

Cases Count: 98

Case Number: 231685

Gender: U

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

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Doctor gave sample of Zoloft to patient which reacted well to it.

Reaction:

Preferred Term Severity Report Description Treatment

Panic attack Patient experienced CM Sertraline replaced with tightening of the throat, Zoloft.

tightening of the throat, panic attack and swollen

tongue.

Therapeutic response unexpected with drug substitution

Throat tightness

Tongue oedema

Medicine details:

Chem Mart Sertraline (Suspected) Reason :

Tablet 25 Milligram Daily Oral

Batch: **Started**: 25/06/2007 **Stopped**: 08/07/2007

PUTRAN02 Page 1 of 107



Cases Count: 98

Case Number: 232006

Hospitalisation: Age: 54Y

Onset Date: 06/05/2007 DOB:

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced Serotonin Syndrome - confusion, visual hallucinations, paranoia, tremors. Three days later patient describes feeling odd, confused, thought her husband was trying to poison her.	Sertraline withheld, ceased tramodol, sertraline only restored on discharge.
Confusional state	Caused or prolonged inpatient hospitalisation		
Hallucination, visual	Caused or prolonged inpatient hospitalisation		
Paranoia	Caused or prolonged inpatient		

hospitalisation Medicine details: TRAMADOL HYDROCHLORIDE (Interaction) Reason: Synovitis, bursitis&tenosynovit Tablet 150 Milligram Daily Oral **Stopped**: 11/05/2007 Batch: Started: 04/05/2007 **ZOLOFT (Interaction)** Reason: Depression Tablet 100 Milligram Daily Oral Batch: Started: Stopped: **ASPIRIN** (Other drug) Reason: Batch: Started: Stopped: **HYDROCHLOROTHIAZIDE** (Other drug) Reason: Batch: Started: Stopped: **OESTRADIOL** (Other drug) Reason: Stopped: Batch: Started:

PUTRAN02 Page 2 of 107

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

PUTRAN02 Page 3 of 107



Cases Count: 98

Case Number : 232157

Gender: F

Data Entry Date: 17/08/2007 Weight (kg): 90
Hospitalisation:
Age:

Onset Date: 25/07/2007 DOB: 28/08/1990

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicide attempt Caused or prolonged Patient experienced four Ceased Sertraline.

inpatient increasingly severe

hospitalisation impulsive overdoses in the one month period since recommencing Sertraline.

Suicidal behaviour Caused or prolonged

inpatient

hospitalisation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason : Depression

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped: 27/07/2007

LEVLEN ED (Other drug) Reason : Contraception

Tablet 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

QVAR AUTOHALER (Other drug) Reason :

Inhalation 4 Dose Unspec Daily Inhalation

Batch: Started: L TERM Stopped:

PUTRAN02 Page 4 of 107



Cases Count: 98

Gender: F

Case Number: 232702

Data Entry Date: 29/08/2007 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 22/05/2007 **DOB**: 25/08/1958

Outcome: 28/06/2007 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Akathisia Commenced Sertraline Sertraline ceased

due to depression. Gradual onset over 2-3 weeks of classic akathisia - inner restlessness, needing to pace, interfering with sleep. Rapid cessation once Sertraline ceased. This significantly added to her anxiety and suicidal

thinking.

Anxiety

Restlessness

Suicidal ideation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 50 Milligram Daily Oral

Stopped: 21/06/2007 Started: 22/05/2007 Batch:

GLICLAZIDE (Other drug) Reason:

Batch: Started: Stopped:

METFORMIN HYDROCHLORIDE (Other drug) Reason:

Batch: Started: Stopped:

OGEN (Other drug) Reason:

Batch: Started: Stopped:

Seretide 250/50 Accuhaler (Other drug) Reason:

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason:

Started: Stopped: Batch:

PUTRAN02 Page 5 of 107

Medicine details :				
THYROXINE SODIUM (Other drug)		Reason:		
Batch :	Started :		Stopped:	

PUTRAN02 Page 6 of 107



Cases Count: 98

Case Number : 233263

Gender: M

Data Entry Date: 11/09/2007

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Report Description

Treatment

Hypomania

Medicine details:

ZOLOFT (Suspected) Reason : Depression

Severity

Oral

Batch: Started: Stopped:

PUTRAN02 Page 7 of 107



Report Description

Cases Count: 98

Gender: F

Treatment

Case Number: 233803

Data Entry Date: 26/09/2007 Weight (kg): 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 06/09/2007 **DOB**: 26/11/1929

Outcome : Causality : Causality possible

Not yet recovered

Severity

Started :

Started:

Information:

Reaction:
Preferred Term

Batch:

Batch:

PARACETAMOL (Other drug)

Hyponatraemia		Hyponatraemia. SIADH.		
Inappropriate antidiure hormone secretion	tic			
Medicine detail	s:			
SERTRALINE HYDROCHL	ORIDE (Suspected)	Reason:		
		1 Dose Unspec Daily		
Batch :	Started :		Stopped :	
AMIODARONE HYDROCHI	LORIDE (Other drug)	Reason :		
Batch :	Started :		Stopped :	
GALANTAMINE HYDROBR	ROMIDE (Other drug)	Reason :		
Batch :	Started :		Stopped :	
LOPERAMIDE HYDROCHL	ORIDE (Other drug)	Reason :		
Batch :	Started :		Stopped :	
OXYCONTIN (Other drug)		Reason :		
Batch :	Started :		Stopped :	
PANTOPRAZOLE (Other d	rug)	Reason :		

Reason:

Stopped:

Stopped:

PUTRAN02 Page 8 of 107



Cases Count: 98

Case Number: 233963

Gender: M

Data Entry Date: 03/10/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 08/11/2006

DOB: 04/08/1959

Outcome: 08/11/2006

Causality: Causality possible

Death

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Completed suicide Death Apathy

Death

Patient completed suicide.

