

Cases Count: 35

Age:

Case Number: 232889

Gender: F

Data Entry Date: 03/09/2007 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor

Onset Date : DOB : 28/03/1971

Outcome: Causality: Causality possible

Not yet recovered

Information: +ve dechallenge

Reaction:

Preferred Term Severity Report Description Treatment

Ageusia Patient taking Lovan for 5 Changed medication

years. Lost sense of taste

and smell.

Anosmia

Medicine details:

LOVAN (Suspected) Reason : Depression

1 Dose Unspec Daily

Batch: Started: Stopped:

PUTRAN02 Page 1 of 38



Cases Count: 35

Case Number: 232956

Gender: F

Data Entry Date: 04/09/2007 **Weight (kg)**: 0

Hospitalisation: Age: 18Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion A patient experienced a seizure while taking Lovan

Medicine details:

LOVAN (Suspected) Reason :

Oral

Batch: Started: Stopped:

PUTRAN02 Page 2 of 38



Cases Count: 35

Case Number : 232980

Gender: F

Data Entry Date: 04/09/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 30/07/2007

DOB: 01/10/1033

Outcome: 02/08/2007

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description

Treatment

Ceased Fluoxetine, phenytoin.

Tremor Life threatening

After increasing the dosage of Fluoxetine to 60mg daily the patient experienced tremors, was sweaty, feverish, had

mental changes, was rigid and had a seizure.

Convulsion

Hyperhidrosis

Hyperreflexia

Hypertonia

Hyponatraemia

Mental impairment

Life threatening

Life threatening

Life threatening

Life threatening

Life threatening

Pyrexia Life threatening

Therapy regimen changed Life threatening

<u>-</u>

Medicine details:

PROZAC (Suspected) Reason :

Tablet 60 Milligram Daily Oral

Batch: Started: Stopped: 0

ASASANTIN SR (Other drug) Reason :

Tablet 200 Milligram Oral

Batch: Started: Stopped:

ATACAND (Other drug) Reason :

Tablet 4 Milligram Oral

Batch: Started: Stopped:

Simvar (Other drug) Reason :

Tablet 40 Milligram Oral

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Sodium Sodium 115

PUTRAN02 Page 3 of 38



Cases Count: 35

Case Number: 233111

Gender: U

Data Entry Date: 06/09/2007

Weight (kg): 0

Hospitalisation: Hospitalisation prolonged

Age: 14D

Onset Date:

DOB:

Outcome: 23/08/2007

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Congenital anomaly

Congenital anomaly /

Exposure during mother's

undergoing special diagnostic

birth defect

Pregnancy; outcome for baby is an undetermined syndrome with abnormal

tests

facial structure.

Dysmorphism

Congenital anomaly /

birth defect

Medicine details:

LOVAN (Suspected)

Reason:

Batch:

Started: 01/08/2006

Stopped: 01/08/2007

PUTRAN02 Page 4 of 38



Cases Count: 35

Case Number: 233350

Gender: M

Data Entry Date: 13/09/2007

Weight (kg): 0

Hospitalisation:

Age: 9Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Self injurious behaviour

has grabbed a blunt knife on 5 occasions and

attempted to cut himself he talks often of wanting to

die

Medicine details:

LOVAN (Suspected)

Suicidal ideation

Reason:

1 time

Oral

Batch :

Started: 15/09/2006

Stopped:

0

0

RISPERIDONE (Suspected)

Reason :

20 Milligram

Oral

Batch:

Started :

Stopped :

PUTRAN02 Page 5 of 38



Cases Count: 35

Gender: F

Case Number: 233387

Data Entry Date: 14/09/2007 **Weight (kg)**: 0

Hospitalisation: Age: 74Y

Onset Date: 31/08/2007 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation	The son of a 74 year old female patient reported that his mother had been experiencing worsening of anxiety and mild confusion with Lovan. On 27 August 2007 the dosage was decreased however the symptoms continued to worsen and the patient became restless. On 31 August 2007 the patient woke at 3 am feeling dizzy, unsteady and nauseous. The patient's weight has decreased from 60 to 49kgs. Low potassium levels.	Taken off Lovan. Given IV potassium. Discontinued Natrilix and Norvasc.
Agitation	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Hypokalaemia	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Restlessness	Caused or prolonged inpatient hospitalisation		
Weight decreased	Caused or prolonged inpatient hospitalisation		

