacturer Report Number

8. Adverse Event Term(s)

E. INITIAL REPORTER

1. Name and Address

Phone #

JAN 23 2009

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☐ Unk.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

B. ADVERSE EVENT OR PRODUCT PROBLEM

B.5 Describe Event or Problem (Cont...)

depression. Suspect medication XANAX (ALPRAZOLAM) was initiated in October 2003 at an unknown dose for anxiety, depression and sleep. Suspect medication ZOLOFT (SERTRALINE) was initiated in October 2003 at an unknown dose for an unknown indication. Suspect medication NEURONTIN (GABAPENTIN) was initiated in October 2003 at an unknown dose for memory loss and restless legs syndrome. Suspect medication TRAZODONE was initiated in October 2003 at an unknown dose for an unknown indication. Suspect medication SEROQUEL (QUETIAPINE) was initiated in October 2003 at an unknown dose for depression. Suspect medication WELLBUTRIN (BUPROPION) was initiated in October 2003 at an unknown dose for depression. Suspect medication RESTORIL (TEMAZEPAM) was initiated in October 2003 at an unknown dose for depression. Suspect medication CYMBALTA (DULOXETINE) was initiated in October 2003 at an unknown dose for depression. Suspect medication EFFEXOR (venlafaxine) was initiated on an unknown date at an unknown dose for an unknown indication. Concomitant medications included lisinopril, fenofibrate, levothyroxine, Ambien (zolpidem), hydrochlorothiazide, hydrocodone with acetaminophen and carisoprodol. Concurrent medical conditions included high blood pressure, high tryglycerides, high cholesterol, thyroid disorder and back pain. Past medical history included an accident (nos) on 02-Aug-2002 resulting in severe shoulder and arm injuries. The patient reported that in October 2003, he immediately became "a living zombie". He was so medicated that there were times when he did not know what day of the week or what month it was. There were also periods of time where the patient had no memory at all. He also reported that he became strange/bizarre from the medications, causing his wife to leave him. The patient was in 5 auto accidents on unknown dates. Details related to the accidents were not provided. Sometime in late 2006 or early 2007, the patient started having unusual movements of his mouth, lips and tongue. His mouth started moving involuntarily up and down and his tongue would move back and forth uncontrollably. His teeth would also grind. After researching, he found out that what he probably had was known medically as tardive dyskinesia; defined as 'uncontrollable mouth movements'. The tardive dyskinesia caused the patient embarrassment, and he was reluctant to leave his home and interact with other people. Trazodone, gabapentin, sertraline and venlafaxine were discontinued on unknown dates. The patient reported that his physician dismissed him as a patient due to excessive missed appointments. The patient acknowledged that he had missed appointments. He explained that he was "literally stoned" most of the time and there was a time or two that he was not cognizant of an existing appointment. A letter was sent to the patient on 10-May-2007 giving him 2 weeks notice to find a new physician. Upon receiving the letter of dismissal from the physician, in a fit of panic, rage and insanity, the patient swallowed a full bottle of pills (nos) and vomited. The patient reported that he wanted to die and had unsuccessfully attempted suicide by swallowing a bunch of pills. He was unable to get the medicines through another physician via his worker's compensation program and was not able to afford private care. As a result, he was forced to abruptly discontinue the medications he was currently taking including, escitalopram, alprazolam, duloxetine, quetiapine, bupropion and temazepam in May 2007. Shortly after, he went into severe withdrawal. The patient was experiencing hallucinations, screaming/hollering, insomnia, fever, profuse sweating, cramps, severe headaches, inability to eat, night sweats, paranoia, uncontrollable body shaking and had a couple of seizures. Details related to these events were not provided. The patient would lay on the couch for several days at a time, unable to function except for using the bathroom. He was only able to sleep sporadically and when he would drift off to sleep, he would wake screaming and hollering. The patient also reported having horrifying nightmares. After this period of time, he had lost 12-15 pounds. Since this experience, he stated that his thyroid had "shut down" and his blood pressure was "sky high". He reported that his physician told him he was in the "third phase of renal failure" and is close to needing dialysis. The patient reported that his triglycerides and cholesterol were "out of control". He also reported experiencing high anxiety levels, Restless Legs Syndrome, Attention Deficit Disorder, constipation, sleep apnea and pancreatitis. Details related to these events were not provided. Additionally, on unknown dates, the patient experienced asbestosis, early morning awakening, muscle twitching, emotional distress, tachycardia, urinary incontinence, inability to hold down solid foods, lethargy, aphasia, pyrexia and impaired daily living activities. Details related to these events were not provided. As of 15-Jan-2009, escitalopram, alprazolam, sertraline, gabapentin, trazodone, quetiapine, bupropion, temazepam, duloxetine and venlafaxine remained discontinued. The events of suicidal ideation, renal failure, high blood pressure, tardive dyskinesia, memory loss, insomnia, screaming, nightmares, night sweats, paranoia, uncontrollable body shaking, aggravated anxiety and aggravated depression were unresolved. The status of all other events was unknown.