Loss of libido Death Mood swings Death

Personality change Death Social avoidant behaviour Death

Medicine details:

STILNOX (Suspected) Reason:

Started: Batch: Stopped: 0

ZOLOFT (Suspected) Reason:

Batch: Started: 01/11/2006 0 **Stopped**: 08/11/2006

PUTRAN02 Page 9 of 107



Cases Count: 98

Case Number: 234447

Gender: F

Data Entry Date: 16/10/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 08/02/1971

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentLoss of libidoIncapacity/disabilityLoss of libidoreassurance

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason :

Capsule 150 Milligram 1 time Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 10 of 107



Cases Count: 98

Case Number: 234493

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

Hospitalisation: Age: 64Y

Onset Date: 24/09/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vomiting Patient experienced vomiting and loss of

appetite.

Anorexia

Medicine details: **ZOLOFT (Suspected)** Reason: Depression Tablet 25 Milligram Daily Oral Batch: Started: 24/09/2007 Stopped: **ASPIRIN** (Other drug) Reason: Batch: Started: L TERM Stopped: LIPITOR (Other drug) Reason: Othr&unspec metabolic diseases Batch: Started: L TERM Stopped: 0 LOSEC (Other drug) Reason: Batch: Started: L TERM Stopped: **METFORMIN HYDROCHLORIDE (Other drug)** Reason: Diabetes mellitus L TERM Batch: Started: Stopped: 0 TRITACE (Other drug) Reason: Essential benign hypertension L TERM Batch: Started: Stopped: ZANIDIP (Other drug) Reason: L TERM Batch: Started: Stopped:

PUTRAN02 Page 11 of 107



Cases Count: 98

Case Number: 234577

Gender: F

Data Entry Date: 15/10/2007 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 10/09/2007 DOB: 01/12/1924

Outcome: 24/09/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dysgeusia Presented with bad taste in Went back on Zoloft.

her mouth. Began when Zoloft was substituted by

pharmacy.

Therapeutic response unexpected with drug

substitution

Medicine details:

Setrona (Suspected) Reason : Depression

Tablet 50 Milligram Daily Oral

Batch: **Started**: 10/09/2007 **Stopped**: 17/09/2007

PUTRAN02 Page 12 of 107



Cases Count: 98

Case Number: 234618

Gender: F

Data Entry Date: 19/10/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 16Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

K	е	a	C	τı	O	1	ē

Reaction.			
Preferred Term	Severity	Report Description	Treatment
Aggression	Life threatening	Prescribed Zoloft as part of treatment of polycystic ovarian syndrome. Became violent aggressive, suicidal, personality change, depressed mood within days of starting Zoloft.	Admitted to mental health facility. Ceased zoloft and given fluoxetine and quetiapine.
Suicide attempt	Life threatening	the patient made several suicide attempts, including poisoning herself, drug overdose, cutting wrists	
Aggression	Life threatening		
Agitation	Life threatening		
Depressed mood	Life threatening		
Personality change	Life threatening		
Suicidal behaviour	Life threatening		

Medicine details:

ZOLOFT (Suspected) Reason: Otr&unspec ovarian dysfunction

1 Dose Unspec Daily

Batch: Started: Stopped:

PUTRAN02 Page 13 of 107



Cases Count: 98

Case Number: 234623

Data Entry Date: 22/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information: The patient had used Zoloft 7 years prior for 4 weeks without problems.

Reaction :				
Preferred Term	Severity	Report Description	Treatment	
Paranoia				
Modicino dotaile				

Medicine details: **ZOLOFT (Suspected)** Reason: 50 Milligram Daily Oral Batch: Started: Stopped: 0 **AURORIX (Other drug)** Reason: Oral Stopped: Batch: Started:

PUTRAN02 Page 14 of 107



Cases Count: 98

Case Number: 234777

Gender: M

Data Entry Date: 25/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 80Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Patient is a retired cardiologist. Has been taking warfarin for 10 years. His INR is within

the normal range.

Reaction:

Preferred Term Severity Report Description Treatment

Blood urine present

Increased tendency to bruise

Medicine details:

WARFARIN SODIUM (Suspected) Reason :

Oral

Batch: Started: L TERM Stopped: 0

ZOLOFT (Suspected) Reason :

50 Milligram Oral

Batch: Started: Stopped: ongoing

PUTRAN02 Page 15 of 107



Cases Count: 98

Gender: F

Case Number: 235253

Weight (kg): 0 **Data Entry Date:** 14/11/2007

Hospitalisation: Age: 39Y

DOB: Onset Date: 10/09/2003

Causality: Causality possible Outcome:

Not yet recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	'Seizures' - Serotonin syndrome, persistent right side weakness. Much twitching. Loss of taste. Diahrroea, headaches, malaise, leg cramps, clammy and sweaty prior to admission.	
Ageusia	Caused or prolonged inpatient hospitalisation		
Cold sweat	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		
Hemiparesis	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		
Muscle spasms	Caused or prolonged inpatient hospitalisation		
Muscle twitching	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

PUTRAN02 Page 16 of 107 **Medicine details:**

TRAMAL (Interaction) Reason : Pain

200 Milligram Daily

Batch: **Started**: 07/08/2003 L TERM **Stopped**: 10/09/2003 0

ZOLOFT (Interaction) Reason : Depression

150 Milligram Daily

Batch: Started: 07/08/2003 L TERM Stopped:

