

Cases Count: 61

Case Number: 231483

Gender: F

Data Entry Date: 02/08/2007

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age:

DOB: 12/11/1989

Outcome: 27/06/2007

Causality: Causality possible

Recovered

Information:

Onset Date: 25/06/2007

Reaction:

Preferred Term Opisthotonus

Severity

Report Description

Treatment

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: 61

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)	1	Reason: Depression	ason : Depression		
Tablet	10 Milligram	Daily	Oral		
Batch :	Started: 15/03/2006	Stop	ped:		
ALODORM (Other drug)	,	Reason :			
Batch :	Started :	Stop	ped:		
ENDONE (Other drug)	,	Reason :			
Batch :	Started :	Stop	ped:		
PANADEINE FORTE (Other drug)	1	Reason :			
Batch :	Started :	Stop	ped:		
PREDNISONE (Other drug)	1	Reason :			
Batch :	Started :	Stop	ped:		
TEMTABS (Other drug)	1	Reason :			
Batch :	Started :	Stop	ped:		

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Hospitalisation:

Public Case Detail

Cases Count: 61

Case Number: 232490

Gender: M

Data Entry Date: 24/08/2007 **Weight (kg)**: 96

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 leg

inpatient hospitalisation

 $\underset{\cdot}{\text{legs, arms and along}}$

spine.

Abdominal pain upper Caused or prolonged

inpatient

hospitalisation

Blood creatine phosphokinase

increased

Myalgia

Caused or prolonged

inpatient hospitalisation

1100pitalloation

Caused or prolonged

inpatient hospitalisation

Medicine details:

Lexapro (Suspected) Reason :

Tablet 20 Milligram 1 time Oral

Batch: Started: 26/06/2007 Stopped: 24/08/2007

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Cases Count: 61

Case Number: 232597

Onset Date: 15/07/2007

Information:

Outcome:

Gender: M

Age:

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

Hospitalisation: Required a visit to the doctor

DOB: 05/01/1940

Causality: Causality probable

Recovered

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: 61

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: 61

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: 61

Case Number: 233086

Gender: F

Data Entry Date: 06/09/2007 **Weight (kg)**: 80

Hospitalisation : Age :

Onset Date: 20/10/2006 **DOB**: 15/02/1987

Outcome: 05/01/2007 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 Warfarin and Panadeine Forte

large deep vein thrombosis whilst on Lexapro.(this

report, SEQ .1)

Medicine details:

Lexapro (Suspected) Reason : Depression

Tablet 20 Milligram Daily Oral

Batch: **Started**: 15/08/2006 **Stopped**: 03/01/2007

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Cases Count: 61

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

233116 is a seq of 233489.

Reaction:

Preferred Term Severity Report Description Treatment

Chromaturia Incapacity/disability dark urine
Blood creatine phosphokinase Incapacity/disability up to 8000

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: 61

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 :

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Stopped:

Creatine

phosphokinase

8000

Liver function tests

Elevated

PUTRAN02



Cases Count: 61

Case Number: 233662

Gender: F

Data Entry Date: 20/09/2007

Weight (kg): 77

Hospitalisation:

Age:

Onset Date :

DOB: 03/01/1990

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Suicide attempt Severity

Report Description

Treatment

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: 61

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: 61

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 Description		Treatment
Cerebral haemorrhage			Intracerebral/ventricular bleed.		
Medicine details :					
CLEXANE (Suspected)			Reason :		
Batch :	Started :			Stopped :	
Escitalopram (Suspected)			Reason :		
Tablet		10 Milligram	n Daily		Oral
Batch :	Started :			Stopped :	
WARFARIN SODIUM (Suspected)			Reason :		
Batch :	Started :			Stopped :	
CEPHAZOLIN SODIUM (Other drug)			Reason :		
Batch :	Started :			Stopped :	
MIXTARD 30/70 (Other drug)			Reason :		
Batch :	Started :			Stopped :	
MODURETIC (Other drug)			Reason :		
Batch :	Started :			Stopped :	
PARACETAMOL (Other drug)			Reason :		
Batch :	Started :			Stopped :	
SOTALOL HYDROCHLORIDE (Other	r drug)		Reason :		
Batch :	Started :			Stopped :	

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Hospitalisation:

Public Case Detail

Cases Count: 61

Case Number : 234058

Gender: F

Data Entry Date: 05/10/2007 **Weight (kg)**: 74

Age: 52Y

Outcome:

190. 02.

