

Cases Count: 102

Case Number: 231483

Gender: F

Data Entry Date: 02/08/2007 Weight (kg): 0

Hospitalisation: Required a visit to the doctor

DOB: 12/11/1989

Age:

Outcome: 27/06/2007 Causality: Causality possible

Recovered

Information:

Onset Date: 25/06/2007

Reaction:

Preferred Term Severity Report Description Treatment

Opisthotonus Patient experienced a dystonic reaction

(opisthotonus) lasting in a mild way for a further 24

hours.

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 5 Milligram Daily Oral

Batch: **Started**: 05/06/2007 **Stopped**: 07/06/2007

Logicin Flu Strength Day & Night (Suspected) Reason : Acute nasopharyngitis,com cold

Tablet 1 Dose Unspec Daily Oral

Batch: **Started**: 05/06/2007 **Stopped**: 07/06/2007

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Cases Count: 102

Case Number: 231507

Gender: F

Data Entry Date: 03/08/2007 Weight (kg): 100 Hospitalisation: Admitted to hospital Age:

Onset Date: 15/03/2006 **DOB**: 26/10/1953

Outcome: Causality: Causality possible

Recovered

Information: Patient was changed from sertraline (on which she was stable) to escitalopram. When

changed back to sertraline she improved.

Reaction:

Preferred Term Severity **Report Description Treatment**

Depression Life threatening Patient experienced severe Ceased Lexapro, started

depression, attempted Sertraline.

suicide.

Suicide attempt Life threatening

Medicine details :				
Lexapro (Suspected)				
Tablet	10 Milligram	n Daily	Or	al
Batch :	Started: 15/03/2006		Stopped :	
ALODORM (Other drug)		Reason :		
Batch :	Started :		Stopped :	
ENDONE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
PANADEINE FORTE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
PREDNISONE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
TEMTABS (Other drug)		Reason :		
Batch :	Started :		Stopped :	

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Cases Count: 102

Case Number: 231605

Data Entry Date: 07/08/2007 **Weight (kg)**: 48

Hospitalisation : Age :

Onset Date: DOB: 22/09/1938

Outcome : Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient experienced retrosternal chest pain, aching and constant in quality, oesophageal movements essentially normal.	Gastroscopy, cardiac angiogram. Cipramil ceased.

Medicine details :						
CIPRAMIL (Suspected)	Reason: Depression					
Tablet	20 Milligra	m Daily	Oral			
Batch :	Started : 25/01/2007		Stopped : 23/06/2007	0		
INDERAL (Other drug)		Reason :				
Batch :	Started :		Stopped :			
KARVEA (Other drug)		Reason :				
Batch :	Started :		Stopped :			
NEXIUM (Other drug)		Reason :				
Batch :	Started :		Stopped :			
OSTELIN 1000 (Other drug)		Reason :				
Batch :	Started :		Stopped :			
XANAX (Other drug)		Reason :				
Batch :	Started :		Stopped :			

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Cases Count: 102

Case Number: 231803

Gender: F

Data Entry Date: 10/08/2007 **Weight (kg)**: 99

 Hospitalisation :
 Age :

 Onset Date : 04/07/2007
 DOB : 15/10/1970

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Feeling jittery Jittery feeling, hand tremor, Cease Talohexal

involuntary jaw clenching and feeling of tightness when opening mouth.

Stopped:

Joint stiffness

Batch:

Tremor Trismus

Medicine details:

TALOHEXAL (Suspected) Reason : Anxiety neurosis

Tablet 20 Milligram Daily Oral

Batch: Started: 22/06/2007 Stopped: 16/07/2007

LIPEX (Other drug) Reason : Othr&unspec metabolic diseases

Tablet 80 Milligram Daily Oral

OROXINE (Other drug) Reason :

Started:

Tablet 150 Milligram Oral

Batch: Started: Stopped:

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Cases Count: 102

Gender: F

Case Number: 231929

Data Entry Date: 14/08/2007 **Weight (kg)**: 0

Hospitalisation: Age: 91Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: recovered from everything except memory loss

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome

An elderly patient missed approximately 5 days dosing of Celapram and experienced severe shaking, trance-like state and accelerated memory loss. Memory loss had been declining prior to event but more rapidly

since missing doses Medicine details: **CELAPRAM (Suspected)** Reason: Depression 20 Milligram Oral Tablet 1 time Batch: Started: L TERM Stopped: Blackmores Macu Vision (Other drug) Reason: Batch: Started: Stopped: FOSAMAX (Other drug) Reason: Batch: Started: Stopped: KARVEA (Other drug) Reason: 75 Milligram Oral Batch: Started: Stopped: NORVASC (Other drug) Reason: 10 Milligram Started: Stopped: Batch: **OMEPRAZOLE** (Other drug) Reason: 40 Milligram Daily 0 Batch: Started: Stopped: PREDNISONE (Other drug) Reason: 25 Milligram Daily Batch: Started: Stopped: 0

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Medicine details :			
SOLPRIN (Other drug)		Reason :	
Batch :	Started :		Stopped :
TAMBOCOR (Other drug)		Reason :	
		50 Milligram	
Batch :	Started :		Stopped:
VITAMIN D NOS (Other drug)		Reason :	
Batch :	Started :		Stopped :

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Cases Count: 102

Case Number : 232023

Gender: F

Data Entry Date: 15/08/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date : 25/05/2007

Outcome:

5 ·

DOB:

Causality: Causality possible

Unknown

Information: Patient has no history of sleep walking, no alcohol.

Reaction:

Preferred Term Severity Report Description Treatment

Abnormal sleep-related event Patient got in her car drove Ceased Stilnox.

on the footpath and ploughed into a phone box, taken to hospital, woke up during the CAT scan. She ran away from the hospital,

police caught her and took her to a psych hospital. Patient had taken 6 extra Stilnox tablets, she had no memory of the whole day.

..........

Medicine details:

CIPRAMIL (Suspected) Reason: Unspecifid affective psychosis

Tablet 20 Milligram Daily Oral

Batch: Started: L TERM Stopped: Contin

STILNOX (Suspected) Reason:

Tablet 10 Milligram As necessary Oral

Batch: **Started**: **Stopped**: 25/05/2007

VALPRO (Suspected) Reason: Unspecifid affective psychosis

Tablet 1 Gram Daily Oral

Batch: Started: LTERM Stopped: Contin

LEVLEN ED (Other drug) Reason : Contraception

Tablet 1 Dose Unspec Daily Oral

Batch: Started: L TERM Stopped:

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Cases Count: 102

Case Number: 232490

Gender: M

Data Entry Date: 24/08/2007

Weight (kg): 96

Hospitalisation:

Age:

Onset Date: 18/08/2007

DOB: 29/04/1988

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Muscle spasms

Caused or prolonged inpatient

legs, arms and along

hospitalisation

spine.

Abdominal pain upper

Caused or prolonged

inpatient

hospitalisation

Blood creatine phosphokinase increased

Caused or prolonged

inpatient

hospitalisation

Myalgia

Caused or prolonged

inpatient

hospitalisation

Medicine details:

Lexapro (Suspected)

Reason:

1 time

20 Milligram

Oral

Tablet Batch:

Started: 26/06/2007

Stopped: 24/08/2007

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Cases Count: 102

Case Number: 232588

Gender: F

Age:

Data Entry Date: 28/08/2007 Weight (kg): 0

Hospitalisation: Required a visit to the doctor

DOB: 01/02/1959

Outcome: Causality: Causality possible

Recovered

Information:

Onset Date: 12/08/2007

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome, Self managed by resting.

agitated, confused, hot and sweaty lasting a few hours.

Agitation

Confusional state

Feeling hot Hyperhidrosis

Medicine details:

CITALOPRAM HYDROBROMIDE (Interaction) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped: Continuing.

DOLOXENE (Interaction) Reason :

Capsule 200 Milligram Daily Oral

Batch: Started: Stopped: 0

PHENERGAN (Interaction) Reason: Specific disorders of sleep

Tablet 50 Milligram Daily Oral

Batch: **Started**: 12/08/2007 **Stopped**: 12/08/2007 0

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Cases Count: 102

Case Number: 232597

Gender: M

Data Entry Date: 28/08/2007 Weight (kg): 95

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 15/07/2007 **DOB**: 05/01/1940

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urticaria Patient developed an Cessation of escitalopram.

urticarial rash.

Medicine details:

Escitalopram (Suspected) Reason : Depression

10 Milligram Daily Oral

Batch: **Started**: 15/07/2007 **Stopped**: 15/07/2007

SEROQUEL (Other drug) Reason : Anxiety neurosis

Tablet 300 Milligram Daily Oral

Batch: Started: 15/07/2006 Stopped:

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Cases Count: 102

Gender: F

Stilnox.

Case Number : 232599

Data Entry Date: 28/08/2007 **Weight (kg)**: 0

Hospitalisation: Required a specialist consultation Age: 32Y

Onset Date: 23/07/2007 DOB:

Outcome: 25/07/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Confusional state Caused or prolonged Confusion, altered mental Withheld Epilim, Valium and

inpatient state, drowsiness, nausea hospitalisation and vomitting.

Mental disorder Caused or prolonged

inpatient hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Somnolence Caused or prolonged

inpatient hospitalisation

Vomiting Caused or prolonged

inpatient hospitalisation

Medicine details:

EPILIM EC 500 (Suspected) Reason : Other&unspecified epilepsy

1 Gram Daily Oral

Batch: **Started**: **Stopped**: 23/07/2007

Lexapro (Suspected) Reason : Depression

10 Milligram Daily Oral

Batch: **Started**: 20/07/2007 **Stopped**: 23/07/2007

Stilnox CR (Suspected) Reason : Specific disorders of sleep

Tablet 6.3 Milligram As necessary Oral

Batch: Stopped: 23/07/2007

SEROQUEL (Other drug) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason : Anxiety neurosis

Batch: Started: Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number: 233026

Gender: F

Data Entry Date: 04/09/2007 **Weight (kg)**: 60

Age:

Onset Date: 01/08/2007

DOB: 31/12/1958

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash erythematous

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 10 Milligram 1 time Oral

Batch: Started: 06/01/2007 Stopped:

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Cases Count: 102

Case Number: 233086

Gender: F

Data Entry Date: 06/09/2007

Weight (kg): 80

Hospitalisation:

Age:

Onset Date: 20/10/2006

Outcome: 05/01/2007

DOB: 15/02/1987

Causality: Causality possible

Death, maybe drug

Information: No family history of clotting disorders.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Deep vein thrombosis

Death

Patient developed a very large deep vein thrombosis Warfarin and Panadeine Forte

whilst on Lexapro.(this

report, SEQ .1)

Medicine details:

Lexapro (Suspected)

Reason: Depression Daily

Tablet

20 Milligram

Oral

Batch:

Started: 15/08/2006

Stopped: 03/01/2007

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Cases Count: 102

Case Number: 233114

Gender: M

Data Entry Date: 06/09/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 13/04/2007

DOB: 14/10/1946

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

cease citalopram, iv fluids

Serotonin syndrome

Caused or prolonged inpatient

Serotinin syndrome, manifest as syncope, agitation, hyperreflexia,

hospitalisation

sweating, cold feet, diarrhoea, vomiting.

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected)

Reason:

Tablet

40 Milligram

Daily

Stopped: 13/04/2007

Batch:

Started: 11/04/2007

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Cases Count: 102

Case Number : 233116

Gender: M

Data Entry Date: 06/09/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/07/2007

DOB: 05/04/1946

Outcome:

Causality: Causality possible

Unknown

Information:

history of ischaemic heart disease post acute myocardial infarction

up to 8000

233116 is a seq of 233489.