PUTRAN02 Page 17 of 107



Cases Count: 98

Case Number: 235346

Gender: F

Data Entry Date: 16/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Abortion spontaneous

Medicine details:

ZOLOFT (Suspected) Reason :

Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 18 of 107



Cases Count: 98

Case Number: 235403

Gender: F

Data Entry Date: 19/11/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

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

Weight increased

gained 7-8 kg while taking Zoloft

Drug withdrawal syndrome

patient had gradually reduced dose and had been experiencing electric shockwaves in her head,

feeling teary

Medicine details:

ZOLOFT (Suspected)

Reason:

100 Milligram

Daily

Oral

Batch:

Started:

Stopped: 03/11/2007

PUTRAN02 Page 19 of 107



Cases Count: 98

Case Number : 235485

Gender: F

Data Entry Date: 21/11/2007 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 26/02/2007 **DOB**: 05/10/1974

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Therapy regimen changed Previously on zoloft 100mg

then increased on 4/2/07 to 150mg then on 26/2/07 decreased back to 100mg. rhythm strip from MAS

Conduction disorder rhythm strip from MAS

resports interseptal conduction defected unspecified cardiac arrhythmias Intermittent

palpitations self resolving previously since increased

dose.

Rhythm strip from MAS resports interseptal conduction defected sinus

tachycardia

Dizziness

Arrhythmia

Palpitations

Sinus tachycardia

Medicine details:

ZOLOFT (Suspected) Reason :

Tablet 150 Milligram Daily Oral

Batch: Started: 04/02/2007 Stopped:

Seretide MDI Nos (Other drug) Reason :

Inhalation

Batch: Started: Stopped:

VENTOLIN (Other drug) Reason :

Inhalation

Batch: Started: Stopped:

PUTRAN02 Page 20 of 107



Cases Count: 98

Case Number: 235527

Gender: F

Data Entry Date: 21/11/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 08/10/2007

DOB: 11/07/1980

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

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

Rash

Patient developed a rash all over her body.

Treated with antihistamines, diprosone cream and calamine

lotion.

Medicine details:

ZOLOFT (Suspected)

Reason:

Tablet

Oral

Batch:

Stopped:

Risperdal Consta (Other drug)

Reason: Unspecified schizophrenia

Injection

375 Milligram Daily

Batch:

Stopped:

Risperdal Quicklet (Other drug)

Reason: Unspecified schizophrenia Daily

Tablet

2 Milligram

Batch:

Started:

Started:

Started:

L TERM

Stopped: 09/11/2007

PUTRAN02



Cases Count: 98

Case Number: 235546

Gender: F

Data Entry Date: 22/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 35Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Self injurious behaviour cutting her wrists

Intentional overdose during this period the patient had overdosed on

numerous drugs

Suicidal ideation suicidal thoughts for the

first time in her life within a week of starting Zoloft

Akathisia

Crying

Mood swings

Panic attack

Personality change

Medicine details:

ZOLOFT (Suspected) Reason : Depression

Batch: Started: Stopped:

PUTRAN02 Page 22 of 107



Cases Count: 98

Case Number: 235763

Data Entry Date: 28/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Started:

Information:

Reaction:

Batch:

patient switching from	
	patient switching from fluoxetine to sertraline

experienced a seizure, Also ingested alcohol and took benzodiazepine nos

Stopped:

during this time

Medicine details:

ALCOHOL (Suspected)

Batch: Started: Stopped:

ZOLOFT (Suspected)

Reason:

Batch: Started: Stopped:

Reason:

PUTRAN02 Page 23 of 107



Hospitalisation:

Public Case Detail

Cases Count: 98

Case Number: 235768

Gender: M

Data Entry Date: 29/11/2007 Weight (kg): 0

Age:

Onset Date: 15/07/2007

DOB: 17/11/1981

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Drug withdrawal syndrome Treated with analgesics,

amitriptyline and nortriptyline.

with headaches, muscle tension, neck and shoulder Zoloft ceased.

pain.

Medicine details:

Drug withdrawal syndrome

ZOLOFT (Suspected) Reason: Depression

Tablet 300 Milligram Daily Oral

Stopped: 15/07/2007 Batch: Started: 15/03/2007

PUTRAN02 Page 24 of 107



Cases Count: 98

Case Number: 235842

Gender: F

Data Entry Date: 03/12/2007 **Weight (kg)**: 0

Hospitalisation: Age: 38Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urinary retention Patient experienced

urinary retention, agitation and hypertonia for 8-10

hours.

Agitation

Hypertonia

Medicine details:

TRAMADOL HYDROCHLORIDE (Interaction) Reason : Pain

4 Dose Unspec Daily Oral

Batch: **Started**: 15/05/2007 **Stopped**: 15/07/2007

ZOLOFT (Interaction) Reason : Depression

Tablet 2 Dose Unspec Daily Oral

Batch: Started: L TERM Stopped: 15/08/2007

PUTRAN02 Page 25 of 107



Cases Count: 98

Case Number: 235945

Gender: M

Data Entry Date: 05/12/2007

Weight (kg): 0

Hospitalisation:

Age: 54Y

DOB:

Outcome: 21/09/2007

Onset Date: 20/09/2007

Causality: Causality possible

Death

Information:

Reaction: **Preferred Term**

Severity

Report Description

Treatment

Nausea

Death

Hepatic failure. Sertraline started on 13/9/07. Unwell Sertraline ceased.

and nauseated immediately post.