PUTRAN02 Page 6 of 38

Medicine details :				
LOVAN (Suspected)		Reason: Anxiety n	eurosis	
	40 Milligra	m Daily	Oral	
Batch :	Started : 01/06/2007		Stopped : 31/08/2007	0
NATRILIX (Suspected)		Reason :		
Batch :	Started :		Stopped :	0
NORVASC (Suspected)		Reason :		
Batch :	Started :		Stopped :	0
ALODORM (Other drug)		Reason :		
Batch :	Started :		Stopped :	
CARDIPRIN 100 (Other drug)		Reason :		
Batch :	Started :		Stopped :	
INDERAL (Other drug)		Reason :		
Batch :	Started :		Stopped :	
LUMIN (Other drug)		Reason :		
Batch :	Started :		Stopped :	
STEMETIL (Other drug)		Reason :		
Batch :	Started :		Stopped :	
THYROXINE SODIUM (Other drug)		Reason :		
Batch :	Started :		Stopped :	
XANAX (Other drug)		Reason :		
Batch :	Started :		Stopped :	
ZOCOR (Other drug)		Reason :		
Batch :	Started :		Stopped :	

PUTRAN02 Page 7 of 38



Cases Count: 35

Case Number: 233720

Gender: M

Data Entry Date: 24/09/2007

Weight (kg): 0

Hospitalisation:

Age: 81Y

Onset Date:

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Hyponatraemia

Treatment

Hyponatraemia

Caused or prolonged

inpatient

hospitalisation

Gait disturbance

Caused or prolonged

inpatient hospitalisation

Medicine details:

LOVAN (Suspected)

Reason:

Batch:

Started:

Stopped:

PUTRAN02 Page 8 of 38



Cases Count: 35

Case Number: 234719

Gender: F

Data Entry Date: 23/10/2007

Weight (kg): 70

Hospitalisation:

Age: 55Y

Onset Date: 15/08/2007

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neutropenia Neutropenia. Seroquel being reduced.

Medicine details:

PROZAC (Suspected) Reason : Depression

Tablet 40 Milligram Daily Oral

Batch: Started: 15/08/2006 Stopped:

SEROQUEL (Suspected) Reason : Depression

Tablet 200 Milligram Daily Oral

Batch: Started: 15/08/2006 Stopped:

PUTRAN02 Page 9 of 38



Onset Date:

Public Case Detail

Cases Count: 35

DOB:

Case Number: 235040

Gender: F

Data Entry Date: 05/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 45Y

Outcome: 01/11/2006 Causality: Causality possible

Death

Information: Coroner's report has been requested.

Reaction:

Preferred TermSeverityReport DescriptionTreatmentDeathDeath due to fluoxetineno information

toxicity.

Medicine details:

LOVAN (Suspected) Reason :

Tablet 80 Milligram Daily Oral

Batch: Started: 01/11/2002 Stopped:

DIAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 10 of 38



Cases Count: 35

Case Number : 236156

Gender: M

Data Entry Date: 11/12/2007

Weight (kg): 0

Hospitalisation:

Age: 49Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information: the patient's daughter is also been taking tablets from the same batch and has also

experienced a deterioration in her condition which has steadily improved since starting

a new batch (see case 236157)

Reaction:

Preferred Term

Severity

Report Description

Treatment

Drug ineffective

A patient using lovan long term received a new pack ceased, and started new batch with improvement

0

and gradually experienced a decline in mood control and lack of drug effect resulting in suicidal ideation, lack of motivation,

difficulty concentrating, headaches and nausea.