Onset Date: 01/06/2007

DOB:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hepatitis Incapacity/disability suspected drug induced

hepatitis

Hypertension Incapacity/disability

Visual impairment Incapacity/disability

Medicine details:

EDRONAX (Suspected) Reason : Depression

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: 61

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 Term Severity

Report Description Treatment

Hot flush

Caused or prolonged

After taking the first escitalopram tablet the

Ceased drug

inpatient hospitalisation

patient experienced waves 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

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: 61

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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Cases Count: 61

Case Number : 235377

Gender: F

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

Hospitalisation : 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 Patient experienced waves Escitalopram discontinued.

inpatient of hot and cold flushes hospitalisation 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: 61

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

Reason:

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 0

NALTREXONE HYDROCHLORIDE (Interaction)

Tablet Oral

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

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Cases Count: 61

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

Report Description

Treatment

Coagulopathy

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

into nasal passages.

Tranexamic acid 1g tds, Vitamin

K 5mg stat, Kaltostat packing

every 20-30 minutes). ? SSRI - associated coagulopathy.

Haemorrhage

Secretion discharge

Medicine details:

Escitalopram (Suspected) Reason: Depression

Severity

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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Cases Count: 61

Case Number : 236458

Gender: F

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

Hospitalisation: 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.

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)

Reason:

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: 61

Gender: F

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 rigers, mild headache, nausea, sweats, dizzy on

> tremor, weaknes, hyperaesthesia.

Flushing, hot and cold ceased Buprenorphine and escitalopram.

> standing, photophobia, myalgia, neck stiffness,

Asthenia

Dizziness postural

Headache

Chills

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 details :				
PANTOPRAZOLE (Other drug)		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: 61

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

Severity

Report Description

Treatment

Lexapro stopped.

Influenza like illness Flu-like reaction, rash

developed 7 days after flu injection and starting

Lexapro.

Rash

Medicine details:

INFLUENZA VACCINE (Suspected) Reason: Prophylactic inoculation and vaccination

Injection 1 Dose Unspec 1 time

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: 61

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

Took Lexapro in early 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.

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: 61

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

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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Hospitalisation:

Public Case Detail

Cases Count: 61

Case Number: 238689

Gender: M

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

Age:

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 Daily Oral

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

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Cases Count: 61

Case Number : 238722

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 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

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

symptoms started at

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 30 Milligram Tablet 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: 61

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: Stopped:

SALBUTAMOL (Other drug) Reason : Asthma

Inhalation 6 Dose Unspec Daily Inhalation

Batch: Started: Stopped:

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Report Description

Complained of Panic attack, agitation, tension,

Cases Count: 61

Treatment

Oral

Stopped:

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

Started:

Information:

Reaction:
Preferred Term

Panic attack

STILNOX (Suspected)

Batch:

		irritability, anxie	
		myalgia and nig	
Agitation			
Anger			
Anxiety			
Irritability			
Musculoskeletal pain			
Myalgia			
Nightmare			
Tension			
Medicine details :			
Lexapro (Suspected)		Reason:	
Batch :	Started :		Stopped :

Reason:

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Report Description

interaction

Delirium; amnesia; drug

Cases Count: 61

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 detail	s:				
ALPRAZOLAM (Interaction	n)	Reason :			
Batch :	Started :		Stopped :		
DI-GESIC (Interaction)		Reason :			
Batch :	Started :		Stopped :		
Lexapro (Interaction)		Reason:			
Batch :	Started :		Stopped :		
OXYCODONE HYDROCHLORIDE (Interaction)		Reason :			
Batch :	Started :		Stopped :		
STILNOX (Interaction)		Reason :			
Batch :	Started :		Stopped :	0	
TEMAZEPAM (Interaction)		Reason :			
Batch :	Started :		Stopped :		
NOTEN (Other drug)		Reason :			
Batch :	Started :		Stopped :		
ZANIDIP (Other drug)		Reason :			
Batch :	Started :		Stopped :		