Hepatic failure

Death

Liver function test abnormal

Death

Malaise

Death

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

Oral

Tablet

Started: 13/09/2007

25 Milligram

5 Milligram

Daily

Stopped: 18/09/2007

FOLIC ACID (Other drug)

Batch:

Reason:

Oral

Batch:

Started: 17/08/2007

Stopped: 21/09/2007

Pemetrexed Disodium Heptahydrate (Other drug)

Reason: Suppurative hepa&liver abscess Intravenous

Injection

1 Gram

Cyclical

Batch:

Started: 31/08/2007

Stopped: 31/08/2007

Laboratory Investigations:

Type

Range

Date Tested

Result

Details

Bilirubin

20/09/2007

26

Normal on 29/08/2007.

SAP = ALP

20/09/2007

107

Normal on 29/08/2007

ALT = SGPT

20/09/2007

2483

Normal on 20/09/2007

PUTRAN02

Page 26 of 107



Cases Count: 98

Case Number: 235955

Gender: F

Data Entry Date: 05/12/2007 Weight (kg): 0

Hospitalisation : Age :

Onset Date : DOB : 11/09/1987

Outcome: 09/08/2007 Causality: Causality possible

Death

Information: Levlen-this had been prescribed elsewhere, not sure if she was still taking it.

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal behaviour Death Successful suicide attempt

(overdose of panadol and nurofen) while taking Zoloft for anxiety. Had been on Zoloft for 3 months. ? increased suicidality.

Completed suicide Death

Medicine details:

ZOLOFT (Suspected) Reason : Anxiety neurosis

Tablet 50 Milligram Daily Oral

Batch: **Started**: 02/04/2007 **Stopped**: 09/08/2007

PUTRAN02 Page 27 of 107



Cases Count: 98

Case Number: 236279

Data Entry Date: 13/12/2007 **Weight (kg)**: 55

Hospitalisation : Age :

Onset Date: 22/11/2007 **DOB**: 25/02/1975

Outcome: 28/11/2007 Causality: Causality probable

Recovered

Information: Had beenOK taking Zoloft brand for 8 months.

Reaction:

Preferred Term Severity Report Description Treatment

Therapeutic response unexpected with drug

unexpected with drug substitution

More irritable, irrational, angry, insomnia, felt very obsessional. Change in

Gender: F

behaviour noticed by self, partner and friends.

Medicine details:

Sertraline-DP 100 (Suspected) Reason :

Tablet 100 Milligram Daily Oral

Batch: **Started**: 22/11/2007 **Stopped**: 26/11/2007

PUTRAN02 Page 28 of 107



Cases Count: 98

Case Number: 236486

Gender: F

Data Entry Date: 21/12/2007

Weight (kg): 0

Hospitalisation:

Age: 36Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Postpartum haemorrhage

patient using Zoloft during

her pregnancy

experienced post partum

haemorrhage

Medicine details:

ZOLOFT (Suspected)

Reason: Depression

150 Milligram

Daily

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 29 of 107



Cases Count: 98

Case Number : 236514

Gender: F

Data Entry Date: 24/12/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Patient also takig Herbalife Milkshake.

Reaction:

Preferred Term Severity Report Description Treatment
Serotonin syndrome Suspected serotonin

syndrome.

Medicine details: SERTRALINE HYDROCHLORIDE (Suspected) Reason: Tablet 100 Milligram Total Oral Batch: Started: Stopped: TRAMADOL HYDROCHLORIDE (Suspected) Reason: 100 Milligram Total Batch: Started: Stopped: **PANADEINE FORTE (Other drug)** Reason: Tablet 2 Dose Unspec Oral

Batch: Started: Stopped:

PARIET (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

PUTRAN02 Page 30 of 107



Cases Count: 98

Gender: F

Stopped:

Stopped:

Case Number: 236624

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

Hospitalisation: Age:

Onset Date: DOB: 16/11/1981

Outcome: Causality: Causality possible

Unknown

Information:

Batch:

Batch:

Reaction :				
Preferred Term Paranoia	Severity	Report Description increasing paranoia	Treatment	
Suicidal ideation				
Medicine details :				
ZOLOFT (Suspected)		Reason:		
	12.5 Milligr	am	Oral	

CLONAZEPAM (Other drug) Reason :

2 Milligram

Batch: Started: Stopped:

Started: 17/12/2007

Olmetec (Other drug) Reason :

40 Milligram Oral

STILNOX (Other drug) Reason :

Started:

Batch: Started: Stopped:

PUTRAN02 Page 31 of 107



Cases Count: 98

Case Number: 236715

Gender: M

Data Entry Date: 07/01/2008 Weight (kg): 62.4

Age:

Hospitalisation:

Outcome: 07/02/2007

Causality: Causality possible

DOB: 18/08/1997

Recovered

Information:

Onset Date: 05/02/2007

Reaction: **Preferred Term**

Severity

Report Description

Treatment

Rash macular

Caused or prolonged

inpatient

Reported to be drowsy at school. Eyes rolled to back of his head, had blotchy

All drugs ceased.

hospitalisation

red patches over his torso, face was 'burning', tongue was sticking out to one

side, felt 'clammy'. Was on Sertraline and ceased

abruptly.

Eye rolling

Caused or prolonged

inpatient

hospitalisation

Flushing

Caused or prolonged

inpatient

hospitalisation

Medicine details:

RISPERIDONE (Suspected)

Reason:

2 Milligram

100 Milligram

Oral

Batch:

Batch:

Started: 03/02/2007

Daily

Stopped: 06/02/2007

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

Started:

Daily

Stopped: 03/02/2007

PUTRAN02 Page 32 of 107



Cases Count: 98

Case Number: 236917

Gender: M

Data Entry Date: 14/01/2008 Weight (kg): 70

Hospitalisation: Age:

Onset Date: 14/04/2006 **DOB**: 24/06/1963

Outcome: Causality: Causality probable

Recovered

Consumer reports: For more information see: Information:

> http://users.bigpond.net.au/savio-reality/MyStory.htm These anti-depressants should be banned outright - how many more people have to die or be affected for the rest of their lives?. When will the TGA DO SOMETHING instead of blindly following the US FDA?