Incapacity/disability

Reaction:

Preferred Term Severity Report Description Treatment

Chromaturia
Blood creatine phosphokinase

Incapacity/disability dark urine

ırıne

increased

Liver function test abnormal Incapacity/disability
Muscular weakness Incapacity/disability
Myalgia Incapacity/disability
Myopathy Incapacity/disability

Medicine details:

Lexapro (Suspected) Reason : Depression

Milligram Daily Oral

Batch: **Started**: 24/05/2007 **Stopped**: 16/08/2007 0

LIPITOR (Suspected) Reason:

Tablet 80 Milligram Daily Oral

Batch: **Started**: 15/03/2006 **Stopped**: 16/08/2007 0

ALLOPURINOL (Other drug) Reason :

100 Milligram

Batch: Started: Stopped:

ASPIRIN (Other drug) Reason :

100 Milligram

Batch: Started: Stopped:

METOPROLOL TARTRATE (Other drug) Reason :

25 Milligram

Batch: Started: Stopped:

RAMIPRIL (Other drug) Reason :

2.5 Milligram

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Liver function tests refer to attached CIOMS for data

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Cases Count: 102

Case Number : 233166

Gender: F

Data Entry Date: 07/09/2007 **Weight (kg)**: 70

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 13/12/2006 DOB: 16/07/1942

Outcome: 27/12/2006 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Liver function test abnormal Abnormal LFT's and

neutropenia.

Neutropenia

Medicine details:

CIPRAMIL (Suspected) Reason : Anxiety neurosis

Tablet Oral

Batch: **Started**: 01/12/2006 **Stopped**: 13/12/2006 0

Dithiazide (Other drug) Reason : Essential benign hypertension

 Tablet
 12.5 Milligram
 Daily
 Oral

 Batch :
 Started : 30/10/2006
 Stopped : 13/12/2006

Dithiazide (Other drug) Reason :

Tablet 12.5 Milligram Daily Oral

Batch: Started: 30/10/2006 **Stopped:** 13/12/2006

RAMIPRIL (Other drug) Reason : Essential benign hypertension

10 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

ALT = SGPT ALT = 275

Neutrophils Neutropenia = 0.8

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Cases Count: 102

Case Number: 233236

Gender: F

Data Entry Date: 10/09/2007

Weight (kg): 60.4

Hospitalisation: Required a specialist consultation

Age:

Onset Date: 12/03/2007

DOB: 20/04/1993

Outcome: 13/03/2007

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Suicidal ideation

Caused or prolonged

Child experienced suicidal ideation.

Drug withdrawn until review.

inpatient

hospitalisation

Medicine details:

CIPRAMIL (Suspected)

Reason:

40 Milligram

Daily

Oral

Batch:

Tablet

Started: 20/02/2007

Stopped: 13/03/2007

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Weight (kg): 0

Cases Count: 102

Case Number: 233361

Gender: F

Hospitalisation: Age: 52Y

Onset Date : DOB :

Outcome : Causality : Causality probable

Recovered

Information:

Data Entry Date: 13/09/2007

Reaction: **Preferred Term** Severity **Report Description Treatment** Suicidal ideation Whilst on Cipramil "worst Changed from Cipramil to six days of my life". Patient Edronex.. is a nurse and very aware of medications and management of her depression. Changed from Efexor to Cipramil and became actively suicidal. Wanted to set herself on fire or "take pills". Kept picturing it - one thought all the time. Had panic attacks about her capability to lose control. Terrified.

Medicine details: CIPRAMIL (Suspected) Reason: Oral Tablet 10 Milligram Daily Batch: Started: Stopped: Centrum Select 50+ (Other drug) Reason: 1 Dose Unspec Daily Oral **Tablet** Batch: Started: L TERM Stopped: **OROXINE** (Other drug) Reason: **Tablet** 500 Microgram Weekly Oral L TERM Batch: Started: Stopped:

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Cases Count: 102

Case Number: 233398

Outcome:

Gender: M

Data Entry Date: 12/09/2007 Weight (kg): 95

Age:

Hospitalisation: Required a visit to the doctor

DOB: 15/06/1972

Onset Date: 01/06/2007

Causality: Causality possible

Not yet recovered

Information: Operations on both ears (gramets) when 7-10 years of age.

Reaction:

Preferred Term Severity **Report Description Treatment**

Deafness unilateral High pitch whistle in right ear only - also hearing loss

in right ear only. Tinnitus a real problem in last few

days.

Tinnitus

Medicine details:

CELAPRAM (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

Batch: Started: 01/09/2006 Stopped: 0

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Cases Count: 102

Case Number: 233489

Gender: M

Data Entry Date: 18/09/2007

Weight (kg): 0

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Blood creatine phosphokinase

Creatine kinase increased.

Lexapro ceased

increased

Liver function test abnormal

Liver function tests raised.

Medicine details:

Lexapro (Suspected)

Reason: Depression

Batch:

Started:

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Creatine

phosphokinase

8000

Liver function tests

Elevated

PUTRAN02



Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number: 233662

Gender: F

Data Entry Date: 20/09/2007 **Weight (kg)**: 77

Age:

Onset Date : DOB : 03/01/1990

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicide attempt precipitated suicide act 2 x OD within 2 weeks, and

continuing suicide ideation after starting escitalopram 10mg m. Never experience that before and can't explained why OD

occured.

Suicidal ideation

Medicine details:

Escitalopram (Suspected) Reason :

Tablet 10 Milligram Daily Oral

Batch: **Started**: 20/08/2007 **Stopped**: 14/09/2007

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Cases Count: 102

Case Number : 233907

Gender: F

Data Entry Date: 02/10/2007

Weight (kg): 82.5

Hospitalisation: Required a visit to the doctor

Age: 45Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Weight increased

Severity

Report Description

Treatment

Patient has been taking Lexapro with an initial dose Ceased medication.

of 10mg. After 6 weeks it was increased to 20mg. Her initial weight was 63.5kg and by Sept 2007 it

was 82.5kg.

Medicine details:

Lexapro (Suspected)

Reason:

20 Milligram

Daily

Oral

Batch :

Tablet

Started:

Stopped:

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Cases Count: 102

Case Number: 234014 Gender: F

Data Entry Date: 04/10/2007 **Weight (kg)**: 80

Hospitalisation: Age: 73Y

Onset Date: 04/09/2007 **DOB**:

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term	Severity		Report Des	scription	Treatment
Cerebral haemorrhage			Intracerebra bleed.	al/ventricular	
Medicine details :					
CLEXANE (Suspected)		F	Reason :		
Batch :	Started :			Stopped :	
Escitalopram (Suspected)		F	Reason :		
Tablet		10 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
WARFARIN SODIUM (Suspected)		F	Reason :		
Batch :	Started :			Stopped :	
CEPHAZOLIN SODIUM (Other drug)	F	Reason :		
Batch :	Started :			Stopped :	
MIXTARD 30/70 (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	
MODURETIC (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	
PARACETAMOL (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	
SOTALOL HYDROCHLORIDE (Other	er drug)	F	Reason :		
Batch :	Started :			Stopped :	

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Cases Count: 102

Case Number: 234058

Gender: F

Data Entry Date: 05/10/2007

Weight (kg): 74

Hospitalisation:

Age: 52Y

Onset Date: 01/06/2007

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Hepatitis Incapacity/disability suspected drug induced

Hypertension Incapacity/disability

Visual impairment

Incapacity/disability

Medicine details:

EDRONAX (Suspected)

Reason: Depression

hepatitis

Tablet

4 Milligram

2 times

Oral

Batch:

Started: 10/03/2005

Stopped:

Lexapro (Suspected)

Reason: Depression

Tablet

30 Milligram

1 time

Oral

Batch:

Started: 30/06/2006

Stopped:

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Cases Count: 102

Case Number: 234303

Gender: F

Data Entry Date: 12/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date: 15/09/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentHot flushCaused or prolongedAfter taking the firstCeased drug

inpatient

hospitalisation

After taking the first escitalopram tablet the patient experienced waves of hot and cold flushes passing over her shoulder, blurred vision and difficulty

passing urine.

Dysuria Caused or prolonged

inpatient hospitalisation

Feeling of body temperature

change

Caused or prolonged

inpatient hospitalisation

Medicine details:

Esipram (Suspected) Reason: Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 15/09/2007 **Stopped**: 16/09/2007

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Cases Count: 102

Case Number: 234721

Onset Date: 11/10/2007

Gender: M

Age:

Data Entry Date: 23/10/2007 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor

DOB: 18/07/1963

Outcome : Causality : Causality possible

Not yet recovered

Information: Patient had the same issue with Zoloft in 2006.

Reaction:

Preferred Term Severity Report Description Treatment

Paraesthesia Burning paraesthesia of soles of foot 2 days after

commencing Cipramil.

Burning sensation

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CIPRAMIL (Suspected) Reason :

Tablet Oral

Batch: Started: Stopped:

Seretide 125/25 MDI (Other drug) Reason :

Inhalation Inhalation

Batch: Started: Stopped:

VENTOLIN (Other drug) Reason :

Inhalation Inhalation

Batch: Started: Stopped:

Vesicare (Other drug) Reason :

Tablet 5 Milligram Daily Oral

Batch: Started: 24/09/2007 Stopped:

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Cases Count: 102

Case Number: 235265

Gender: F

Data Entry Date: 14/11/2007 **Weight (kg)**: 78

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 31/07/2007 **DOB**: 10/12/1964

Outcome: 07/08/2007 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pruritus generalised Generalised itch, 4/7 after Ceased Lexapro.

starting Lexapro. No rash

noted.

Medicine details:

Lexapro (Suspected) Reason : Depression

10 Milligram Daily

Batch: **Started**: 27/07/2007 **Stopped**: 06/08/2007

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number : 235377

Gender: F

Data Entry Date: 16/11/2007 **Weight (kg)**: 62

Age:

Onset Date: 15/09/2007

DOB: 05/05/1943

Outcome: Causality: Causality possible

Not yet recovered

Information: Patient was also on Hormone replacement therapy.

Reaction:

Preferred Term Severity Report Description Treatment

Flushing Caused or prolonged

inpatient hospitalisation

Patient experienced waves Escitalopram discontinued. of hot and cold flushes

of hot and cold flushes passing over her shoulder, blurred vision and difficulty

passing urine.

Dysuria Caused or prolonged

inpatient

hospitalisation

Vision blurred Caused or prolonged

inpatient hospitalisation

Medicine details:

Esipram (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 15/09/2007 **Stopped**: 16/09/2007

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number : 235619

Gender: M

Data Entry Date: 24/11/2007 **Weight (kg)**: 92

Age:

Onset Date: 07/11/2007

DOB: 12/09/1945

Outcome :

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome Incapacity/disability serotonin syndrome - Stopped na

sweating profusely, impending doom, agitation,

chest pain

Stopped naltrexone. reduced lexapro to 5mg. Much better in 24 hours. Hypomania for a week after. then stopped lexapro. started seroquel, hypomania abated in another

week.

Medicine details:

Lexapro (Interaction) Reason : Depression

Tablet 20 Milligram 1 time Oral

Batch: **Started**: 11/01/2007 **Stopped**: 11/07/2007

NALTREXONE HYDROCHLORIDE (Interaction) Reason:

Tablet Oral

Batch: **Started**: 11/01/2007 **Stopped**: 11/07/2007

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Cases Count: 102

Gelofusine 500ml, oxygen.

Gender: F

Case Number: 235828

Data Entry Date: 03/12/2007 **Weight (kg)**: 93

Hospitalisation: Age: 75Y

Onset Date: 09/11/2007 **DOB**:

Outcome: 09/11/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Syncope Patient collapsed in the shower where she had a ~10 second convulsion,

she had had a large, explosive, loose bowel

action.

Convulsion Diarrhoea

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason : Depression

Tablet 20 Milligram Daily Oral

Batch: Started: 09/11/2007 **Stopped:** 09/11/2007

ASPIRIN (Other drug) Reason :

Batch: Started: Stopped:

ATORVASTATIN (Other drug) Reason :

Batch: Started: Stopped:

ENOXAPARIN (Other drug) Reason :

Batch: Started: Stopped:

OMEPRAZOLE (Other drug) Reason :

Batch: Started: Stopped:

RAMIPRIL (Other drug) Reason :

Batch: Started: Stopped:

THYROXINE SODIUM (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Case Number : 236033

Gender: M

Data Entry Date: 07/12/2007

Weight (kg): 0

Hospitalisation:

Age: 56Y

Onset Date: 23/11/2007

Outcome:

DOB:

Causality: Causality possible

Recovered

Information: Also taking Mannatech products for OsteoArthritis: Ambrotose Complex, PhytAloe and

Ambrotose AO Capsules and Plus capsules.