Medicine details:

LOVAN (Suspected)

Reason: Depression

Tablet

60 Milligram 1 time Oral

Batch:

Started:

L TERM

Stopped:

PUTRAN02 Page 11 of 38



Cases Count: 35

Case Number : 236157

Gender: F

Data Entry Date: 11/12/2007

Weight (kg): 0

Hospitalisation:

Age: 17Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information: the patient father has experienced the same reaction. Refer to case 236156

Reaction:

Preferred Term

Severity Report Description

Treatment

Drug ineffective

A patient using lovan for many years started a new pack of tablets and experienced a decline in mood and lack of drug effect resulting in suicidal ideation, lack of motivation, difficulty concentrating, headaches and nausea.

Medicine details:

LOVAN (Suspected)

Reason: Depression

Tablet

60 Milligram

1 time

Oral

Batch : A347210

Started :

Started:

L TERM

Stopped:

SEROQUEL (Other drug)

Reason:

Batch :

Stopped:

PUTRAN02 Page 12 of 38



Cases Count: 35

Case Number: 236641

Data Entry Date: 03/01/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date : DOB : 07/04/1938

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Oral mucosal exfoliation Desquamation of gingival Biopsy of oral condition.

labial teeth 12-11 and low

anterior region 32.

Lichenification

Medicine details:

LIPEX (Suspected) Reason :

Oral

Gender: F

Batch: Started: Stopped:

LOVAN (Suspected) Reason : Depression

Oral

Batch: Started: Stopped:

PUTRAN02 Page 13 of 38



Cases Count: 35

Case Number: 237073

Gender: M

Data Entry Date: 18/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 23Y

Onset Date: 15/01/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: Fluoxetine was continued.

Reaction:

Preferred Term Severity Report Description Treatment

Glaucoma Patient had increased Corrective treatment intraocular pressure 36 recommended was latanoprost.

intraocular pressure 36 mmHg in both eyes, which

was diagnosed as glaucoma in both eyes.

Pigment dispersion syndrome

Medicine details:

PROZAC (Suspected) Reason: Depression

20 Milligram Daily Oral

Batch: Started: L TERM Stopped: Ongoing.

Laboratory Investigations:

Type Range Date Tested Result Details

Other data 20,10 01/2008 Interocular pressure test =

36mmHg, high both eyes.

Jan 2008- opthalmic examination

revealed probable pigment dispersion

syndrome

PUTRAN02 Page 14 of 38



Cases Count: 35

Case Number : 240152

Gender: F

Data Entry Date: 18/04/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Somnambulism Severity Report Description

Treatment

Sleep walking, sleep talking, other sleep

activities.

Abnormal sleep-related event

Amnesia

Sleep talking

Medicine details:

LOVAN (Suspected)

Reason: Depression

Batch:

Started :

Stopped:

PUTRAN02 Page 15 of 38



Cases Count: 35

Gender: U

Case Number: 241703

Data Entry Date: 10/06/2008 Weight (kg): 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 21/05/2008 **DOB**: 30/11/1949

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction :					
Preferred Term	Severity	Report Descriptio	n	Treatment	
Tremor		Tremor of hands ar lightheadedness.	nd	Stop Lovan	
Dizziness					
Medicine details :					
LOVAN (Suspected)	F	Reason: Dyspnea			
	20 Milligram	Daily			
Batch :	Started : 03/04/2008	Sto	pped :	07/05/2008	

CODEINE (Other drug) Reason: Batch: Started: Stopped: COVERSYL (Other drug) Reason: Batch: Started: Stopped: **Duatrol SR (Other drug)** Reason: Batch: Started: Stopped: MAREVAN (Other drug) Reason: Batch: Started: Stopped: **NEXIUM (Other drug)**

Batch: Started: Stopped:

Reason:

PUTRAN02 Page 16 of 38



Cases Count: 35

Case Number: 241793

Gender: M

Data Entry Date: 11/06/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date:

DOB: 19/07/1960

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity **Report Description** **Treatment**

Suicidal ideation

Suicidal ideation.

Medicine details:

LOVAN (Suspected)

Reason: Depression

Oral

Batch:

Started:

Stopped:

Strattera (Suspected)

Reason: 18 Milligram

Daily

Oral

Capsule Batch:

Started:

Stopped:

0

PUTRAN02 Page 17 of 38



Cases Count: 35

Case Number: 242129

Gender: M

Data Entry Date: 20/06/2008

Weight (kg): 70

Hospitalisation:

Age:

Onset Date: 28/05/2008

DOB: 05/10/1983

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

other generic brand.