Reaction:

Preferred Term Severity **Report Description Treatment**

Self injurious behaviour About 4 weeks after taking Zoloft attempted self harm,

requiring mutiple hospital visits. Antidepressants were recommended by a

specialist

(Gastroentrologist)- who missed an actual diagnosis of Eosinophilic Esophagtis. nausea and headaches

Drug withdrawal syndrome

during the weaning off

process

Medicine details:

ZOLOFT (Suspected) Reason:

Capsule 50 Milligram Daily

Started: 07/03/2006 **Stopped**: 25/04/2006 Batch:

PUTRAN02 Page 33 of 107



Cases Count: 98

Case Number: 236953

Gender: F

Data Entry Date: 15/01/2008

Weight (kg): 0

Hospitalisation:

Age: 75Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: History of MI and hypertension.

Literature report: Australian Pharmacist;2008;27; pp 40-41.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Blood pressure increased

Oedema peripheral

Medicine details:

ZOLOFT (Suspected)

Reason: Depression

50 Milligram

Daily

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 34 of 107



Cases Count: 98

Case Number: 237287

Gender: M

Data Entry Date: 24/01/2008

Weight (kg): 70

Hospitalisation:

Age: 26Y

Onset Date :

DOB:

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Muscle rigidity

Dystonia, truncal rigidity,

tension headache

Dystonia

Tension headache

Medicine details:

QUETIAPINE (Suspected)

Reason:

Oral

Batch :

Started :

Stopped :

ZOLOFT (Suspected)

Reason: Depression

300 Milligram

Daily

Oral

Batch :

Started:

Stopped:

PUTRAN02 Page 35 of 107



Cases Count: 98

Case Number: 237371

Gender: F

Data Entry Date: 29/01/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 13/01/2008 **DOB**: 18/08/1971

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Dissociation " out of body experience"

Hypoaesthesia arms and face felt numb Thirst

patient had a prescription for Zoloft that she had not ever had dispensed. A year later she experienced depressed mood and took 1 tablet of zoloft and experienced dissociation,

numbness, excessive thirs

Medicine details:

ZOLOFT (Suspected) Reason:

> 50 Milligram Daily

Batch: Started: 13/01/2008 Stopped:

PUTRAN02 Page 36 of 107



Cases Count: 98

Case Number: 237374

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder psychotic episodes

Agitation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason :

Oral

Batch: Started: Stopped:

PUTRAN02 Page 37 of 107



Cases Count: 98

Case Number: 237547

Gender: F

Data Entry Date: 04/02/2008

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity **Report Description**

100 Milligram

Treatment

Drug ineffective

The patient was switched from Zoloft to GenRx sertraline and complained of lack of efficacy. She is

now back taking Zoloft and

is feeling OK.

Therapeutic response unexpected with drug

substitution

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

Daily

Oral

Batch:

Tablet

Started:

Stopped:

PUTRAN02 Page 38 of 107



Cases Count: 98

Case Number : 237739

Gender: F

Data Entry Date: 08/02/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 72Y

Onset Date: 07/02/2008

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Hyponatraemia

Preferred Term Severity **Report Description**

Treatment Normal saline

Life threatening

Patient presented with 5 days of increasing confusion and ataxia.

Started vomiting on the day prior to admission and

became verbally unresponsive at GP review. Serum sodium 107umol/I. CT of brain-NAD. A serum sodium level measure in

September 2007 was

normal

Ataxia Life threatening

Confusional state Life threatening

Unresponsive to stimuli Life threatening

Vomiting Life threatening

Medicine details:

IRBESARTAN (Suspected)

Tablet

Reason:

1 time

Tablet 150 Milligram Oral Started: 24/01/2008 Stopped: 07/02/2008 Batch:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

50 Milligram 1 time Oral

Batch: Started: 02/02/2008

Stopped: 07/02/2008

PUTRAN02 Page 39 of 107



Cases Count: 98

Gender: F

Case Number : 238228

Data Entry Date: 22/02/2008 Weight (kg): 47

Hospitalisation: Age:

Onset Date: 15/01/2008 DOB: 29/09/1976

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Caused or prolonged

inpatient hospitalisation

Went from a girl with anxiety and a little depression to a girl who could not function and could quite easily have commited suicide. This drug was given to her with very little information on these side effects and a mental health registrar told her to double the dose she was on, which in my mind would have killed her.

Depression Caused or prolonged

inpatient

hospitalisation

Suicidal ideation Caused or prolonged

inpatient hospitalisation

Medicine details:

ZOLOFT (Suspected) Reason : Anxiety neurosis

25 Milligram Daily

Batch: **Started**: 14/01/2008 **Stopped**: 21/01/2008

Seretide MDI Nos (Other drug) Reason :

1 Dose Unspec Daily Inhalation

Batch: Started: L TERM Stopped:

PUTRAN02 Page 40 of 107



Cases Count: 98

Case Number : 238508

Gender: F

Data Entry Date: 03/03/2008

Weight (kg): 0

Hospitalisation:

Age: 12Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Treatment

Unknown

Information:

Reaction:

Batch:

Deafness

Preferred Term

Severity Report Description

hearing loss

Daily

Medicine details:

ZOLOFT (Suspected)

Reason: Anxiety neurosis

150 Milligram

Started:

Stopped :

PUTRAN02 Page 41 of 107



Cases Count: 98

Case Number: 238574

Gender: M

Data Entry Date: 04/03/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Nausea

Patient was feeling nauseated and shaky.