Reaction:

Preferred Term Suicide attempt

Severity

Report Description

Treatment

Patient had been acting strangely, with aggressive mood swings for past 3 months (since starting Stilnox). Does not believe Stilnox helped him sleep. Just lay awake for hours, getting anxious. Began taking more Serepax due to increased anxiety and at least one panic attack, day and night. Doctor started him on Cipramil on 13/11/07 saying it was just depression.. On morning of 23/11/07 patient got up early, ?wide awake? and said the only thought he had in his mind was to end his life. He said? In my mind it was perfectly justified and made perfect sense?. First he took ?a handful of Serepax, but that didn?t work?. Then he took about 20x Doloxene and what was left in the Stilnox box (~6x). He said he has no recollection of what happened after that. His wife found him asleep in the bedroom, and he slept all day. Still hasn?t told her what he tried to do. Read about Stilnox in paper last week so went to his doctor and confessed his suicide attempt. Doctor told him to stop taking Cipramil and Stilnox, just take Serepax. Has been feeling much better. Anxiety and agitation significantly reduced, and sleeping better (all night).

Aggression

PUTRAN02 Page 31 of 118 Reaction:

Preferred Term Severity Report Description Treatment

Anxiety

Drug ineffective Mood swings

Panic attack

Medicine details:

CIPRAMIL (Suspected) Reason : Depression

20 Milligram Daily

Batch: Started: 13/11/2007 Stopped: 29/11/2007

STILNOX (Suspected) Reason: Specific disorders of sleep

Tablet 10 Milligram Daily Oral

Batch: **Started**: 15/10/2007 **Stopped**: 29/11/2007

DOLOXENE (Other drug) Reason : Osteoarthritis

800 Milligram Daily

Batch: Started: L TERM Stopped:

KEPPRA (Other drug) Reason :

2 Gram

Batch: Started: 15/11/2006 Stopped:

LIPITOR (Other drug) Reason :

20 Milligram Daily

Batch: Started: L TERM Stopped:

NORVASC (Other drug) Reason :

5 Milligram Daily

Batch: Started: L TERM Stopped:

SEREPAX (Other drug) Reason: Specific disorders of sleep

15 Milligram As necessary Oral

Batch: Started: L TERM Stopped:

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Cases Count: 102

Case Number: 236055

Gender: M

Data Entry Date: 10/12/2007

Weight (kg): 0

Hospital is at ion:

Age:

Onset Date: 04/12/2007

Information:

DOB: 23/08/1942

Outcome:

Causality: Causality probable

Recovered

Reaction:

Preferred Term Severity

Report Description

Treatment

Somnolence Cold sweat Incapacity/disability

difficult to rouse

Pyrexia

Incapacity/disability
Incapacity/disability

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected)

Reason: Depression

Tablet

10 Milligram

1 time

Oral

Batch:

Started: 04/12/2007

Stopped: 04/12/2007

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Cases Count: 102

Case Number: 236165

Gender: F

Data Entry Date: 11/12/2007

Weight (kg): 95

Hospitalisation:

Age: 65Y

Onset Date: 10/11/2007

DOB:

Outcome:

Causality: Causality possible

Treatment

Recovered

Information:

Reaction:

Langerhans' cell

granulomatosis

Preferred Term Severity **Report Description**

> Incapacity/disability rash biopsy result

enclosed Clinical Notes: Biopsy red raised sl

blistery rash present for at least 3 weeks pretibial ?? drug reaction and secondary contact

dermatitis. Macroscopic: 'Biopsy left leg rash': Pale punch biopsy 3 x 3 x 3 mm. Embedded whole. (sj) Microscopic: Sections of the biopsy show very mild spongiosis and compact

hyperkeratosis. The underlying dermis contains

a perivascular and interstitial chronic

inflammatory infiltrate with readily visible eosinophils present. There is a background of oedema. The infiltrate is histiocytic with giant cells present. Distinct granulomas are not seen. There is no evidence of fungus, atypia or malignancy. Summary: **BIOPSY SKIN LEFT LEG:**

STRONGLY SUGGESTIVE OF INTERSTITIAL **GRANULOMATOUS**

DRUG REACTION.

Drug eruption Incapacity/disability

Rash Incapacity/disability

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason:

Oral

Batch: Started: 30/10/2007 Stopped: 20/11/2007

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Lahoratory	Invactinatione	•
Laboratory	Investigations	•

Date Tested Result Type Range Details

Skin biopsy

Macroscopic: 'Biopsy left leg rash': Pale punch biopsy 3 x 3 x 3 mm. Embedded whole. (sj) Microscopic: Sections of the biopsy show very mild spongiosis and compact hyperkeratosis. The underlying dermis contains a perivascular and interstitial chronic inflammatory infiltrate with readily visible eosinophils present.
There is a background of oedema. The infiltrate is histiocytic with giant cells present. Distinct granulomas are not seen. There is no evidence of fungus, atypia or malignancy. Summary: BIOPSY SKIN LEFT LEG: STRONGLY SUGGESTIVE OF INTERSTITIAL **GRANULOMATOUS DRUG**

REACTION.

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Cases Count: 102

Case Number : 236361

Gender: F

Data Entry Date: 17/12/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 13/11/2007

DOB: 10/05/1960

Outcome: 15/11/2007

Causality: Causality possible

Recovered

.

Information: Patient is hepatitis C Virus positive.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Coagulopathy

Patient experienced ongoing haemoserous ooze for 2 days. External derssing applied (changed

derssing applied (change every 20-30 minutes). ? SSRI - associated coagulopathy.

Tranexamic acid 1g tds, Vitamin K 5mg stat, Kaltostat packing

into nasal passages.

Haemorrhage

Secretion discharge

Medicine details:

Escitalopram (Suspected) Reason : Depression

10 Milligram Daily

Batch: Started: Stopped:

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)Reason: Other diseases of esophagus

20 Milligram Daily

Batch: Started: Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number : 236458

Gender: F

Data Entry Date: 20/12/2007 **Weight (kg)**: 0

Age: 70Y

Onset Date: 01/06/2007 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: Transaminases >2000.

Reaction:

Preferred Term Severity Report Description Treatment

Hepatitis Caused or prolonged ? Drug induced hepatitis, Withdrawal of SSRI and statin.

Reason:

inpatient dark urine, pruritis and hospitalisation arthralgias.

Arthralgia Caused or prolonged

inpatient hospitalisation

Chromaturia Caused or prolonged

inpatient hospitalisation

Jaundice Caused or prolonged

inpatient hospitalisation

Medicine details :

Escitalopram (Suspected)

Batch: Started: 21/05/2007 Stopped: 01/06/2007

SIMVASTATIN (Suspected) Reason :

Tablet 40 Milligram Oral

Batch: Started: Stopped: 0

FLUVAX (Other drug) Reason: Prophylactic inoculation and vaccination

Injection 1 Dose Unspec 1 time Subcutaneous

Batch: Started: 28/04/2007 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Bilirubin 20 01/06/2007 63

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Cases Count: 102

Case Number: 236869

Data Entry Date: 10/01/2008 Weight (kg): 0

Age: 41Y **Hospitalisation:**

Onset Date: 10/11/2007 DOB:

Outcome: 14/11/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Flushing Flushing, hot and cold rigers, mild headache, nausea, sweats, dizzy on standing, photophobia,

myalgia, neck stiffness, tremor, weaknes, hyperaesthesia.

ceased Buprenorphine and escitalopram.

Gender: F

Asthenia

Chills

Dizziness postural

Headache

Hyperaesthesia

Hyperhidrosis

Musculoskeletal stiffness

Myalgia

Nausea

Photophobia

Therapy regimen changed

Tremor

Medicine details:

BUPRENORPHINE HYDROCHLORIDE (Suspected) Reason:

Drug delivery system, transder 5 Milligram Weekly Transdermal

Started: 01/11/2007 Batch: Stopped:

Reason: **Escitalopram (Suspected)**

Tablet 20 Milligram Daily Oral

L TERM Batch: Started : Stopped:

TRAMADOL HYDROCHLORIDE (Suspected) Reason: Otr&unsp vertebrogen pain synd

Oral Tablet 400 Milligram Daily

Started: Batch: Stopped:

MELOXICAM (Other drug) Reason:

Started: Batch: Stopped:

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Medicine detail	s:		
PANTOPRAZOLE (Other d	rug)	Reason :	
Batch :	Started :	Stopped :	
Symbicort Turbuhaler (Oth	ner drug)	Reason:	
Batch :	Started :	Stopped :	
VENTOLIN (Other drug)		Reason:	
Batch :	Started :	Stopped :	

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Cases Count: 102

Case Number: 237437

Gender: F

Data Entry Date: 30/01/2008

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age: 37Y

Onset Date: 15/06/2007

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Influenza like illness

Flu-like reaction, rash developed 7 days after flu

Lexapro stopped.

injection and starting

Lexapro.

Rash

Medicine details:

INFLUENZA VACCINE (Suspected) Reason: Prophylactic inoculation and vaccination

Injection 1 Dose Unspec 1 time

Severity

Batch: Started: 15/06/2007 Stopped: 15/06/2007

Lexapro (Suspected) Reason: Depression

Tablet Oral

Batch: Started: 15/06/2007 Stopped:

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Cases Count: 102

Case Number : 237443

Gender: M

Data Entry Date: 30/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 64Y

Onset Date: 15/07/2007 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Leveteracetam induced per (oncologist).

"Would never go back on 'Keppra' again".

Reaction:

Preferred Term Severity Report Description Treatment

Acute psychosis Caused or prolonged Aggression, aggravation, Ceased Keppra.

inpatient anxiety, distressed, vacant, hospitalisation confused. Psychotic

confused. Psychotic symptoms. Tried to jump out of car travelling 80

km/hr.

Anxiety Caused or prolonged

inpatient hospitalisation

Confusional state Caused or prolonged

inpatient hospitalisation

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason:

Batch: **Started**: 15/10/2006 **Stopped**: 14/09/2007 0

DEXAMETHASONE (Suspected) Reason :

4 Milligram Daily

Batch: Started: L TERM Stopped: 0

FLUDROCORTISONE (Suspected) Reason :

0.1 Milligram Daily

Batch: Started: 12/01/2007 **Stopped:** 20/09/2007 0

KEPPRA (Suspected) Reason : Convulsions

Batch: **Started**: 15/05/2006 L TERM **Stopped**: 03/09/2007

TEGRETOL CR (Suspected) Reason :

800 Milligram Daily

Batch: **Started**: 15/02/2007 **Stopped**: 0

NEXIUM (Other drug) Reason :

20 Milligram Daily

Batch: Started: L TERM Stopped: 0

NULAX FRUIT LAXATIVE (Other drug) Reason :

1 Dose Unspec Daily

Batch: Started: Stopped: 0

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Medicine details :			
TEMAZEPAM (Other drug)		Reason :	
Batch :	Started :		Stopped:

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Cases Count: 102

Case Number: 238234

Data Entry Date: 22/02/2008

Hospitalisation:

Onset Date: 03/07/2007

Outcome: 31/07/2007

Recovered

DOB: 08/12/1940

Gender: F

Age:

Weight (kg): 65

Causality: Causality probable

Treatment

Oral

Information:

Reaction:

Tachycardia

Preferred Term Severity

> Caused or prolonged inpatient

hospitalisation

tachycardia, hypotension, sweaty, decreased level of conciousness, oxygen

Report Description

Patient experienced

levels decreased to 64%.