DSS
JAN 23 2009

Information received on 15-Jan-2009 updated the following: additional events, additional co-suspect medication, dates of discontinuation of suspect drugs, outcome of events.

C. SUSPECT PRODUCT(S) (Cont...)

Seq No. : 1
C.1 Suspect Product : LEXAPRO(ESCITALOPRAM OXALATE)
C.4 Diagnosis for Use (Indication) : 2) ANXIETY

JAN 2 1 2009

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JAN 23 2009

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

C.5 Dechallenge

:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) N/A
:9) UNK
:10) N/A
:11) N/A
:12) UNK
:13) UNK
:14) UNK
:15) N/A
:16) N/A
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
:29) UNK
:30) UNK
:31) UNK
:32) UNK
:33) UNK
:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge

:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) N/A
:9) UNK
:10) N/A
:11) N/A
:12) UNK
:13) UNK
:14) UNK
:15) N/A
:16) N/A
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
:29) UNK
:30) UNK
:31) UNK

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Plaz
Jers
USA

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:32) UNK
:33) UNK
:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. :2
C.1 Suspect Product :XANAX
C.4 Diagnosis for Use (Indication) :2) SLEEP DISORDER
C.5 Dechallenge :2) N/A
:3) N/A
:4) UNK
:5) N/A
:6) N/A
:7) N/A
:8) UNK
:9) UNK
:10) UNK
:11) UNK
:12) UNK
:13) UNK
:14) UNK
:15) N/A
:16) UNK
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
:29) UNK
:30) UNK
:31) UNK
:32) UNK
:33) UNK
:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge :2) N/A
:3) N/A
:4) UNK
:5) N/A
:6) N/A
:7) N/A
:8) UNK
:9) UNK

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JAN 23 2009

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Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:10) UNK
:11) UNK
:12) UNK
:13) UNK
:14) UNK
:15) N/A
:16) UNK
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
:29) UNK
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:35) UNK
:36) N/A
:37) UNK
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:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. : 3
C.1 Suspect Product : ZOLOFT
C.5 Dechallenge
:2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
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:35) UNK
:36) N/A

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:37) UNK
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:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge

:2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
:7) UNK
:8) UNK
:9) UNK
:10) UNK
:11) UNK
:12) UNK
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:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
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:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. :4
C.1 Suspect Product :NEURONTIN
C.4 Diagnosis for Use (Indication) :2) RESTLESS LEG SYNDROME
C.5 Dechallenge :2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
:7) UNK
:8) UNK
:9) UNK
:10) UNK
:11) UNK
:12) UNK
:13) UNK
:14) UNK

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Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:15) UNK
:16) UNK
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:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge

:2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
:7) UNK
:8) UNK
:9) UNK
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:28) UNK
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:31) UNK
:32) UNK
:33) UNK
:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
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:44) UNK

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Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. :5
C.1 Suspect Product :TRAZODONE HYDROCHLORIDE
C.5 Dechallenge
:2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
:7) UNK
:8) UNK
:9) UNK
:10) UNK
:11) UNK
:12) UNK
:13) UNK
:14) UNK
:15) UNK
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:27) UNK
:28) UNK
:29) UNK
:30) UNK
:31) UNK
:32) UNK
:33) UNK
:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge
:2) UNK
:3) UNK
:4) UNK
:5) UNK
:6) UNK
:7) UNK
:8) UNK
:9) UNK
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Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:24) UNK
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:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. : 6
C.1 Suspect Product : SEROQUEL
C.4 Diagnosis for Use (Indication) :2) ANXIETY
C.5 Dechallenge :2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) UNK
:9) UNK
:10) N/A
:11) N/A
:12) UNK
:13) UNK
:14) UNK
:15) N/A
:16) UNK
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:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
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:31) UNK
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:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

C.8 Rechallenge

:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) UNK
:9) UNK
:10) N/A
:11) N/A
:12) UNK
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:15) N/A
:16) UNK
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A
:28) N/A
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:34) UNK
:35) UNK
:36) N/A
:37) UNK
:38) UNK
:39) UNK
:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