Chemmart Sertraline discontinued. Changed back to

Zoloft.

Therapeutic response unexpected with drug

substitution Tremor

Medicine details:

Chem Mart Sertraline (Suspected)

Reason: Depression

Tablet

50 Milligram

Daily

Oral

Batch:

Started: 02/02/2008

Severity

Stopped :

0

PUTRAN02 Page 42 of 107



Cases Count: 98

Case Number : 238649

Data Entry Date: 06/03/2008 **Weight (kg)**: 70

Hospitalisation: Age:

Onset Date: 03/03/2008 DOB: 20/12/1962

Outcome: Causality: Causality possible

Recovered

Information:

Preferred Term	Severity

Reaction:

Chest pain

Palpitations Life threatening

Report Description
Patient presented with

Palpitations, chestpain, tremors, diarrhoea, hot flushes, some muscle rigidity and a generalized feeling of being unwell after staritng treatment with "Antistress-St John's Wort 3600" whilst being treated with Sertraline (Zoloft) for

major depression.

Treatment

Gender: F

Supportive care provided with all checks for chest pain origin. Patient advised not to mix other medications with antidepressants without professional advice. Also, asked to withold sertraline for 48 hours and not take The AntiStress formula again

Diarrhoea Life threatening
Hot flush Life threatening

Malaise Life threatening

Muscle rigidity Life threatening

Tremor Life threatening

Medicine details:

Nutra-Life Antistress St Johns Wort 3600 (Interaction) Reason : Depression

Life threatening

Capsule 1 Dose Unspec Daily Oral

SERTRALINE HYDROCHLORIDE (Interaction) Reason: Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 43 of 107



Cases Count: 98

Case Number: 238971

Gender: M

Data Entry Date: 14/03/2008

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age: 32Y

Onset Date: 15/12/2007

DOB:

Outcome: 15/12/2007

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Malaise

After taking Xydep 100mg, patient felt quite ill with sweating and a confused

status.

Confusional state

Hyperhidrosis

Medicine details:

Xydep (Suspected)

Reason:

100 Milligram

Daily

Oral

Batch :

Tablet

Started:

Stopped:

PUTRAN02 Page 44 of 107



Cases Count: 98

Case Number: 239022

Gender: F

Data Entry Date: 17/03/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 27/02/2008 **DOB**: 30/11/1979

Outcome: 27/02/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Grand mal convulsion Caused or prolonged Collapsed and had seizure inpatient activity while swiming in

hospitalisation hotel pool.

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason : Depression

Tablet 50 Milligram Daily Oral

Batch: **Started**: 18/02/2008 **Stopped**: 27/02/2008

NORIMIN-1 (Other drug) Reason : Contraception

Tablet 1 Dose Unspec Daily Oral

Batch: Started: 25/02/2002 Stopped:

PUTRAN02 Page 45 of 107



Cases Count: 98

Case Number: 239068

Gender: M

Data Entry Date: 18/03/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Amnesia

The patient's memory and walking ability have

diminished noticeably.

Gait disturbance

Medicine details:

NORMISON (Suspected) Reason: Specific disorders of sleep

Severity

10 Milligram

Daily

Oral

Batch:

Batch:

Started:

Started:

L TERM

L TERM

L TERM

Stopped:

PANADEINE FORTE (Suspected)

1 Gram

Reason: Daily

Stopped:

TRAMAL SR (Suspected)

Reason:

Oral

0

Oral

Tablet

Tablet

Started:

200 Milligram Daily

Stopped:

Batch:

Reason: Anxiety neurosis

XANAX (Suspected) Tablet

1 Milligram

200 Milligram

As necessary

Oral

Batch:

Started:

L TERM

Stopped:

ZOLOFT (Suspected)

Reason:

Daily

Oral

Tablet Batch:

Started:

L TERM

Stopped:

PUTRAN02 Page 46 of 107



Cases Count: 98

Gender: M

Case Number: 239108

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

Hospitalisation: Age: 49Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Caused or prolonged Agitated, shakiness, admitted to psychiatric unit and

inpatient suicidal ideation, ceased Zoloft hospitalisation nervousness

Nervousness Caused or prolonged

inpatient hospitalisation

Suicidal ideation Caused or prolonged

inpatient hospitalisation

Tremor Caused or prolonged

inpatient

hospitalisation

Medicine details:

ZOLOFT (Suspected) Reason : Depression

50 Milligram Oral

Batch: Started: Stopped:

CAMPRAL (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 47 of 107



Cases Count: 98

Case Number: 239123

Gender: F

Data Entry Date: 19/03/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity **Report Description**

150 Milligram

Treatment

Visual field defect

Had eye surgery in Nov 2006 and lost 80% of her

peripheral vision days

later.

Medicine details:

ZOLOFT (Suspected)

Reason:

Batch:

Started:

L TERM

Stopped:

PUTRAN02 Page 48 of 107



Cases Count: 98

Case Number: 239236

Gender: M

Data Entry Date: 26/03/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date:

DOB: 08/01/1993

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Accommodation disorder

Changes in vision

Medicine details:

ZOLOFT (Suspected)

Reason:

Daily

50 Milligram

Stopped:

0

Batch:

Started: 01/01/2007

PUTRAN02 Page 49 of 107



Cases Count: 98

Gender: M

Case Number: 239515

D-1- 00/04/0000 W-1-14/1-2 (

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

Age:

Onset Date: 25/03/2008 DOB: 26/08/1987

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentAbdominal painIncapacity/disabilitySevere abdominal painceased zoloft

after taking zoloft 25 mg for 4 days, then 50 mg for 4 days Settled after zoloft ceased LFT/amylase nad

Medicine details:

ZOLOFT (Suspected) Reason : Depression

25 Milligram Daily Oral

Batch: **Started**: 17/03/2008 **Stopped**: 27/03/2008

PUTRAN02 Page 50 of 107



Cases Count: 98

Case Number : 239689

Gender: M

Data Entry Date: 08/04/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Report Description

Treatment

Somnambulism

sleep walking and

assaulted his partner while

sleepwalking.