Depressed level of

consciousness

Caused or prolonged

inpatient hospitalisation

Hypotension Caused or prolonged

inpatient hospitalisation

Caused or prolonged Oxygen saturation decreased

inpatient

hospitalisation

Medicine details:

TALOHEXAL (Suspected)

Reason:

Tablet 20 Milligram Daily

Stopped: 03/07/2007 Batch: Started: 03/07/2007

AVAPRO (Other drug)

Reason:

Batch: Started: Stopped:

CLEXANE (Other drug) Reason:

Batch: Started: Stopped:

COUMADIN (Other drug) Reason:

Batch: Started: Stopped:

PRAVACHOL (Other drug) Reason:

Stopped: Batch: Started:

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Cases Count: 102

Case Number: 238415

Gender: F

Data Entry Date: 28/02/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor **Age**: 65Y

Onset Date: 11/01/2008 **DOB**:

Outcome: 22/01/2008 Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation suffering from mild anxiety cease Talam

and depression. She was prescribed Talam 20 mg 6 wks ago. She took it for 6 days, during which she couldn't sleep, had suicidal thoughts and could hardly eat because of dry mouth and inappetence and she lost 2 kg over 6 days

Anorexia

Dry mouth Insomnia

Weight decreased

Medicine details:

Talam (Suspected) Reason : Depression

20 Milligram Daily

Batch: Started: 10/01/2008 **Stopped:** 16/01/2008

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Cases Count: 102

Case Number: 238530

Gender: F

Data Entry Date: 03/03/2008

Weight (kg): 70

Hospitalisation: Required a visit to the doctor

Age: 46Y

Onset Date: 10/02/2008

DOB:

Outcome:

Causality: Causality certain

Recovered

Information: Cert(rechall)

Same symptoms recurred after re-exposure of Citalopram.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Nausea

Nausea on Citalopram

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected)

Reason:

10 Milligram

Daily

Batch:

Started: 05/02/2008

Stopped: 19/02/2008

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Cases Count: 102

Gender: F

Case Number : 238586

Data Entry Date: 04/03/2008 **Weight (kg)**: 61.5

Hospitalisation: Age:

Onset Date: 26/01/2007 **DOB**: 26/05/1959

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Aggression

Preferred Term Severity Report Description Treatment

evening. Symptoms 30 mins later, felt euphoric, 2 hours later getting agitation, then agro - mean and snappy, aching and arthralgia all main joints, awful, skin felt on fire at same time, started nuchal area - back of head something burning, crept all over, including hands and feet, then half an hour after that neck felt itchy, then nausea. Sharp central fontal headache. Had swallowing sensation, lump in throat, tingly bottom lip. Next day twitches in multiple muscle groups. This was the second time

this happened.

Took Lexapro in early

Agitation Arthralgia

Euphoric mood

Headache

Nausea

Pruritus

Skin burning sensation

Medicine details:

Lexapro (Suspected) Reason :

10 Milligram 1 time

Batch: Started: 26/01/2007 Stopped:

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Cases Count: 102

Case Number: 238674

Gender: F

Data Entry Date: 06/03/2008 **Weight (kg)**: 75

Hospitalisation: Required a visit to the doctor **Age**: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pathological gambling Client had begun

gambling, lost \$5000, and developed compulsive behaviours like nail biting,

washing hands.

Impulsive behaviour

Onychophagia

Medicine details:

Escitalopram (Suspected) Reason : Depression

10 Milligram Daily

Batch: **Started**: 08/10/2007 **Stopped**: 31/01/2008

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Cases Count: 102

Case Number: 238689

Gender: M

Data Entry Date: 06/03/2008 Weight (kg): 76

Age:

Hospitalisation:

Onset Date: 22/01/2008

DOB: 08/02/1942

Outcome: 23/01/2008

Causality: Causality probable

Recovered

Information: History: of type 2 diabetes.

Reaction:

Preferred Term Severity **Report Description Treatment**

Nightmare Patient reported that for

the third time he had noted that whenever he forgot to take his daily dose of escitalopram he

experienced nightmares for

that night only.

Drug withdrawal syndrome

Medicine details:

Lexapro (Suspected) Reason: Anxiety neurosis

Tablet 30 Milligram Daily Oral

Batch: Started: 27/03/2007 Stopped:

STILNOX (Other drug) Reason: Specific disorders of sleep

Tablet 10 Milligram Oral Daily

Batch: Started: 07/11/2007 Stopped:

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Cases Count: 102

Gender: F

Case Number: 238722

Data Entry Date: 07/03/2008 **Weight (kg)**: 0

Hospitalisation : Admitted to hospital Age :

Onset Date: 02/12/2007 DOB: 04/01/1965

Outcome: 04/12/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Depression

Preferred Term Severity Report Description Treatment

Life threatening

The patient was a smoker and was advised by a respiratory physician to quit smoking due to recent finding of decreased lung function. After seeking advice from both her GP (who according to patient provided thorough councelling including psychiatric adverse effect risk) and her psychiatrist, the patient agreed to try varenicline (Champix) to help her quit smoking. A few days after starting the medication, patient gradually developed depression and agitation (patient stated that the symptoms started at around day 7), and later patient threatened to kill

people around her and developed suicidal behaviour. While in-patient the patient was transferred from general ward to the Psychiatric Intensive Care Unit due to agressive and erratic behaviour towards

ward staff.

Agitation Life threatening
Homicidal ideation Life threatening
Suicidal behaviour Life threatening

Medicine details:

Champix (Interaction) Reason : Smoker

Tablet 1 Dose Unspec Daily Oral

Batch: Started: 07/11/2007 Stopped: 02/12/2007 0

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Medicine details: **Escitalopram (Interaction)** Reason: Depression Tablet 30 Milligram Daily Oral Started: Stopped: Batch: **METHYLPREDNISOLONE** (Interaction) Reason: 40 Milligram Daily 0 Batch: Started: Stopped: **SODIUM VALPROATE (Interaction)** Reason: Unspecifid affective psychosis Tablet 1.5 Gram Daily Oral Stopped: Started: Batch: ALPRAZOLAM (Other drug) Reason: Oral 1 Milligram Daily Started: Stopped: Batch: **RABEPRAZOLE SODIUM (Other drug)** Reason: Tablet 20 Milligram Daily Oral Batch: Started: Stopped:

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Cases Count: 102

Case Number: 238724

Gender: F

Data Entry Date: 07/03/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 02/12/2007 **DOB**: 04/01/1965

Outcome: 04/12/2007 Causality: Causality certain

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Overdose Life threatening Previously stabilised on

psychiatric medications,

was admitted to

emergency on 03/12/07 with low conscious state secondary to overdose with sodium valproate.

Depressed level of Life threatening

consciousness

Medicine details:

ALPRAZOLAM (Interaction)

Reason: Depression

Tablet 1 Milligram Daily Oral

Batch: Started: Stopped:

Escitalopram (Interaction) Reason : Depression

Tablet 30 Milligram Daily Oral

Batch: Started: Stopped:

METHYLPREDNISOLONE (Interaction) Reason :

40 Milligram Daily

Batch: Started: Stopped:

SODIUM VALPROATE (Interaction) Reason: Unspecifid affective psychosis

Tablet 1.5 Gram Daily Oral

Batch: Started: Stopped:

MIRTAZAPINE (Other drug) Reason : Depression

Tablet 75 Milligram Daily Oral

Batch: Started: Stopped:

RABEPRAZOLE SODIUM (Other drug) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

SALBUTAMOL (Other drug) Reason : Asthma

Inhalation 6 Dose Unspec Daily Inhalation

Batch: Started: Stopped:

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Cases Count: 102

Case Number : 238860

Gender: M

Data Entry Date: 12/03/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 74Y

Onset Date: 18/02/2008

DOB:

Outcome:

Causality: Causality possible

fludrocortisone.

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Orthostatic hypotension Caused or prolonged Drug induced SIADH. Withdraw carbamazepine, start

inpatient

hospitalisation

Circulatory collapse Caused or prolonged

inpatient hospitalisation

Hyponatraemia Caused or prolonged

inpatient hospitalisation

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason :

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped:

TEGRETOL CR (Suspected) Reason : Other&unspecified epilepsy

Tablet 600 Milligram Daily Oral

Batch: Started: L TERM Stopped:

DIAZEPAM (Other drug) Reason :

Tablet 5 Milligram Oral

Batch : Started : Stopped :

OMEPRAZOLE (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

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Report Description

Cases Count: 102

Treatment

Case Number: 239039	Gender: M

Data Entry Date: 18/03/2008 **Weight (kg)**: 0

Hospitalisation: Age: 28Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Severity

Information:

Reaction:
Preferred Term

Panic attack	Complained of Panic attack, agitation, tension, irritability, anxiety, anger, musculoskeletal pain, myalgia and nightmare.
Agitation	
Anger	
Anxiety	
Irritability	
Musculoskeletal pain	
Myalgia	
Nightmare	
Tension	

Medicine details	S :		
Lexapro (Suspected)		Reason:	
Batch :	Started :	Stopped :	
STILNOX (Suspected)		Reason :	
		Oral	
Batch :	Started :	Stopped :	

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Cases Count: 102

Case Number: 239112 Gender: F

Data Entry Date: 19/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Suicidal ideation

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt; homicidal ideation; overdose; feeling abnormal; fatigue; loss of consciousness; nightmare; somnolence	
Fatigue			
Feeling abnormal			
Homicidal ideation			
Insomnia			
Loss of consciousness			
Nightmare			
Overdose			
Somnolence			

Medicine details	:				
ALCOHOL (Suspected)		Reason :			
Batch :	Started :		Stopped :		
CIPRAMIL (Suspected)		Reason :			
			Oral		
Batch :	Started :		Stopped :	0	
STILNOX (Suspected)		Reason :			
Tablet			Oral		
Batch :	Started :		Stopped :		

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Report Description

interaction

Delirium; amnesia; drug

Cases Count: 102

Treatment

Case Number: 239117

Data Entry Date: 19/03/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date : DOB : 24/09/1966

Outcome : Causality : Causality possible

Unknown

Severity

Information:

Reaction:
Preferred Term

Amnesia

Delirium					
Drug interaction					
Medicine details):				
ALPRAZOLAM (Interaction)		Reason :			
Batch :	Started :		Stopped :		
DI-GESIC (Interaction)		Reason :			
Batch :	Started :		Stopped :		
	Starteu .	Danas .	эторреа .		
Lexapro (Interaction)		Reason :			
Batch :	Started :		Stopped :		
OXYCODONE HYDROCHLO	RIDE (Interaction)	Reason :			
Batch :	Started :		Stopped :		
STILNOX (Interaction)		Reason :			
Batch :	Started :		Stannad	0	
	Starteu .		Stopped :	0	
TEMAZEPAM (Interaction)		Reason :			
Batch :	Started :		Stopped :		
NOTEN (Other drug)		Reason :			
Batch :	Started :		Stopped :		
ZANIDIP (Other drug)		Reason :			
Batch :	Started :		Stopped :		
Daton .	Otal leu .		оторреи.		

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Cases Count: 102

Case Number: 239402

Gender: F

Data Entry Date: 31/03/2008 Weight (kg): 58

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 13/03/2008 DOB: 07/11/1988

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Somnolence Somnolence

Medicine details:

Lexapro (Suspected) Reason : Depression

10 Milligram Daily

Batch: Started: 13/03/2008 **Stopped:** 16/03/2008

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Cases Count: 102

Case Number: 239497

Gender: F

Data Entry Date: 02/04/2008 **Weight (kg)**: 0

Age:

Hospitalisation :
Onset Date :

DOB: 24/04/1988

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentExtrapyramidal disorderIncapacity/disabilityextrapyramidal reaction -Cogentin im

jerking of both arms and legs - ceased after im cogentin injection Cipramil

ceased

Medicine details:

CIPRAMIL (Suspected) Reason : Depression

20 Milligram Daily Oral

Batch: **Started**: 17/10/2006 **Stopped**: 16/03/2008

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Cases Count: 102

Case Number: 239784

Gender: F

Data Entry Date: 10/04/2008 **Weight (kg)**: 90

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 06/06/2007 **DOB**: 27/05/1969

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Gingival bleeding

Bleeding gums to light pressure, vaginal bleeding

- unusual mid-cycle.

Vaginal haemorrhage

Medicine details:

CIPRAMIL (Suspected) Reason : Anxiety neurosis

Tablet 40 Milligram Daily Oral

Batch: Started: 15/10/2006 Stopped:

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Cases Count: 102

Case Number: 239873

Gender: F

Data Entry Date: 11/04/2008

Weight (kg): 70

Hospital is at ion:

Age:

Onset Date: 08/10/2007

DOB: 21/11/1959

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description 1

Treatment

Vomiting

Incapacity/disability

vomitning, visual disturbance and insomnia

cease medication

for 24 after taking one 10mg lexapro tablet

Insomnia

Incapacity/disability

Visual impairment

Incapacity/disability

Medicine details:

Lexapro (Suspected)

Reason: Depression

Tablet

10 Milligram

1 time

Oral

Batch:

Started: 08/10/2007

Ū

Stopped: 08/10/2007

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Cases Count: 102

Case Number: 240023

Gender: F

Data Entry Date: 15/04/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 18/02/2007

DOB: 27/11/1927

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Chest pain

Caused or prolonged

Rash - itchy, erythematous spots on her thighs, back,

Ceased statin, citalopram, risedronate and diazepam. Given promethazine 10mg oral

inpatient hospitalisation

forearms, lip swelling, chest pain.

stat, hydrocortisone 100mg IV, anginine. Required 5 further doses of promethazine over the next 24 hours then changed to

cetirizine 10mg daily with gradual resolution of symptoms.