Seq No. :7
C.1 Suspect Product :WELLBUTRIN
C.4 Diagnosis for Use (Indication) :2) ANXIETY
C.5 Dechallenge :2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) N/A
:9) UNK
:10) N/A
:11) N/A
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:13) UNK
:14) UNK
:15) N/A
:16) N/A
:17) N/A
:18) N/A
:19) N/A
:20) N/A
:21) N/A
:22) N/A
:23) N/A
:24) N/A
:25) N/A
:26) N/A
:27) N/A

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Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:28) N/A
:29) UNK
:30) UNK
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:38) UNK
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:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge

:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) N/A
:9) UNK
:10) N/A
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:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

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Seq No.
C.1 Suspect Product
C.5 Dechallenge

:8
:RESTORIL
:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A

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JAN 23 2009

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:7) N/A
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:23) N/A
:24) N/A
:25) N/A
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:35) UNK
:36) N/A
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:40) UNK
:41) UNK
:42) UNK
:43) UNK
:44) UNK
:45) UNK
:46) N/A
:47) N/A
:48) N/A

C.8 Rechallenge

:2) N/A
:3) N/A
:4) N/A
:5) N/A
:6) N/A
:7) N/A
:8) N/A
:9) UNK
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:36) N/A

Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

:37) UNK
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:42) UNK
:43) UNK
:44) UNK
:45) N/A
:46) N/A
:47) N/A
:48) N/A

C.10 Concomitant Medical Products and Therapy Dates

Seq No. : 1
Concomitant Medical Product : FENOFIBRATE
Diagnosis for Use (Indication) : 1) TRIGLYCERIDES HIGH
2) CHOLESTEROL

Seq No. : 2
Concomitant Medical Product : LEVOTHYROXINE
Diagnosis for Use (Indication) : 1) THYROID DISORDER

Seq No. : 3
Concomitant Medical Product : AMBIEN
Diagnosis for Use (Indication) : 1) SLEEP DISORDER

Seq No. : 5
Concomitant Medical Product : HYDROCODONE W/ACETAMINOPHEN
Diagnosis for Use (Indication) : 1) BACK PAIN

Seq No. : 6
Concomitant Medical Product : CARISOPRODOL
Diagnosis for Use (Indication) : 1) BACK PAIN

Seq No. : 7
Concomitant Medical Product : LISINOPRIL
Diagnosis for Use (Indication) : 1) BLOOD PRESSURE HIGH

G. ALL MANUFACTURERS

G.8 Adverse Event Term(s)

1) Suicide attempt [v.11.1]
2) Suicidal ideation [v.11.1]
3) Tardive dyskinesia [v.11.1]
4) Renal failure [v.11.1]
5) Hallucination [v.11.1]
6) Convulsion [v.11.1]
7) Anxiety [v.11.1]
8) Hypertension [v.11.1]
9) Pancreatitis [v.11.1]
10) Blood cholesterol increased [v.11.1]
11) Blood triglycerides abnormal [v.11.1]
12) Attention deficit/hyperactivity disorder [v.11.1]
13) Restless legs syndrome [v.11.1]
14) Withdrawal syndrome [v.11.1]
15) Weight decreased [v.11.1]
16) Hypothyroidism [v.11.1]
17) Road traffic accident [v.11.1]
18) Sedation [v.11.1]
19) Feeling abnormal [v.11.1]
20) Bruxism [v.11.1]
21) Hyperhidrosis [v.11.1]
22) Headache [v.11.1]
23) Insomnia [v.11.1]
24) Screaming [v.11.1]
25) Pain [v.11.1]
26) Sleep apnoea syndrome [v.11.1]
27) Nightmare [v.11.1]
28) Depression [v.11.1]
29) Panic attack [v.11.1]
30) Anger [v.11.1]

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Continuation Sheet for FDA-3500A Form

Mfr. Report # : 1000001582

Date of This Report : 01/19/2009

31) Mental disorder [v.11.1]
32) Vomiting [v.11.1]
33) Amnesia [v.11.1]
34) Back pain [v.11.1]
35) Constipation [v.11.1]
36) Anorexia [v.11.1]
37) Asbestosis [v.11.1]
38) Pallor [v.11.1]
39) Activities of daily living impaired [v.11.1]
40) Tachycardia [v.11.1]
41) Urinary incontinence [v.11.1]
42) Lethargy [v.11.1]
43) Aphasia [v.11.1]
44) Pyrexia [v.11.1]
45) Abnormal behaviour [v.11.1]
46) Night sweats [v.11.1]
47) Paranoia [v.11.1]
48) Tremor [v.11.1]