Treatment

Drug ineffective

Patient claimed that he feels the capsules are only "working in half dose" as compared to Prozac and Changed brand back to Prozac.

Therapeutic response unexpected with drug

substitution

Medicine details:

LOVAN (Suspected)

Reason: Depression

Capsule

40 Milligram

Daily

Oral

Batch:

Started: 26/05/2008

Stopped:

PUTRAN02 Page 18 of 38



Cases Count: 35

Case Number: 242169

Gender: F

Data Entry Date: 23/06/2008 **Weight (kg)**: 55

Hospitalisation: Required a visit to the doctor **Age**: 17Y

Onset Date: 29/03/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash Rash with itchy hives, Telfast, phenergan

facial oedema, throat swelling with wheeze.

Face oedema

Pharyngeal oedema

Pruritus
Urticaria
Wheezing

Medicine details:

LOVAN (Suspected) Reason : Depression

20 Milligram Daily Oral

Batch: **Started**: 29/02/2008 **Stopped**: 30/03/2008

PUTRAN02 Page 19 of 38



Cases Count: 35

Case Number: 242510

Gender: M **Data Entry Date:** 01/07/2008

Hospitalisation: Age: 99u

Onset Date: DOB:

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Report Description Severity **Treatment**

Caused or prolonged Haematuria

inpatient hospitalisation

Medicine details:

LOVAN (Suspected) Reason:

Oral

Weight (kg): 0

Started: Batch: Stopped:

PUTRAN02 Page 20 of 38



Cases Count: 35

Case Number: 242644 Gender: M

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

Hospitalisation: Age: 60Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Bradycardia		Patient presented with unexplained bradycardia.	Taken off all three medications.

			похранто	a Braayearaia.	
Medicine detail	s:				
ANTABUSE (Suspected)		Re	ason:		
Batch :	Started :			Stopped :	
NALTREXONE HYDROCHLORIDE (Suspected)		Re	ason :		
		50 Milligram	Daily		
Batch :	Started :			Stopped :	
PROZAC (Suspected)		Re	ason :		
Batch :	Started :			Stopped :	

PUTRAN02 Page 21 of 38



Cases Count: 35

Case Number : 242855

Gender: F

Data Entry Date: 11/07/2008 **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

Suicidal ideation Patient experienced Fluoxetine discontinued.

suicidal ideation.

Medicine details:

PROZAC (Suspected) Reason : Depression

Tablet Oral

Batch: Started: Stopped:

PUTRAN02 Page 22 of 38



Cases Count: 35

Case Number: 243301

Gender: F

Data Entry Date: 29/07/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

DOB:

Onset Date: Outcome:

Causality: Causality possible

Unknown

Information: Patient has had approximately 4 miscarriages, all in the first trimester.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Abortion spontaneous

Multiple miscarriages while

taking Lovan and

olanzapine.

Drug exposure during

pregnancy

Medicine details:

LOVAN (Suspected)

Reason: Depression

20 Milligram

5 Milligram

Daily

Oral

0

Batch:

Started: 15/09/1996

Stopped: 15/07/2008

ZYPREXA (Suspected)

Reason:

Daily

Oral Stopped:

0

Tablet

Batch:

Started: 15/11/2004

PUTRAN02 Page 23 of 38



Cases Count: 35

Gender: F

Case Number: 243813

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

Hospitalisation: Admitted to hospital **Age**: 71Y

Onset Date: 15/03/2008 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Possible interaction between fluoxetine and risperidone, increase the risperidone!?

Interaction description in MIMS

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Caused or prolonged

inpatient hospitalisation

Patient was hospitalised in mid-June 2008 for management of "convulsions". Jerky, involuntary movements, including arms flung in the air, grunts. She was hospitalised for two weeks where they reduced the Epilim to zero and ceased.

where they reduced the Epilim to zero and ceased the fluoxetine and jerky movements gradually faded away. They gradually reintroduced the

Epilim and the jerky movements did not return.