Chest discomfort Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Lip swelling

inpatient

hospitalisation

Pruritus Caused or prolonged

inpatient

hospitalisation Caused or prolonged

inpatient

hospitalisation

Medicine details:

Rash

Actonel Combi (Suspected) Reason: Osteoporosis

> 35 Milligram Daily

Started: 15/12/2006 **Stopped**: 18/02/2007 Batch:

ATORVASTATIN (Suspected) Reason:

> 10 Milligram Daily

Batch: Started: 15/12/2006 Stopped: 18/02/2007

CITALOPRAM HYDROBROMIDE (Suspected)

Reason:

20 Milligram Daily

Started: 15/12/2006 **Stopped**: 18/02/2007 Batch:

DIAZEPAM (Suspected) Reason:

Daily

1 Milligram

Batch: Started: Stopped:

ASPIRIN (Other drug) Reason:

> 100 Milligram Daily

Batch: Started: Stopped:

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Medicine details :				
CHOLECALCIFEROL (Other drug)		Rea	son :	
		25 Microgram	Daily	
Batch :	Started :			Stopped :
THYROXINE SODIUM (Other drug)		Rea	son :	
		100 Microgram	Daily	
Batch :	Started :			Stopped :

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Cases Count: 102

Gender: F

Case Number: 240119

Data Entry Date: 17/04/2008 Weight (kg): 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 09/04/2008 **DOB**: 26/11/1953

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Epilepsy had influenza vaccine on Brufen 400mg tid for back pain

9/4/08 am. She had a "black-out" late afternoon on the same day and 3 more on 10/4/08. She said she had fallen over onto her back each time and her

back is sore.

Follow-up 17/4/08: She

had had 2 more

?black-outs? with falls on 11 & 12/4/08. A locum doctor visited her 12/4/08. said her blood pressure was fairly low (did not tell her the reading), and said she had internal bruising, but he thought her spine was all right. On 16/4/08 she had seen her GP who prescribed Brufen 400mg tid for her back pain. Her blood pressure was OK then. doctor did not think she needed further treatment or change of treatment for the

?blackouts?. She says she

is still in a lot of pain

Fall

Loss of consciousness

Medicine details:

ENDEP (Suspected) Reason: Depression

> 50 Milligram Daily

Started: 07/04/0110 Batch: Stopped:

INFLUENZA VACCINE (Suspected) Reason: Prophylactic inoculation and vaccination

1 Dose Unspec 1 time

Batch: Started: 09/04/2008 Stopped: 0

PUTRAN02 Page 62 of 118 **Medicine details:** Lexapro (Suspected) Reason: 25 Milligram Daily Started: 01/10/2007 0 Stopped: Batch: Reason: Epilepsy **EPILIM** (Other drug) 200 Milligram Daily Batch: Started: Stopped: FEMARA (Other drug) Reason: Malignant neoplasm of breast 2.5 Milligram Daily Batch : Stopped: Started:

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Cases Count: 102

Gender: F

Case Number: 240233

Data Entry Date: 22/04/2008 **Weight (kg)**: 83

Hospitalisation: Admitted to hospital Age:

Onset Date: 29/02/2008 **DOB**: 07/09/1947

Outcome: 03/03/2008 Causality: Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Serotonin Syndrome - hot, sweaty, sense of impending doom, nausea, diarrhoea, feeling of anxiety, nightmares, auditory and visual hallucinations, legs moving involuntarily, febrile (38C)	Ceased tramadol and citalopram
Anxiety	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Feeling hot	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Respiratory rate increased	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

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Medicine details: CITALOPRAM HYDROBROMIDE (Suspected) Reason: Depression 20 Milligram Daily **Stopped:** 01/03/2008 Batch: Started: TRAMADOL HYDROCHLORIDE (Suspected) Reason: Pain 100 Milligram Daily Batch: Started: 24/02/2008 **Stopped**: 01/03/2008 TRAMADOL HYDROCHLORIDE (Suspected) Reason: Pain 50 Milligram Daily Started: 21/02/2008 **Stopped:** 22/02/2008 Batch: **BRICANYL** (Other drug) Reason: 2 Dose Unspec Daily Inhalation Stopped: Batch: Started: **DILTIAZEM HYDROCHLORIDE (Other drug)** Reason: 180 Milligram Daily Batch: Started: Stopped: FRUSEMIDE (Other drug) Reason:

Daily

Stopped:

80 Milligram

Started:

Batch:

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Cases Count: 102

mirtazepine instead.

Gender: M

Case Number: 240532

Data Entry Date: 01/05/2008 Weight (kg): 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 04/12/2007 **DOB**: 29/12/1924

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Lethargy Caused or prolonged Increased lethargy and Escitalopram ceased. Given

inpatient sleeplessness secondary

hospitalisation to hyponatraemia and

hypoglycaemia. Hypoglycaemia

Caused or prolonged inpatient

hospitalisation

Caused or prolonged Hyponatraemia

inpatient hospitalisation

Insomnia

Caused or prolonged

inpatient hospitalisation

Medicine details:

Escitalopram (Suspected) Reason:

Oral

Batch: Started: Stopped: 04/12/2007

ASPIRIN (Other drug) Reason:

> 150 Milligram Oral

Batch: Started: Stopped:

CLOPIDOGREL (Other drug) Reason:

75 Milligram Oral

Batch: Started: Stopped: 0

CRANBERRY (Other drug) Reason:

Tablet 1 Dose Unspec Oral

Batch: Started: Stopped:

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug) Reason:

> 20 Milligram Oral

Stopped: Batch: Started:

IRBESARTAN (Other drug) Reason:

> 300 Milligram Oral

Batch: Started: Stopped:

PUTRAN02 Page 66 of 118 Medicine details:

OSTELIN 1000 (Other drug)

Reason:

1 Dose Unspec Oral

Batch: Started: Stopped:

Ranoxyl (Other drug) Reason :

16 Milligram Oral

Batch: Started: Stopped:

SIMVASTATIN (Other drug) Reason :

40 Milligram Oral

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

 Sodium
 03/12/2007
 120

 Sodium
 10/12/2007
 129

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Cases Count: 102

Case Number: 241134

Gender: M

Data Entry Date: 23/05/2008

Weight (kg): 72

Hospitalisation:

Age:

Onset Date: 15/04/2008

DOB: 12/11/1962

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Urinary retention

Preferred Term Severity

Report Description Treatment

Acute urine retention. Ceased Lexapro.

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 02/04/2008 **Stopped**: 15/04/2008

Laboratory Investigations:

Type Range Date Tested Result Details

Ultrasound -> incomplete emptying.

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Cases Count: 102

Case Number: 241208

Gender: F

Data Entry Date: 22/05/2008 Weight (kg): 75

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 01/11/2007 DOB: 04/07/1970

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Furuncle 3 weeks after Lexapro ceased.

commencement of Lexapro, skin boils over torso, thighs and

upperarm. Also hair loss.

Alopecia

Medicine details:

Lexapro (Suspected) Reason : Depression

10 Milligram Daily Oral

Batch: Started: 15/10/2007 Stopped:

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Cases Count: 102

Case Number: 241873

Gender: M

Data Entry Date: 13/06/2008

Weight (kg): 96

Hospitalisation:

Age:

Onset Date: 18/04/2008

DOB: 09/12/1974

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Syncope

Life threatening

Syncopal episode while

driving.

Medicine details:

TALOHEXAL (Suspected)

Reason: Depression

Tablet

40 Milligram

Daily

Oral

Batch:

Started: 04/12/2007

Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number: 241949

Gender: F

Data Entry Date: 16/06/2008 Weight (kg): 50

Age:

Onset Date: 22/05/2008 **DOB**: 23/01/1983

Outcome: 22/05/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Dystonia

Preferred Term Severity **Report Description Treatment**

Life threatening Dystonia reaction, tongue Benztropine

protrusion, airway

obstructions.

Dyskinesia Life threatening Obstructive airways disorder

Medicine details:

CLOPIXOL-ACUPHASE (Suspected) Reason: Otr spec symp psychopathol nec

Injection 100 Milligram 1 time Intramuscular

Batch: Started: 22/05/2008 Stopped:

Life threatening

Lexapro (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

Batch: Started: 28/04/2008 **Stopped**: 22/05/2008 0

ATIVAN (Other drug) Reason: Otr spec symp psychopathol nec

2 Milligram **Tablet** Daily Oral

Batch: Started: 28/04/2008 Stopped:

SEROQUEL (Other drug) Reason: Unspecified psychosis

Tablet 300 Milligram Daily Oral

Batch: Started: 18/04/2008 Stopped:

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Cases Count: 102

Gender: F

Case Number : 242175

Data Entry Date: 23/06/2008 **Weight (kg)**: 0

Hospitalisation: Age: 89Y

Onset Date: 09/05/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Inappropriate antidiuretic hormone secretion

Drug induced SIADH. Presented with nausea, lethargy, and anorexia following 4 days of

paroxetine.

Citalopram witheld. Ceased paroxetine. Fluid restriction

Anorexia Lethargy Nausea

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CITALOPRAM HYDROBROMIDE (Suspected) Reason :

20 Milligram Daily

Batch: **Started**: **Stopped**: 02/05/2008

PAROXETINE HYDROCHLORIDE (Suspected) Reason :

Batch: Started: Stopped:

ALENDRONATE SODIUM (Other drug) Reason :

70 Milligram Weekly

Batch: Started: Stopped:

COLOXYL (Other drug) Reason :

1 Dose Unspec As necessary

Batch: Started: Stopped:

IRBESARTAN (Other drug) Reason :

300 Milligram Daily

Batch: Started: Stopped:

OMEPRAZOLE (Other drug) Reason :

20 Milligram Daily

Batch: Started: Stopped:

OXAZEPAM (Other drug) Reason :

7.5 Milligram Daily

Batch: Started: Stopped: 02/05/2008

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Medicine details:

PARACETAMOL (Other drug)

Reason:

2 Dose Unspec As necessary

Batch: Started:

Stopped:

TIMOLOL MALEATE (Other drug)

Reason:

122

128

Daily

Batch :

Started :

Stopped:

Laboratory Investigations:

Type Sodium Range

Date Tested Result

0.5 Percent

Result 120

Details

Sodium Sodium

Sodium

Sodium

12/03/2007 13/03/2007 14/03/2007

23/03/2007 129 08/05/2008 127

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Cases Count: 102

Case Number: 242215

Gender: M

Data Entry Date: 24/06/2008 **Weight (kg)**: 76

Age:

Hospitalisation: Required a visit to the doctor

DOB: 03/04/1936

Onset Date: 30/04/2008
Outcome: 01/05/2008

Causality: Causality probable

Recovered

Information:

Reaction:

Hallucination

Preferred Term Severity Report Description Treatment

Auditory and visual Ceased Cipramil.

hallucinations.

Medicine details:

CIPRAMIL (Suspected) Reason : Depression

20 Milligram Daily

Batch: **Started**: 15/10/2007 **Stopped**: 30/04/2008

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Cases Count: 102

Case Number: 242316

Gender: F

Data Entry Date: 26/06/2008 **Weight (kg)**: 50

Hospitalisation: Age: 51Y
Onset Date: 12/05/2008
DOB:

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tongue disorder Writhing tongue, twitching muscles, upper and lower

lips, slurred speech, twitching in fingers.