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Cases Count: 61

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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Hospitalisation:

Public Case Detail

Cases Count: 61

Case Number: 239873

Gender: F

Data Entry Date: 11/04/2008 Weight (kg): 70

Age:

Onset Date: 08/10/2007

DOB: 21/11/1959

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Vomiting Incapacity/disability vomitning, visual cease medication

disturbance and insomnia 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 **Stopped:** 08/10/2007 Started: 08/10/2007 Batch:

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Cases Count: 61

Weight (kg): 0

Case Number: 240119

Data Entry Date: 17/04/2008

Gender: F

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:

Reason: Prophylactic inoculation and vaccination **INFLUENZA VACCINE (Suspected)**

1 Dose Unspec 1 time

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

PUTRAN02 Page 33 of 68 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: 61

Case Number: 240532

Gender: M

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 mirtazepine instead.
hospitalisation to hyponatraemia and

hypoglycaemia.

Hypoglycaemia Caused or prolonged

inpatient hospitalisation

Hyponatraemia Caused or prolonged

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

Batch: Started: Stopped:

IRBESARTAN (Other drug) Reason :

300 Milligram Oral

Batch: Started: Stopped:

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Medicine details:

OSTELIN 1000 (Other drug)

Reason:

1 Dose Unspec Oral

Batch: Started: Stopped:

Ranoxyl (Other drug)

Reason:

16 Milligram Oral

Batch: 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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Hospitalisation:

Public Case Detail

Cases Count: 61

Case Number: 241134

Gender: M

Data Entry Date: 23/05/2008 **Weight (kg)**: 72

Age:

Onset Date: 15/04/2008

DOB: 12/11/1962

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urinary retention 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: 61

Case Number: 241208

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: 61

Case Number: 241949

Gender: F

Data Entry Date: 16/06/2008

Weight (kg): 50

Hospitalisation:

Age:

Onset Date: 22/05/2008

DOB: 23/01/1983

Outcome: 22/05/2008

Causality: Causality possible

Recovered

Information:

Reaction: **Preferred Term**

Severity

Report Description

Treatment

Dystonia

Life threatening

Dystonia reaction, tongue protrusion, airway

Benztropine

obstructions.

Dyskinesia

Life threatening

Obstructive airways disorder

Life threatening

Medicine details:

CLOPIXOL-ACUPHASE (Suspected)

Reason: Otr spec symp psychopathol nec

Injection

100 Milligram

1 time

Intramuscular

Batch:

Started: 22/05/2008

Started: 28/04/2008

Started: 28/04/2008

Stopped:

Lexapro (Suspected)

Reason: Depression

Oral

Tablet Batch: 20 Milligram

Daily

Stopped: 22/05/2008

0

ATIVAN (Other drug)

Reason: Otr spec symp psychopathol nec

Oral

Batch:

2 Milligram

Daily

Stopped:

SEROQUEL (Other drug)

Reason: Unspecified psychosis

Tablet

Tablet

300 Milligram

Daily

Oral

Batch:

Started: 18/04/2008

Stopped:

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Cases Count: 61

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 line, sturred speech

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: 61

Age:

Case Number: 242542

Hospitalisation: Required a visit to the doctor

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: 61

Age:

Case Number: 242792

Hospitalisation: Admitted to hospital

Gender: M

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

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

hospitalisation (bilateral arm to back) and reduced appetite. ??

serotonin syndrone.

fever, diarrhoea, rash,

Decreased appetite Caused or prolonged

inpatient

hospitalisation

Diarrhoea Caused or prolonged

> inpatient hospitalisation

Caused or prolonged Pyrexia

> 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

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

IRBESARTAN (Other drug) Reason:

Tablet 300 Milligram Daily Oral

Batch: Started: L TERM Stopped:

NIFEDIPINE (Other drug) Reason:

> 30 Milligram Oral Daily

Batch: Started: L TERM Stopped:

SEROQUEL (Other drug) Reason:

Tablet 25 Milligram Oral

Batch: Started: Stopped:

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Cases Count: 61

Gender: M

Case Number: 243668

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

Hospitalisation: Admitted to hospital Age:

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

hospitalisation

Drug withdrawal syndrome Caused or prolonged neonatal inpatient

hospitalisation

Feeling jittery Caused or prolonged

inpatient hospitalisation

Medicine details:

Escitalopram (Suspected) Reason : Depression

20 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 61

Case Number: 243744

Gender: M

Data Entry Date: 12/08/2008

Weight (kg): 69

Hospitalisation:

Age:

Onset Date: 15/07/2008

DOB: 31/10/1989

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hallucination

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: 61

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:

Preferred Term Severity Report Description Treatment

Hyponatraemia Caused or prolonged

inpatient hospitalisation Significant hyponatremia, hypokalemia secondary to recent commencement of escitalopram for anxiety /

depression

Escitalopram ceased; fluid restriction commenced. 3% normal saline given, carefully titrating to increase sodium levels. Mirtazapine later

commenced

Hypokalaemia Caused or prolonged

inpatient

hospitalisation

Medicine details:

Escitalopram (Suspected) Reason : Depression

Tablet 10 Milligram Daily Oral

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

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Cases Count: 61

Case Number: 244318

Gender: M

Data Entry Date: 02/09/2008

Weight (kg): 0

Hospitalisation:

Age: 59Y

Onset Date: 16/07/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Rash

Raised LFT's, swelling of ankles, rash, fever.

Ceased amlodipine,

atorvastatin, escitalopram, reduced dose paracetamol.

Hepatic function abnormal

Joint swelling

Pyrexia

Medicine details:

Lexapro (Suspected) Reason : Depression

Severity

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

Details

Batch: Started: Stopped:

16/07/2008

Laboratory Investigations:

Range Type Date Tested Result SAP = ALP16/07/2008 408 SAP = ALP76 24/06/2008 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: 61

Age:

Case Number: 244392

Gender: M

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

Onset Date : DOB : 20/12/1968

Outcome: 16/07/2008 Causality: Causality certain

Recovered

Hospitalisation: Required a visit to the doctor

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: 61

Case Number: 244490

Gender: M

Age:

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

Hospitalisation: Required a visit to the doctor

DOB: 27/04/1954 **Onset Date:**

Causality: Causality possible Outcome:

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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Cases Count: 61

Case Number: 245232

Gender: F

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

Hospitalisation: Admitted to hospital Age:

Onset Date : DOB : 11/03/1933

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Fall Caused or prolonged ? Delusional disorder, Seroquel ceased. Medication

inpatient Seroquel ceased because changed to risperidone 0.5mg hospitalisation of fall and postural daily.

hypotention.

Neuroleptic malignant Caused or prolonged syndrome inpatient

hospitalisation

Orthostatic hypotension Caused or prolonged

inpatient hospitalisation

Medicine details :

ARICEPT (Interaction) Reason :

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: 61

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: 61

Aspalgin - moderately effective.

Panadeine forte - more useful

but cannot drive or care for

children while so drowsy. Nil

treatment for rash - not itchy.

Case Number : 245363

Gender: F

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 2Disprin Max - ineffective.

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

Therapy regimen changed Incapacity/disability

Medicine details:

Lexapro (Suspected) Reason: Depression

Tablet 20 Milligram Daily Oral

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Cases Count: 61

Gender: F

Case Number: 245389

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

Weight (kg).

 Hospitalisation :
 Age :

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

Outcome: Causality: Causality possible

Not yet recovered

Information:

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т.				
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Preferred Term Severity Report Description Treatment

Headache Caused or prolonged Constant headache,

inpatient

hospitalisation

nausea, increased on confusion.