Medicine details:

LOVAN (Interaction) Reason :

40 Milligram Daily

Batch: Started: Stopped: 15/06/2008

RISPERDAL (Interaction) Reason :

2.5 Milligram Daily

Batch: Started: Stopped:

ALPHA-TOCOPHEROL (Other drug) Reason :

1 Gram Daily

Batch: Started: Stopped:

ARICEPT (Other drug) Reason :

10 Milligram Daily

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

200 Milligram Daily

Batch: Started: Stopped:

LIPITOR (Other drug) Reason :

40 Milligram Daily

Batch: Started: Stopped:

PUTRAN02 Page 24 of 38

Medicine details :					
NEXIUM (Other drug)		Rea	ason :		
		40 Milligram	Daily		
Batch :	Started :			Stopped :	

PUTRAN02 Page 25 of 38



Cases Count: 35

Case N	Number :	244006	Gender :	F

Data Entry Date: 21/08/2008 **Weight (kg)**: 0

Hospitalisation: Age: 60Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information:

Preferred Term	Severity	Report Description	Treatmen

Delirium Delirious and sweating.

Hyperhidrosis

Reaction:

Medicine details : Cymbalta (Suspected) Reason : Depression

20.1

Capsule 60 Milligram 1 time Oral

Batch: Started: Stopped:

LOVAN (Suspected) Reason : Depression

Batch: Started: Stopped:

AMITRIPTYLINE HYDROCHLORIDE (Other drug) Reason : Depression

Batch: Started: Stopped:

PUTRAN02 Page 26 of 38



Cases Count: 35

Case Number: 244097

Gender: F **Data Entry Date: 22/08/2008** Weight (kg): 0

Age: 68Y Hospitalisation: Required a visit to the doctor

Onset Date: 20/06/2008 DOB:

Outcome: 01/08/2008 Causality: Causality possible

Recovered

Possible increase in alprazolam levels due to fluconazole, fluoxetine and verapamil all Information:

increasing each other via CYP450 interaction, then increasing alprazolam. Possible QT

prolongation as well.

Reaction:

Preferred Term Severity **Report Description Treatment**

Dizziness Patient has been on Xanax Alprazolam reduced to 0.5mg for quite a while, and has bd, then 0.5mg mane.

been on doses as high as 1mg tds, but developed considerable tolerance to the drowsiness. A special immunologist diagnosed her "intestinal candidiasis" and prescribed the fluconazole, after

commencing it her bowel

symptoms have improvesd, however she has become really, really dizzy. In the past week she has had about seven falls just walking around the house. On the day of her call she had fallen over when she turned around "too fast" after closing the fridge door. she said "I am covered in bruises" and feels quite fragile and unsteady on her feet.

Syncope

Medicine details:

DIFLUCAN (Suspected) Reason: Moniliasis

100 Milligram

Batch: Started: 14/06/2008 Stopped:

ISOPTIN (Suspected) Reason:

> 90 Milligram Daily

Batch: Started : Stopped:

LOVAN (Suspected) Reason:

> 30 Milligram Daily

Started: Batch: Stopped:

PUTRAN02 Page 27 of 38

Medicine details:					
XANAX (Suspected)		Rea	ason :		
		0.2 Milligram	Daily		
Batch :	Started :			Stopped :	
CALTRATE (Other drug)		Rea	ason :		_
		600 Milligram	Daily		
Batch :	Started :			Stopped :	
Ostevit D (Other drug)		Rea	ason :		_
		2 Dose Unspe	c Daily		
Batch :	Started :			Stopped :	
PEPCIDINE (Other drug)		Rea	ason :		_
		40 Milligram	Daily		
Batch :	Started :			Stopped :	

PUTRAN02 Page 28 of 38



Cases Count: 35

Case Number: 244230

Gender: M

Data Entry Date: 28/08/2008

Weight (kg): 0

Hospitalisation:

Age: 45Y

DOB:

Onset Date: 15/08/2008 Outcome: 05/08/2008

Information:

Causality: Causality possible

Death

Reaction:

Preferred Term Severity **Report Description Treatment**

Completed suicide Death Completed suicide:the

subject had a medical history of depression, he had been on citalopram for

4 months with no

improvement He was then switched to Lovan 20 mg day. The patient lives with his mother and she was away on holiday when he

committed suicide.