Muscle twitching

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 21/04/2008 **Stopped**: 14/05/2008

CELEBREX (Other drug) Reason :

Batch: Started: Stopped:

Humira (Other drug) Reason : Other rheumatoid arthritis

Injection 40 Milligram Fortnightly Intravenous

Batch: Started: 15/01/2007 Stopped:

METHOTREXATE (Other drug) Reason :

Batch: Started: Stopped:

OROXINE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Gender: M

Case Number: 242319

Data Entry Date: 26/06/2008 Weight (kg): 0

Hospitalisation: Age: 50Y

Onset Date: 15/06/2007 **DOB**:

Outcome: Causality: Causality probable

Recovered

Information:

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Preferred Term Severity Report Description Treatment

Convulsion

consumer report:
Increased seizure
frequency. The patient
used to experience 5
seizures per week and
since starting Celapram
has experienced 8 per
week. The patient had a
past history of complex

partial seizure

Medicine details:

CELAPRAM (Suspected) Reason : Depression

Tablet 40 Milligram 2 times Oral

Batch: **Started**: 15/06/2007 **Stopped**: 15/10/2007 0

DILANTIN (Other drug) Reason :

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

LAMOTRIGINE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Case Number: 242322

Gender: F

Data Entry Date: 26/06/2008

Weight (kg): 87

Hospitalisation: Required a visit to the doctor

Age: 52Y

Onset Date :

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity F

Report Description Treatment

Oedema peripheral

Severe ankle oedema Ceased Citalopram

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected)

Reason : Depression m Daily

Tablet 20 Milligram

Oral

Batch: **Started**: 15/11/2002 **Stopped**: 15/05/2008

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Cases Count: 102

Case Number: 242542

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 09/06/2008 DOB: 06/08/1961

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urticaria Severe urticaria. High dose steroids.

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 28/04/2008 **Stopped**: 18/06/2008

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Cases Count: 102

Gender: M

Age:

Case Number : 242792

Data Entry Date: 10/07/2008 **Weight (kg)**: 60

Hospitalisation: Admitted to hospital

Onset Date: 25/05/2008 DOB: 20/05/1940

Outcome: 26/05/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Night sweats Caused or prolonged 4 days of night sweats, Escitaloprim stopped.

inpatient fever, diarrhoea, rash, hospitalisation (bilateral arm to back)

(bilateral arm to back) and reduced appetite. ?? serotonin syndrone.

Decreased appetite Caused or prolonged

inpatient

hospitalisation

Diarrhoea Caused or prolonged

inpatient hospitalisation

Pyrexia Caused or prolonged

inpatient hospitalisation

Rash Caused or prolonged

inpatient hospitalisation

Serotonin syndrome Caused or prolonged

inpatient hospitalisation

Medicine details:

Escitalopram (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: Started: 03/05/2008 Stopped: 25/05/2008

IRBESARTAN (Other drug) Reason :

Tablet 300 Milligram Daily Oral

Batch: Started: L TERM Stopped:

NIFEDIPINE (Other drug) Reason :

30 Milligram Daily Oral

Batch: Started: L TERM Stopped:

SEROQUEL (Other drug) Reason :

Tablet 25 Milligram Oral

Batch: Started: Stopped:

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Cases Count: 102

Case Number: 243119

Gender: F

Data Entry Date: 22/07/2008 **Weight (kg)**: 75

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 15/05/2008 **DOB**: 26/07/1959

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Purpura Bruising easily and Ceased Citalopram

purpura.

Increased tendency to bruise

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason : Depression

Tablet 20 Milligram Daily Oral

Batch: **Started**: 15/04/2008 **Stopped**: 25/06/2008

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Bloods NAD

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Cases Count: 102

Case Number : 243280

Gender: M

Data Entry Date: 29/07/2008

Weight (kg): 0

Hospitalisation:

Outcome:

Onset Date: 17/06/2008

Age: 63Y

DOB:

Causality: Causality possible

Not yet recovered

Information:

Mechanism of Action: Cipramil weak inhibition of CIP2D6 - hepatic enzyme. increase of

Risperidone.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Risperidone LAI and

Rispoeridone tablets withdrawn.

Neuroleptic malignant syndrome

The patient was treated with Risperidone long acting injection (microspheres, interpretable) 50 mm.

intra-muscular) 50 mg
initiated on an unknown
date for an unknown
indication and Risperidone
(tablets, oral) 2 mg twice a
day, indication unknown on
an unknown date for an
unknown indication. It was

unknown indication. It was reported that patient started taking Risperidone (tablets, oral) about 6 weeks prior to the suspected onset of neuroleptic malignant syndrome. On 17/06/08, the patient developed suspected neuroleptic malignant syndrome and on an unknown date, the patient showed signs of extrapyramidal syndrome like side effects; he

experienced increase in blood pressure, increase in creatine kinase and suffered from rigidity.

Blood creatine phosphokinase increased
Blood pressure increased

Extrapyramidal disorder

Muscle rigidity

Medicine details:

CIPRAMIL (Suspected) Reason:

Batch: Started: Stopped:

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Medicine details:

Injection

Risperdal Consta (Suspected)

Reason:

50 Milligram Daily Intramuscular

Stopped:

Batch: Started:

Laboratory Investigations :

Type Range Date Tested Result Details

Blood pressure Blood pressure increased Creatine kinase MB Creatine kinase increased

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Cases Count: 102

Gender: M

Age:

Case Number: 243668

Data Entry Date: 11/08/2008 **Weight (kg)**: 2.9

Hospitalisation: Admitted to hospital

Onset Date: 31/07/2008 DOB: 31/07/2008

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neonatal respiratory distress Caused or prolonged Born with significant Respiratory support with

syndrome inpatient respiratory distress, oxygen.

hospitalisation ongoing jitteriness.

Drug exposure during Caused or prolonged pregnancy inpatient

regnancy inpatient hospitalisation

Drug withdrawal syndrome Caused or prolonged

neonatal inpatient hospitalisation

Feeling jittery Caused or prolonged

inpatient hospitalisation

Поорнановноги

Medicine details:

Escitalopram (Suspected) Reason : Depression

20 Milligram Daily

Batch: Started: Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 102

Case Number: 243744

Gender: M

Data Entry Date: 12/08/2008 **Weight (kg)**: 69

Age:

Onset Date: 15/07/2008

DOB: 31/10/1989

Outcome :

Causality: Causality probable

Recovered

Information:

Reaction:

Hallucination

Preferred Term Severity Report Description Treatment

Visual hallucinations, sleep Lexapro ceased

disturbance, depression worsened and agitation.

Agitation

Depression

Sleep disorder

Medicine details:

Lexapro (Suspected) Reason : Depression

10 Milligram Daily

Batch: **Started**: 26/06/2008

Stopped: 30/07/2008

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Cases Count: 102

Gender: F

Case Number: 243806

Data Entry Date: 13/08/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 33Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged	Patient experienced a	Citalopram

Caused or prolonged inpatient hospitalisation

manic episode, with a predomininately irritable mood, agitation, flight of ideas and pressured speech, reduced need for sleep and an increase in goal-directed behaviour.

Citalopram ceased, quetiapine increased to 150mg.

Medicine details:

CIPRAMIL (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

Interferon NOS (Other drug) Reason :

Batch: Started: Stopped:

QUETIAPINE (Other drug) Reason :

Batch: Started: Stopped:

RIBAVIRIN (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Escitalopram ceased; fluid

restriction commenced. 3%

levels. Mirtazapine later

commenced

normal saline given, carefully titrating to increase sodium

Gender: F

Case Number: 244105

Data Entry Date: 25/08/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 04/09/2007 **DOB**: 19/11/1924

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Medicine details: **Escitalopram (Suspected)**

Preferred Term Severity **Report Description Treatment**

Hyponatraemia Caused or prolonged Significant hyponatremia,

> inpatient hypokalemia secondary to

hospitalisation recent commencement of escitalopram for anxiety / depression

Hypokalaemia Caused or prolonged

inpatient hospitalisation

Reason: Depression

Tablet 10 Milligram Daily Oral

Batch: Started: 30/08/2007 Stopped: 04/09/2007

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Cases Count: 102

Gender: M

DOB:

Case Number : 244318

....

Data Entry Date: 02/09/2008 **Weight (kg)**: 0

Hospitalisation: Age: 59Y

Outcome : Causality : Causality possible

Not yet recovered

Information:

Onset Date: 16/07/2008

Reaction:

Preferred Term Severity Report Description Treatment

Rash Raised LFT's, swelling of Ceased amlodipine, ankles, rash, fever. atorvastatin, escitalopram,

reduced dose paracetamol.

Hepatic function abnormal

Joint swelling

Pyrexia

Medicine details :

Lexapro (Suspected) Reason : Depression

15 Milligram Daily

Batch: **Started**: 07/07/2008 **Stopped**: 22/07/2008 0

LIPITOR (Suspected) Reason : Othr&unspec metabolic diseases

40 Milligram Daily

Batch: **Started**: 18/06/2008 **Stopped**: 22/07/2008 0

AMLODIPINE (Other drug) Reason :

5 Milligram Daily

Batch: Started: Stopped:

ASPIRIN (Other drug) Reason :

100 Milligram Daily

Batch: Started: Stopped:

DIAZEPAM (Other drug) Reason :

2.5 Milligram As necessary

Batch: Started: Stopped:

PARACETAMOL (Other drug) Reason :

1 Dose Unspec As necessary

Batch: Started: Stopped:

PROCHLORPERAZINE MALEATE (Other drug) Reason :

5 Milligram As necessary

Batch: Started: Stopped:

QUETIAPINE (Other drug) Reason :

12.5 Milligram As necessary

Batch: Started: Stopped:

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Medicine details:

ZOPICLONE (Other drug) Reason :

15 Milligram As necessary

342

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details SAP = ALP 16/07/2008 408

16/07/2008

SAP = ALP 16/07/2008 408 SAP = ALP 24/06/2008 76 ALT = SGPT 16/07/2008 316 ALT = SGPT 24/06/2008 46

GGT = SGGT = GGTP

GGT = SGGT = 24/06/2008 51

GGTP

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Cases Count: 102

Case Number: 244392

Gender: M

Data Entry Date: 04/09/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date : DOB : 20/12/1968

Outcome: 16/07/2008 Causality: Causality certain

Recovered

Information: Cert/rechallenge.

Reaction:

Preferred Term Severity Report Description Treatment

Rash After patient took the Esipram stopped. generic brand of

escitalopram, he developed facial rash. When he stopped the facial rash disappeard, when he started the escitalopram again the rash came back.

Therapeutic response unexpected with drug

substitution

Medicine details:

Esipram (Suspected) Reason : Depression

Tablet 20 Milligram Daily Oral

Batch: **Started**: L TERM **Stopped**: 14/07/2008 0

ASCORBIC ACID (Other drug) Reason :

Batch: Started: Stopped:

FISH OIL NOS (Other drug) Reason :

Oral

Batch: Started: Stopped:

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Cases Count: 102

Case Number: 244490

Gender: M

Data Entry Date: 08/09/2008 **Weight (kg)**: 65

Hospitalisation: Required a visit to the doctor Age:

Onset Date : DOB : 27/04/1954

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Rapid onset of involuntary Lexapro ceased, cogentin

movements of face and

jaw but not tongue.

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 15 Milligram Daily Oral

Batch: **Started**: 04/07/2005 **Stopped**: 23/10/2007

DIAZEPAM (Other drug) Reason :

570 Milligram As necessary

Batch: Started: Stopped:

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Onset Date:

Outcome:

Public Case Detail

Cases Count: 102

Case Number: 245232

Gender: F

Data Entry Date: 08/10/2008 **Weight (kg)**: 0

Age:

Hospitalisation: Admitted to hospital

DOB: 11/03/1933

Causality: Causality probable

Treatment

Recovered

Information:

Reaction:

Preferred Term Severity Report Description

Fall Caused or prolonged ? Delusional disorder,

inpatient hospitalisation Seroquel ceased because of fall and postural

hypotention.

Reason:

Seroquel ceased. Medication changed to risperidone 0.5mg

daily.