Abnormal sleep-related event

Physical assault

Reason : Anxiety neurosis

Medicine details:

ZOLOFT (Suspected)

Batch: Started: Stopped:

Severity

PUTRAN02 Page 51 of 107



Cases Count: 98

Case Number : 239702

Gender: M

Data Entry Date: 08/04/2008 **Weight (kg)**: 98

Hospitalisation: Required a visit to the doctor **Age**: 63Y

Onset Date: 26/03/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: Previous ok tolerance of Eleva and Zoloft.

Reaction:

Preferred Term Severity Report Description Treatment

Vertigo Patient experienced Ceased Sertraline. Treated with vertigo, dry mouth, Stemzine

vertigo, dry mouth, depressed affect, chest pains, blood pressure increase and nausea

Blood pressure increased

Chest pain
Depression
Dry mouth

Nausea

Medicine details:

GenRx Sertraline (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped: 28/03/2006

ASPIRIN (Other drug) Reason : Congestive heart failure

100 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

Dilzem CD (Other drug) Reason : Congestive heart failure

Tablet 180 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

LIPITOR (Other drug) Reason : Congestive heart failure

Tablet 80 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

NITROLINGUAL SPRAY (Other drug) Reason : Congestive heart failure

Spray 1 Dose Unspec As necessary

Batch: Started: L TERM Stopped: 0

PUTRAN02 Page 52 of 107



Cases Count: 98

Case Number: 239976

Gender: M

Data Entry Date: 15/04/2008

Weight (kg): 0

Hospitalisation:

Age: 79Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Stopped Zoloft

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description Treatment

Epilepsy Epilepsy, aching muscles, no energy, no control of his body and did not sleep well. Also got the shakes

and didnt feel well.

Dyskinesia

Lethargy

Malaise

Myalgia

Poor quality sleep

Tremor

Medicine details:

ZOLOFT (Suspected) Reason :

Batch: **Started**: 15/12/2007 **Stopped**: 23/03/2008

PUTRAN02 Page 53 of 107



Cases Count: 98

Case Number: 240141

Gender: U

Data Entry Date: 18/04/2008

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description Trea

Treatment

Therapeutic response unexpected with drug substitution

When patient changed from Zoloft to Sertraline Generic Health patient showed classic symptoms of Sertraline withdrawal.

Withdrawal syndrome

Medicine details:

Sertraline Generic Health (Suspected)

Reason:

Tablet

200 Milligram Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 54 of 107



Cases Count: 98

Case Number: 240259

Gender: F

Data Entry Date: 22/04/2008

Weight (kg): 0

Hospitalisation:

Age: 34Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: Family history of hypertension.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hypertension Hypertension

Started:

Medicine details:

ZOLOFT (Suspected)

Batch:

Reason:

200 Milligram

Stopped:

PUTRAN02 Page 55 of 107



Cases Count: 98

Case Number: 240478

Gender: M

Data Entry Date: 30/04/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 08/02/2008

DOB: 19/01/1965

Outcome: 20/03/2008

Causality: Causality probable

Recovered

Information:

Reaction:
Preferred Term

Severity

Report Description

Treatment

Hyperhidrosis

Excessive sweating, short

Ceased Zoloft, changed to St Johns Wort.

term memory loss,

,

forgetful, "fuzzy head".

Amnesia

Feeling abnormal

Medicine details:

ZOLOFT (Suspected)

Reason: Depression

Tablet

50 Milligram

Daily

Oral

Batch:

Started: 15/12/2006

Stopped: 17/03/2008

PUTRAN02 Page 56 of 107



Cases Count: 98

Case Number: 240660

Hospitalisation : Age :

Onset Date: 18/04/2008 DOB: 17/04/2008

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Apgar score low Baby was born with Trea APGAR score low and dose

noted to be jittery, cool to touch but temperature of

37.5c.

Treated with penicillin 60mg/kg dose IV hourly and gentamicin

3.5mg/kg IV daily.

Agitation neonatal

Pyrexia

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason :

Tablet 175 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 57 of 107



Cases Count: 98

Case Number: 240751

Gender: M

Data Entry Date: 08/05/2008

Weight (kg): 1.79

Hospitalisation:

Age:

Onset Date: 21/04/2008

DOB: 23/04/2008

Outcome:

Causality: Causality possible

Not yet recovered

Information: Secretariat comment: F/N,

Reaction:

Preferred Term

Severity

Report Description

Treatment

Withdrawal syndrome

Male injant jittery and rigid, requiring swaddling to stop it from moving about cot since birth. Suspected

withdrawal reaction to

sertraline.

Agitation neonatal

Muscle rigidity

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

Tablet

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 58 of 107



Cases Count: 98

Case Number: 240953

Gender: F

Data Entry Date: 16/05/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 20/09/1974

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Bruxism Waking up from grinding of Switched to Lexapro 10mg

teeth. tablet daily.

Medicine details:

GenRx Sertraline (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: **Started**: 25/01/2008 **Stopped**: 17/04/2008 0

ENDEP (Other drug) Reason: Specific disorders of sleep

Tablet 10 Milligram As necessary Oral

Batch: Started: 14/03/2008 Stopped:

PUTRAN02 Page 59 of 107



Cases Count: 98

Case Number: 241513

Gender: F

Data Entry Date: 03/06/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 14/03/2008 **DOB**: 10/10/1978

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vision blurred Incapacity/disability Hazy vision, apprehension.