Medicine details:

LOVAN (Suspected) Reason: Depression

> 20 Milligram Daily

Batch: Started: 08/08/2008 Stopped: 0

CITALOPRAM HYDROBROMIDE (Other drug) Reason: Depression

Batch: Started: Stopped: 0

PUTRAN02 Page 29 of 38



Hospitalisation:

Public Case Detail

Cases Count: 35

Case Number : 244239

Gender: M

Data Entry Date: 29/08/2008 **Weight (kg)**: 30

Age:

Details

Onset Date :

DOB: 19/11/1996

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:

Type

Preferred Term Severity Report Description Treatment

Hepatic function abnormal Raised LFT's. Returned to Ceased Lovan

normal after ceasing

Lovan.

Result

Medicine details:

LOVAN (Suspected) Reason : Depression

20 Milligram Daily

Batch: **Stopped**: 13/06/2008

Date Tested

Laboratory Investigations:

Range

Bilirubin 13/06/2008 23 umol/L (< 20)

Bilirubin 11/07/2008 9 umol/L (< 20) SAP = ALP 13/06/2008 412 U/L (54 - 369)

SAP = ALP 11/07/2008 174 U/L (54 - 369)

Other data 13/06/2008 236 U/L (<22) Gamma-GT
Other data 11/07/2008 21 U/L (<22) Gamma-GT

 Other data
 13/06/2008
 985 U/L (5 - 30)
 Alanine Transaminase

 Other data
 11/07/2008
 75 U/L (5 - 30)
 Alanine Transaminase

 Other data
 13/06/2008
 262 U/L (<38)</td>
 Aspartate Transaminase

Other data 11/07/2008 52 U/L (< 38) Aspartate Transaminase

PUTRAN02 Page 30 of 38



Cases Count: 35

Case Number : 244322

Gender: F

Data Entry Date: 02/09/2008

Weight (kg): 0 **Age:** 35Y

Hospitalisation:

Onset Date: 15/08/2008 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depression Relapse of depression.

Medicine details:

ZACTIN (Suspected) Reason : Depression

Capsule 40 Milligram Daily Oral

Batch: 7104A Started: Stopped:

PUTRAN02 Page 31 of 38



Cases Count: 35

Gender: F

Case Number : 245139

Data Entry Date: 03/10/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 06/11/2003

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Autism

Preferred Term Severity Report Description Treatment

Mother received fluoxetine (Prozac) orally for the treatment of depression, Prozac was taken during all three trimesters and whilst breast-feeding. It was unknown if the mother continued on fluoxetine. On an unspecified date the mother delivered a female infant, the APGAR scores were not reported. The infant was diagnosed with autism at the age of three

years.

Drug exposure during

pregnancy

Drug exposure via breast milk

Medicine details:

PROZAC (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 32 of 38



Hospitalisation:

Public Case Detail

Cases Count: 35

Case Number: 245178

Gender: F

Data Entry Date: 07/10/2008 Weight (kg): 0

Age: 25Y

Outcome:

Onset Date: 28/07/2008

DOB:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Somnolence Felt drowsy, went to sleep Oxazepam

> and when she woke "everything was hurting", severe joint pain, aching all over - shoulders, back, arms and legs. She also had "lockjaw" and was grinding her teeth - for several hours without

abating.

Arthralgia

Bruxism

Myalgia

Trismus

Medicine details:

Cymbalta (Interaction) Reason: Depression

Capsule 1 time 60 Milligram Oral

Started: 28/07/2008 Stopped: 28/07/2008 0 Batch:

PROZAC (Interaction) Reason: Depression

> 20 Milligram Daily

Batch: Started: Stopped: 24/07/2008

PUTRAN02 Page 33 of 38



Cases Count: 35

Case Number: 246290

Gender: F

Data Entry Date: 17/11/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 15/10/2008 DOB: 12/05/1977

Outcome: 06/10/2008 Causality: Causality possible

Recovered

Information: Previous Avanza induced "dream-like" state and Lexapro caused "anxiety attacks".