Neuroleptic malignant

Medicine details:

ARICEPT (Interaction)

syndrome

Caused or prolonged

inpatient hospitalisation

Orthostatic hypotension Caused or prolonged

inpatient hospitalisation

Tablet 10 Milligram Daily Oral

Batch: Started: 11/04/2008 Stopped:

Escitalopram (Interaction) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: 11/04/2008 Stopped:

SEROQUEL (Suspected) Reason :

Tablet 400 Milligram Daily Oral

Batch: **Started**: 01/02/2008 **Stopped**: 02/05/2008

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Cases Count: 102

Case Number : 245249

Gender: M

Data Entry Date: 08/10/2008 **Weight (kg)**: 75

Hospitalisation: Admitted to hospital Age:

Onset Date : DOB : 11/03/1928

Outcome: 15/09/2008 Causality: Causality possible

Recovered

Information: Symptomatic - no seizures

Allergies: Penicillin/Sulpha

Metoprolol - excessive bradycardia

Reaction:

Preferred Term Severity Report Description Treatment

Malaise Life threatening Hyponatraemia Cessation of escitalopram, IV

saline to Na 120mmol/L - slow

resolution

Hyponatraemia Life threatening

Medicine details:

Escitalopram (Suspected) Reason: Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 15/08/2008 **Stopped**: 08/09/2008

TELMISARTAN (Suspected)Reason: Essential benign hypertension

40 Milligram Daily

Batch: Started: Stopped: 0

COLGOUT (Other drug) Reason :

500 Microgram Daily Oral

Batch: **Started**: **Stopped**: 08/09/2008

MOVICOL (Other drug) Reason :

Batch: Started: Stopped:

MYLANTA (Other drug) Reason :

400 Milligram As necessary

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Sodium 113 mmol/L

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Cases Count: 102

Panadeine forte - more useful

but cannot drive or care for

children while so drowsy. Nil

treatment for rash - not itchy.

Gender: F

Case Number : 245363

Data Entry Date: 13/10/2008 **Weight (kg)**: 63

Hospitalisation: Age: 38Y

Onset Date: 08/10/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentArthralgiaIncapacity/disabilityHave taken 10mg for 2
months with no sideDisprin Max - ineffective.
Aspalgin - moderately effective.

months with no side effects. Increased dose to 2x10mg and on next day had aching joints and slight fever, strong headache, lethargy, loss of appetite, nausea, crazy dreams - lasted 5 days - decreasing in severity after day 3. Had day off work on day 2. Unable to drive or work due to headache or stand due to dizziness and aches fine mottled rash appeared

- mainly on torso.

Decreased to 1 and a half 10 mg tablets on 13th.

Abnormal dreams Incapacity/disability
Anorexia Incapacity/disability
Dizziness Incapacity/disability
Headache Incapacity/disability
Lethargy Incapacity/disability
Pyrexia Incapacity/disability
Rash Incapacity/disability

Medicine details:

Therapy regimen changed

Lexapro (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

Incapacity/disability

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Cases Count: 102

Case Number: 245367

Data Entry Date: 13/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 33Y

Onset Date: 15/07/2008 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Past history of heroin dependence.

Reaction:

Preferred Term Severity Report Description Treatment

Mania Caused or prolonged Mani

inpatient hospitalisation

d or prolonged Mania

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason : Depression

20 Milligram Daily

Batch: Started: Stopped: 0

Peg Interferon Alfa-2a (Other drug) Reason :

Batch: Started: Stopped:

QUETIAPINE (Other drug) Reason :

Batch: Started: Stopped:

RIBAVIRIN (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Case Number : 245376

Gender: F

Data Entry Date: 13/10/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 29/06/2008 DOB: 20/02/1975

Outcome: 29/06/2008 Causality: Causality possible

Death, maybe drug

Information: History includes two previous pregnancies, mild asthma, non smoker, half a glass of

wine daily throughout this and previous two pregnancies, chronic psychotic illness and

psychotic disorder.

Reaction:

Preferred Term Severity Report Description Treatment

Stillbirth - Drug Exposure during

pregnancy

- Stillbirth at 33/40 weeks

gestation

NOTE: Patient was enrolled in a Pregnancy Registry Program (The National Register of Antipsychotic Medication in

Pregnancy).

Drug exposure during

pregnancy

Intra-uterine death

Medicine details:

CIPRAMIL (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped: 0

SEROQUEL (Suspected) Reason: Unspecified psychosis

Tablet 1.2 Gram Daily Oral

Batch: Started: Stopped: 0

FOLIC ACID (Other drug) Reason: Unspec vitamin deficien states

Batch: Started: Stopped: 0

Laboratory Investigations:

Type Range Date Tested Result Details

Ultrasound On the 29/06/2008, the baby stopped

moving in utero, ultrasound revealed

fetal demise.

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Cases Count: 102

Termination of pregnancy

Gender: F

Age:

Case Number : 245385

Data Entry Date: 13/10/2008 **Weight (kg)**: 52

Hospitalisation :

Onset Date: 01/10/2008 **DOB**: 11/01/1973

Outcome: 10/06/2008 Causality: Causality possible

Death

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Foetal cardiac disorder Congenital anomaly / Fetal abnormality. - Atrial

birth defect isomerism, double outlet right ventricle, left

ventricular hypoplasia, stomach on right side

Abortion induced Congenital anomaly /

birth defect

Congenital anomaly Congenital anomaly /

birth defect

Drug exposure during

pregnancy

Congenital anomaly /

birth defect

Foetal disorder Congenital anomaly /

birth defect

Ventricular hypoplasia Congenital anomaly /

birth defect

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 06/06/2007 **Stopped**: 0

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Cases Count: 102

Gender: F

Case Number: 245389

Data Entry Date: 13/10/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 30/08/2008 DOB: 10/02/1927

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Headache Caused or prolonged Constant headache,

inpatient nausea, increased hospitalisation confusion.

Confusional state Caused or prolonged

inpatient hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Medicine details:

NOTEN (Other drug)

Batch:

Escitalopram (Suspected) Reason :

Tablet 10 Milligram Daily Oral

Batch: **Started**: 29/08/2008 **Stopped**: 31/08/2008

FEFOL (Other drug) Reason :

Batch: Started: Stopped:

ISCOVER (Other drug) Reason :

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

Batch: Started: Stopped:

PRAVACHOL (Other drug) Reason :

Started:

Batch: Started: Stopped:

Reason:

Stopped:

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Cases Count: 102

Gender: M

Case Number : 245439

Data Entry Date: 14/10/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 17/09/2008 DOB: 01/03/1974

Outcome: Causality: Causality possible

Recovered

Information:

Medicine details :

Reaction: **Preferred Term** Severity **Report Description Treatment** Neuroleptic malignant Caused or prolonged Patient developed fever, Ceased ziprasidone. Treated syndrome inpatient and later in the day had a with bromocriptine hospitalisation grand mal seizure. Patient had also developed Neuroleptic malignant syndrome on an unknown date and symptoms of fever and cardiovascular instability persisted for some days and creatine kinase peaked at 13000 Blood creatine phosphokinase Caused or prolonged increased inpatient hospitalisation Cardiovascular insufficiency Caused or prolonged inpatient hospitalisation Grand mal convulsion Caused or prolonged inpatient hospitalisation Caused or prolonged Pyrexia inpatient hospitalisation

modicino dotano i					
CLOZAPINE (Suspected)	Re	ason :			
Batch :	Started :	s	Stopped :		
Lexapro (Suspected)	Re	ason : Depression			
	10 Milligram	Daily	Oral		
Batch :	Started : 30/03/2008	s	Stopped :		
PERIACTIN (Suspected)	Re	ason :			
	4 Milligram	Daily	Oral		
Batch :	Started :	S	Stopped :		
Zeldox (Suspected)	Re	ason : Unspecified	schizophrenia		
Capsule	160 Milligram	Daily	Oral		
Batch :	Started: 17/07/2008	S	Stopped :	0	

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Laboratory In	vestigations	S :			
Туре	Range	Date Tested	Result	Details	
Creatine phosphokinase	<200	29/09/2008	13000		
Creatine phosphokinase	<200	22/09/2008	4000		
Creatine phosphokinase	<200	29/09/2008	164		

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Cases Count: 102

Case Number: 246019

Gender: F

Data Entry Date: 06/11/2008 **Weight (kg)**: 0

Hospitalisation : Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tinnitus Incapacity/disability Patient developed tinnitus Ceased Cipramil

and arthralgia of her

hands.

Arthralgia Incapacity/disability

Medicine details:

CIPRAMIL (Suspected) Reason :

Tablet 5 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 102

Case Number : 246165

Gender: F

Data Entry Date: 12/11/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 11/06/2008

DOB: 11/03/1933

Outcome:

Causality: Causality possible

Recovered

Information: Recent suspected NMS secondary to risperidone 0.5mg. (Admitted 05/05 -08/05/08)

Reaction:

Preferred Term

Severity

Report Description

Treatment

Pyrexia

Lower oral intake, lower mobility, fever.

Ceased amisulpride and simvastatin, given antipyretics,

IV fluids.

Blood creatine phosphokinase

increased

Cogwheel rigidity

Hyperglycaemia

Hypophagia

Hypotension

Mobility decreased

Neuroleptic malignant

syndrome

Tachycardia

Medicine details:

AMISULPRIDE (Suspected)

Reason:

200 Milligram

Daily

Batch: Started: 15/05/2008 Stopped: 11/06/2008

DONEPEZIL HYDROCHLORIDE (Suspected)

Reason:

10 Milligram

Daily

Started:

Escitalopram (Suspected)

Reason: 20 Milligram

Daily

Batch:

Batch:

Started:

Stopped:

Stopped:

QUETIAPINE (Suspected)

Reason:

Daily

Batch:

Started:

Started:

Started:

Stopped:

RISPERIDONE (Suspected)

Reason:

Daily

Batch:

0.5 Milligram

400 Milligram

Stopped:

SIMVASTATIN (Suspected)

Reason:

40 Milligram

Daily

Batch:

Stopped: 11/06/2008

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Medicine details: **ASPIRIN** (Other drug) Reason: 100 Milligram Oral Daily Stopped: Batch: Started: **CALTRATE** (Other drug) Reason: 600 Milligram Daily Oral Batch: Started: Stopped: **CHOLECALCIFEROL** (Other drug) Reason: 1 Stopped: Batch: Started: **METFORMIN HYDROCHLORIDE (Other drug)** Reason: Daily 1 Gram **Stopped**: 11/06/2008 Batch: Started: Novomix 30 (Other drug) Reason: 16 Unit Daily Subcutaneous Batch: Started: Stopped:

Laboratory Investigations: Type Range Date Tested Result **Details** Other data Febrile 38.1C, MSU (-), BCs (-), CK peaked @7211 on 12/06/08. **Heart Rate** 100 Blood pressure 106/40 Serum glucose 11.8 Creatine kinase MB 19/06/2008 154

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Cases Count: 102

Case Number: 246176

Gender: F

Data Entry Date: 12/11/2008

Weight (kg): 0

Hospitalisation:

Age: 8D

Onset Date: 03/09/2008

DOB:

Outcome: 08/09/2008

Causality: Causality possible

Recovered

Information:

Reaction:
Preferred Term

Severity

Report Description

Treatment

Bradycardia

Caused or prolonged

Bradycardia.

Monitored

Drug exposure during

Caused or prolonged

pregnancy

inpatient

inpatient hospitalisation

hospitalisation

Medicine details:

CITALOPRAM HYDROBROMIDE (Suspected)

Reason: Unspecif personality disorder

20 Milligram

Daily

Batch :

Started:

Stopped :

CLEXANE (Other drug)

Reason:
60 Milligram

Batch :

Started :

Stopped:

FRAGMIN (Other drug)

Reason: Phleb&thrombophleb lowr extrem

10

Batch:

Started :

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Other data

Sinus bradycardia 58-176

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Cases Count: 102

Age:

Case Number: 246203

Data Entry Date: 12/11/2008 **Weight (kg)**: 63

Hospitalisation :

Onset Date : DOB : 17/02/1934

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:				
Preferred Term	Severity	R	eport Descri	ption Treatment
Tremor		Т	remor	
Medicine details :				
Escitalopram (Suspected)		Rea	ason :	
Batch :	Started :			Stopped :
ALEPAM (Other drug)		Rea	ason :	
		60 Milligram	As necessary	Oral
Batch :	Started :			Stopped:
ANTENEX (Other drug)		Rea	ason :	
		5 Milligram	As necessary	
Batch :	Started :			Stopped:
ATACAND (Other drug)		Rea	ason :	
		16 Milligram	Daily	Oral
Batch :	Started :			Stopped:
LIPITOR (Other drug)		Rea	ason :	
		20 Milligram	Daily	Oral
Batch :	Started :			Stopped:
Norspan 5 (Other drug)	Reason :			
		5 Milligram	Weekly	Transdermal
Batch :	Started :			Stopped :
PARIET (Other drug)		Rea	ason :	
		20 Milligram	Daily	Oral
Batch :	Started :			Stopped:

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Cases Count: 102

Case Number: 246314

Gender: M

Data Entry Date: 17/11/2008

Weight (kg): 0

Hospitalisation:

Age: 41Y

Onset Date: 05/09/2008

DOB:

Outcome:

Not yet recovered

Causality: Causality possible

Information: DOCI report.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hepatitis

Acute active hepatitis - ?

secondary to Champix.