Confusional state Caused or prolonged

inpatient

hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Medicine details:

NEXIUM (Other drug)

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:

Batch: Started: Stopped:

PRAVACHOL (Other drug) Reason :

Started:

Batch: Started: Stopped:

Reason:

Reason:

Stopped:

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Cases Count: 61

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:

Capsule

Batch:

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 inpatient increased hospitalisation Caused or prolonged Cardiovascular insufficiency inpatient hospitalisation Grand mal convulsion Caused or prolonged inpatient hospitalisation Pyrexia Caused or prolonged inpatient hospitalisation

CLOZAPINE (Suspected) Reason: Started: Stopped: Batch: Lexapro (Suspected) Reason: Depression Oral 10 Milligram Daily Started: 30/03/2008 Batch: Stopped: **PERIACTIN (Suspected)** Reason: 4 Milligram Oral Daily Batch: Started: Stopped: Zeldox (Suspected) Reason: Unspecified schizophrenia

Daily

Oral

0

Stopped:

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160 Milligram

Started: 17/07/2008

Laboratory Investigations :						
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: 61

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 Ceased amisulpride and

mobility, fever. 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

Batch: Started: Stopped:

Escitalopram (Suspected) Reason :

20 Milligram Daily

Batch: Started: Stopped:

QUETIAPINE (Suspected) Reason :

400 Milligram Daily

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason :

0.5 Milligram Daily

Batch: Started: Stopped:

SIMVASTATIN (Suspected) Reason :

40 Milligram Daily

Batch: **Started**: **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: 61

Case Number: 246203 Gender: F

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

Hospitalisation : Age :

Onset Date : DOB : 17/02/1934

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Tremor	Severity	erity Report Description Tremor		ion Treatment	
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) Reason :					
		5 Milligram	As necessary		
Batch :	Started :		;	Stopped :	
ATACAND (Other drug) Reason :					
		16 Milligram	Daily	Oral	
Batch :	Started :		;	Stopped:	
LIPITOR (Other drug) Reason :					
		20 Milligram	Daily	Oral	
Batch :	Started :		;	Stopped :	
Norspan 5 (Other drug) Reason :					
		5 Milligram	Weekly	Transdermal	
Batch :	Started :		;	Stopped :	
PARIET (Other drug) Reason :					
		20 Milligram	Daily	Oral	
Batch :	Started :		;	Stopped :	

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Cases Count: 61

Case Number: 246314

Gender: M

Data Entry Date: 17/11/2008

Weight (kg): 0

Hospitalisation:

Age: 41Y

Onset Date: 05/09/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

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

0.5 Milligram

Oral

Tablet

Batch:

Started: 15/08/2008

Daily

Stopped: 05/09/2008

Escitalopram (Suspected)

Reason: Depression

m Daily

10 Milligram **Started**: 31/08/2008

Stopped: 05/09/2008

NEXIUM (Suspected)

Batch:

Reason:

Batch :

40 Milligram

Started:

L TERM

Daily

Stopped: 05/09/2008

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Cases Count: 61

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: LTERM Stopped:

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Cases Count: 61

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 Akathisia, anxiety and

insomnia.

Anxiety

Insomnia

Medicine details:

Lexapro (Suspected) Reason : Depression

10 Milligram Daily

Batch: **Started**: 23/10/2008 **Stopped**: 28/10/2008

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Cases Count: 61

Case Number: 246917

Gender: F

Data Entry Date: 08/12/2008

Weight (kg): 0

Hospital is at ion:

Age:

Onset Date :

DOB: 22/07/1984

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Lethargy

Incapacity/disability

generalized lethargy with use of lexapro

cessation of medication and changed to sertraline 25 mg

daily

Medicine details:

Lexapro (Suspected)

Reason:

10 Milligram

1 time

Oral

Batch:

Started: 08/05/2007

Stopped: 08/12/2008

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Cases Count: 61

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 :

Tablet 20 Milligram Daily Oral

Batch: FA01323 11/2010 Started: Stopped:

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Cases Count: 61

Gender: F

Age:

Case Number: 247306

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

Hospitalisation :

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: 61

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

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Cases Count: 61

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

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: 61

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:

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.

Pharyngeal oedema Caused or prolonged

inpatient

hospitalisation

Medicine details:

Lexapro (Suspected) Reason: Depression

10 Milligram **Tablet** 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: 61

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

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

AVAPRO (Other drug) Reason: Essential benign hypertension

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: Escitalopram,

Lexapro, Esipram

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