Reaction:

Preferred Term Severity Report Description Treatment

Monoplegia Paralysis of right arm Cessation of drug by patient

(transient), blurred vision. 05/10/08.

Vision blurred

Medicine details:

LOVAN (Suspected) Reason : Depression

20 Milligram Daily

Batch: **Started**: 03/10/2008 **Stopped**: 09/10/2008

Yaz (Other drug) Reason : Contraception

Pill 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 34 of 38



Cases Count: 35

Case Number: 246724

Gender: M

Data Entry Date: 01/12/2008

Weight (kg): 0

Hospitalisation:

Age: 40Y

Onset Date: 20/11/2008

DOB:

Outcome: 28/11/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description Treatment

Panic attack

Caused or prolonged

Panic attacks, swollen glands, fever, itchy hives

inpatient hospitalisation

around stomach, couldn't

c l

sleep.

Insomnia

Caused or prolonged

inpatient

hospitalisation

Lymphadenopathy

Caused or prolonged

inpatient

hospitalisation

Pruritus

Caused or prolonged

inpatient

hospitalisation

Pyrexia

Caused or prolonged

inpatient

hospitalisation

Urticaria

Caused or prolonged

inpatient

hospitalisation

Medicine details:

LOVAN (Suspected)

Reason: Anxiety neurosis

Tablet

10 Milligram

Daily

Oral

Oral

Batch :

Started: 18/11/2008

Stopped: 20/11/2008

LOVAN (Suspected)

Reason: Anxiety neurosis

Tablet

20 Milligram

1 time

Batch:

Started: 20/11/2008

Stopped: 27/11/2008

PUTRAN02 Page 35 of 38



Cases Count: 35

Case Number: 246737

Gender: F

Data Entry Date: 02/12/2008 **Weight (kg)**: 45

Hospitalisation : Age :

Onset Date: 25/10/2008 **DOB**: 09/12/1990

Outcome: Causality: Causality possible

Not yet recovered

Information: No alcohol, no family history, agitation, confused, aggressive.

Reaction:

Preferred Term Severity Report Description Treatment

Paranoia 1-2 week history of feeling Given rispersidone, diazapam.

down, started Lovan loud disruptive paranoid, combustible assaulted father, no issues prior to 1

month ago.

Aggression

Physical assault

Medicine details:

LOVAN (Suspected) Reason : Depression

20 Milligram Daily Oral

Batch: Started: Stopped:

XANAX (Other drug) Reason :

500 Microgram

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Positive drug screen.

PUTRAN02 Page 36 of 38



Cases Count: 35

Case Number: 246820

Gender: M

Data Entry Date: 04/12/2008

Weight (kg): 0

Hospitalisation:

Age: 35Y

Onset Date: 27/11/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Depression

Changed from Capsules to Tablets and became depressed, nauseous,

tired, dizzy.

Dizziness

Fatigue

Nausea

Medicine details:

LOVAN (Suspected)

Batch: 8442A

Reason: Depression

Tablet

20 Milligram

Oral

0

Daily

Started: 26/11/2008

Stopped: 03/12/2008

PUTRAN02

Page 37 of 38



Cases Count: 35

Case Number: 246879

Gender: M

Data Entry Date: 08/12/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 16Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Convulsion

Caused or prolonged

Patient experienced

Zyprexa discontinued.

inpatient

hospitalisation

Medicine details:

LOVAN (Suspected)

Reason:

seizures.

20 Milligram

Batch :

Started :

Stopped:

Ongoing.

ZYPREXA (Suspected)

Reason :

1.3 Milligram

Batch:

Started:

Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: LOVAN, PROZAC, PROZAC LIQUID, ZACTIN, Auscap, Fluohexal, GenRx Fluoxetine

PUTRAN02 Page 38 of 38