Jaundice

Medicine details:

AMOXYCILLIN SODIUM (Suspected)

Reason:

Batch:

Started: 03/09/2008

Stopped: 05/09/2008

Champix (Suspected)

Reason: Smoker

Tablet

0.5 Milligram

Daily

Oral

Batch:

Started: 15/08/2008

Stopped: 05/09/2008

Escitalopram (Suspected)

Reason: Depression 10 Milligram

Daily

Batch:

Started: 31/08/2008

Stopped: 05/09/2008

NEXIUM (Suspected)

Reason:

40 Milligram

Daily

Batch:

Started:

L TERM

Stopped: 05/09/2008

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Cases Count: 102

Case Number: 246562

Gender: F

Data Entry Date: 25/11/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: History of depression.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Self-injurious ideation

Patient experienced thoughts of self harm, crying, weight gain of

15kgs and drug ineffective.

Crying

Drug ineffective Weight increased

Medicine details:

Lexapro (Suspected)

Reason: Depression

Tablet

20 Milligram

Daily

Oral

Batch:

Started:

L TERM

Stopped:

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Cases Count: 102

Case Number: 246567

Gender: M

Data Entry Date: 25/11/2008

Weight (kg): 99

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 28/10/2008

DOB: 20/01/1972

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Akathisia, anxiety and

insomnia.

Anxiety

Insomnia

Akathisia

Medicine details:

Lexapro (Suspected)

Reason: Depression

10 Milligram

Daily

Batch:

Started: 23/10/2008

Stopped: 28/10/2008

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Cases Count: 102

Case Number: 246627

Data Entry Date: 26/11/2008 Weight (kg): 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 27/12/2007 **DOB:** 14/03/1980

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Vanishing bile duct syndrome

Severity

Caused or prolonged inpatient hospitalisation

Report Description

On presentation this patient was febrile with deranged LFTs and jaundice, malaise, a maculo-papular rash to the trunk and arms that was causing desquamation of pain (+++), and severe ulceration to the tongue and throat. Initial diagnosis was Steven's Johnson Syndrome with cholestatic iaundice of unknown cause.

The pts LFTs continued to deteriorate and the jaundice worsened over the seven days post admission. An atypical pulmonary infection (eg mycoplasma) was queried. Vasculitis was also queried.

By the 09/01/2008 the itching had improved (jaundice still present, LFTs remained significantly elevated). Despite extensive investigation, no diagnosis could be made at this time. The subsequent diagnosis, made by the consultant physician, in light of the timeline and biopsy findings was "citalopram-induced vanishing bile duct syndrome".

Treatment

Gender: F

It was discussed as to whether to cease the patient's citalopram, however this was not done during admission. Supportive care for rash/ulceration.; Aciclovir was used for the queried viral the skin (initially itchy), joint infection. Azithromycin was used for the non specific URTI. ursodeoycholic acid for jaundice, changed to prednisolone 75mg daily due to little response.

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Reaction:

Preferred Term

Vanishing bile duct syndrome

Severity Caused or prolonged

inpatient hospitalisation **Report Description**

On presentation this patient was febrile with deranged LFTs and

Treatment

little response.

Supportive care; ursodeoycholic acid for jaundice, changed to

prednisolone 75mg daily due to

jaundice, malaise, a maculo-papular rash to the trunk and arms that was causing desquamation of the skin (initially itchy), joint pain (+++), and severe ulceration to the tongue and throat. Initial diagnosis was Steven's Johnson Syndrome with cholestatic jaundice of unknown

cause.

The subsequent diagnosis, made by the consultant physician, in light of the timeline and biopsy findings was "citalopram-induced vanishing bile duct

syndrome".

Vanishing bile duct syndrome

Caused or prolonged

inpatient hospitalisation

The overall diagnosis made by the consultant physician in light of the timeline and biopsy

findings was "citalopram-induced vanishing bile duct syndrome".

Supportive care; ursodeoycholic acid for jaundice, changed to prednisolone 75mg daily due to little response.

Arthralgia

Caused or prolonged

inpatient hospitalisation

Exfoliative rash Caused or prolonged

> inpatient hospitalisation

Jaundice cholestatic Caused or prolonged

> inpatient hospitalisation

Medicine details:

Other data

CITALOPRAM HYDROBROMIDE (Suspected) Reason: Depression

Oral Tablet 20 Milligram Daily

Started: 01/12/2006 **Stopped**: 01/02/2008 Batch: 0

VENTOLIN (Other drug) Reason: Asthma

Inhalation Dose Unspec As necessary Inhalation

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result **Details**

Chest X-ray ? infiltrates

Ultrasound Liver no cholestasis, no bile duct

> dilatation Q fever PCR

1. destruction of bile ducts Liver biopsy

2. (post citalopram) regeneration of bile

ducts

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Cases Count: 102

Case Number: 246917

Gender: F

Data Entry Date: 08/12/2008 Weight (kg): 0

Age:

Hospitalisation: Onset Date:

DOB: 22/07/1984

Causality: Causality probable Outcome:

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Lethargy Incapacity/disability generalized lethargy with cessation of medication and use of lexapro changed to sertraline 25 mg

daily

Medicine details:

Lexapro (Suspected) Reason:

> 10 Milligram 1 time Oral

Stopped: 08/12/2008 Batch: Started: 08/05/2007

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Cases Count: 102

Case Number: 247052

Gender: M

Data Entry Date: 10/12/2008

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Drug ineffective

Esipram does not work, it

does nothing for the

patient.

Therapeutic response unexpected with drug

substitution

Medicine details:

Esipram (Suspected)

Reason:

20 Milligram

Tablet

Daily

Oral

Batch: FA01323 11/2010

Started:

Stopped:

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Cases Count: 102

Gender: F

Case Number: 247306

Data Entry Date: 22/12/2008 **Weight (kg)**: 80

Hospitalisation: Age:

Onset Date: 10/11/2008 **DOB**: 15/07/1977

Outcome: 17/11/2008 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Headache Severe headache, sensitive to light and

sound, diarrhoea.

Panadol- 6/day for 4 days.

Diarrhoea

Hyperacusis

Photophobia

Medicine details:

Esipram (Suspected) Reason :

Tablet 20 Milligram Daily Oral

Batch: **Started**: 08/11/2008 **Stopped**: 15/11/2008

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Cases Count: 102

Case Number: 247657

Data Entry Date: 13/01/2009 **Weight (kg)**: 0

Hospitalisation: Age: 48Y

Onset Date: 03/10/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

R	e	a	C	ti	0	n	:

Preferred Term Severity Report Description Treatment

Delirium, hallucinations. Olanzapine stat wafer with good

effect.

Hallucination

Medi	cine	details	-

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason :

Batch: Started: Stopped:

CITALOPRAM HYDROBROMIDE (Suspected) Reason :

Batch: Started: Stopped:

FENTANYL TRANSDERMAL (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Case Number: 247852 Gender: F

Data Entry Date: 21/01/2009 **Weight (kg)**: 0

Hospitalisation: Age: 91Y

Onset Date: 20/10/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia Asymptomatic Ceased Lexapro, fluid

hyponatraemia restricted, sodium replacement

Medicine details:

Lexapro (Suspected) Reason :

Tablet 10 Milligram Daily Ophthalmic

Batch: **Started**: 23/09/2008 **Stopped**: 20/10/2008

ARICEPT (Other drug) Reason :

Batch: Started: Stopped:

ATACAND (Other drug) Reason :

Batch: Started: Stopped:

CALTRATE (Other drug) Reason :

Batch: Started: Stopped:

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug) Reason :

Batch: Started: Stopped:

OSTELIN 1000 (Other drug) Reason :

Batch : Started : Stopped :

VITAMINORUM B.P.C. (Other drug) Reason :

Batch: Started: Stopped:

WARFARIN SODIUM (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Sodium 22/09/2008 139



Cases Count: 102

Case Number: 247870

Gender: F

Data Entry Date: 21/01/2009 **Weight (kg)**: 60

Hospitalisation: Admitted to hospital Age:

Onset Date: 13/10/2008 **DOB**: 13/11/1976

Outcome: Causality: Causality possible

Not yet recovered

Information: History: Used heroine and methamphetamines 10 years ago. Suffers from depression.

Reaction:

Preferred Term Severity Report Description Treatment

Migraine Caused or prolonged Patient experienced Lexapro discontinued.

inpatient episodes of fainting, slurred speech and unilateral weakness. This was followed by a severe

headache and nightmares.

Nightmare Caused or prolonged

inpatient hospitalisation

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

Batch: **Started**: 17/06/2008 **Stopped**: 03/11/2008

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Cases Count: 102

Case Number : 247872

Gender: M

Data Entry Date: 21/01/2009 Weight (kg): 70

Hospitalisation: Admitted to hospital Age:

Onset Date: DOB: 06/05/1947

Outcome: Causality: Causality possible

Recovered

Information: History of asthma, hayfever and depression.

Reaction:

Lexapro (Suspected)

Preferred Term Severity Report Description Treatment

Urticaria Caused or prolonged Two weeks after being Lexapro discontinued. Changed

inpatient prescribed Lexapro, patient to Cipramil 20mg. hospitalisation developed a possible

allergic reaction,

developing three episodes of severe uticaria and laryngel swelling.

Reason: Depression

Pharyngeal oedema Caused or prolonged

inpatient hospitalisation

Medicine details :

Tablet 10 Milligram Daily Oral

Batch: Started: 18/06/2008 Stopped: 03/07/2008

PHENERGAN (Other drug) Reason :

Batch: Started: Stopped:

RHINOCORT (Other drug) Reason :

Batch: Started: Stopped:

VENTOLIN (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 102

Case Number: 247941

Gender: F

Data Entry Date: 23/01/2009 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 18/01/1976

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Abdominal pain upper Caused or prolonged

inpatient hospitalisation Patient experienced epigastric pains, duodenal

ulcerationl.

Told to cease Buprofen, started on Nexium 40mg daily. IV potassium infusion, oral potassium supplements, 2 unit

blood transfusion and iron infusion.

Duodenal ulcer Caused or prolonged

inpatient hospitalisation

Medicine details:

IBUPROFEN (Suspected) Reason : Headache

Batch: Started: Stopped:

Talam (Suspected) Reason: Depression

20 Milligram Daily

Batch: Started: 15/04/2008 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Gastroscopy Showed duodenal

ulceration.

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Cases Count: 102

Case Number : 247985

Gender: M

Data Entry Date: 28/01/2009

Weight (kg): 105

Hospitalisation: Admitted to hospital

Age:

Onset Date: 11/08/2008

DOB: 29/06/1936

Outcome: 21/08/2008

Causality: Causality possible

Recovered

Information: Two cases from same doctor linking temazepam with venous thromboembolism

ADRAC no. 247984. Lexapro has been associated with DVT.

Reaction:

Preferred Term Severity **Report Description Treatment**

Embolism venous Life threatening Patient given Temazepam 16/6/2008 for insomnia after death of wife. Stopped use of Lexapro May 2008 for a short while.

Used Temazepam infrequently. Developed pulmonary embolism

11/8/08.

Pulmonary embolism Life threatening

Medicine details:

Lexapro (Suspected) Reason:

> 10 Milligram Daily

Batch: Started: 07/05/2008 Stopped:

TEMAZEPAM (Suspected) Reason: Specific disorders of sleep

> 10 Milligram As necessary

Started: 16/06/2008 Stopped: 11/08/2008 Batch:

Reason: Essential benign hypertension AVAPRO (Other drug)

1 Dose Unspec Daily

Batch: Started: Stopped:

LIPEX (Other drug) Reason:

> Milligram Daily

Batch: Started: Stopped:

PANAMAX (Other drug) Reason:

Batch: Started: Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: CELAPRAM, CIPRAMIL, CITALOPRAM HYDROBROMIDE, TALOHEXAL, Escitalopram, Lexapro, Talam, Chem Mart Citalopram, GenRx Citalopram, Ciazil, Esipram

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