Anxiety Incapacity/disability

Medicine details:

ZOLOFT (Suspected) Reason : Depression

50 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 60 of 107



Cases Count: 98

Case Number : 241577

Gender: F

Age:

Data Entry Date: 04/06/2008 Weight (kg): 50

Hospitalisation: Required a visit to the doctor

DOB: 07/06/1917

Onset Date: 01/02/2008

Causality: Causality probable

Recovered

Information:

Outcome: 10/04/2008

Reaction:

Confusional state

Preferred Term Severity **Report Description Treatment**

> Confusion, agitation and Sertraline withdrawn.

marked tremor. Believes

she is going "mad".

Agitation Tremor

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 50 Milligram Daily Oral

Batch: Started: 20/12/2007 Stopped: 03/04/2008 0

CANDESARTAN-HYDROCHLOROTHIAZIDE (Other drug) Reason: Essential benign hypertension

> 4 Milligram Daily

Batch: Started: L TERM Stopped:

DIAZEPAM (Other drug) Reason: Abnormal involuntary movement

Tablet 5 Milligram Daily Oral

Batch: Started: 01/02/2008 Stopped:

FRUSEMIDE (Other drug) Reason: Edema and dropsy

4 Gram Daily

Batch: Started: 15/12/2007 Stopped:

MELOXICAM (Other drug) Reason: Osteoarthritis

> 7.5 Milligram Daily Oral

Batch: Started: 15/09/2007 Stopped:

PROTRIPTYLINE HYDROCHLORIDE (Other drug) Reason: Depression

10 Milligram Oral **Tablet** Daily

Batch: Started: Stopped:

PUTRAN02 Page 61 of 107



Cases Count: 98

Case Number: 241642 Gender: F

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

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:					
Preferred Term	Severity	Severity Report Description		Treatment	
Convulsion	seizure				
Medicine details	:				
AMOXYCILLIN SODIUM (Sus	pected)	Reason :			
Batch :	Started :		Stopped :		
LAMICTAL (Suspected)		Reason :			
	20	00 Milligram Daily			
Batch :	Started :		Stopped :		
METRONIDAZOLE (Suspecte	ed)	Reason :			
Batch :	Started :		Stopped :		
ZOLOFT (Suspected)		Reason :			
	10	00 Milligram			
Batch :	Started :		Stopped :		

PUTRAN02 Page 62 of 107



Cases Count: 98

Case Number: 241783

Gender: M

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

Hospitalisation: Age:

Onset Date: 28/11/2007 **DOB**: 13/09/1920

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Salt tablets, fluid restriciton and

Inappropriate antidiuretic Sertraline caused SIADH. hormone secretion

Demecycline.

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

50 Milligram Oral Tablet Daily

Batch: Started: 22/11/2007 Stopped: 26/11/2007

ASPIRIN (Other drug) Reason:

> 100 Milligram Daily Oral

Batch: Started: Stopped:

CLOPIDOGREL (Other drug) Reason:

> 75 Milligram Oral Daily

Batch: Started: Stopped:

FRUSEMIDE (Other drug) Reason:

> 20 Milligram Oral Daily

Batch: Started: Stopped:

Metoprolol Succinate (Other drug) Reason:

> 50 Milligram Daily Oral

Batch: Started: Stopped:

PERINDOPRIL (Other drug) Reason:

> 2.5 Milligram Daily Oral

Started: 22/11/2007 Batch: Stopped: 22/11/2007

PRAVASTATIN SODIUM (Other drug) Reason:

> 40 Milligram Daily Oral

Batch: Started: Stopped:

RISPERIDONE (Other drug) Reason:

1 Milligram Wafer Daily

Batch: Started: **Stopped**: 22/11/2007

Laboratory Investigations:

Type Range Date Tested Result Details

Sodium 28/11/2007 115 04/12/2007 Sodium 126

PUTRAN02 Page 63 of 107 **Laboratory Investigations:**

Type Range Date Tested Result Details

Sodium 11/12/2007 130

PUTRAN02 Page 64 of 107



Cases Count: 98

Case Number: 242489 Gender: F

Data Entry Date: 01/07/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: DOB: 18/06/1953

Outcome: Causality: Causality possible

Unknown

Information: The patient has also received 14 ECT shock treatments and was previously taking

Prozax for her depression without a problem.

Reaction:

Preferred Term Severity Report Description Treatment

Weight increased 22 kg over 7 months

approximately

Increased appetite

Medicine details :

ZOLOFT (Suspected) Reason : Depression

Oral

Batch: Started: Stopped:

LIPITOR (Other drug) Reason :

Batch: Started: Stopped:

MICARDIS (Other drug) Reason :

Batch: Started: Stopped:

SOMAC (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 65 of 107



Cases Count: 98

Case Number: 242608

Gender: F

Data Entry Date: 03/07/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality certain

Unknown

Information: cert: rechallenge

Reaction:

Preferred Term

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

Purpura

The patient developing purpura when she knocked or bumped into things

Medicine details:

ZOLOFT (Suspected)

Reason: Depression

100 Milligram

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 66 of 107



Cases Count: 98

Case Number: 242729

Gender: F

Data Entry Date: 09/07/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 18/05/2008 DOB: 01/12/1919

Outcome: Causality: Causality possible

Unknown

Information:

Preferred Term Severity Report Description Treatment

Gastric ulcer haemorrhage Caused or prolonged Large bleeding gastric Mobic and sert

inpatient ulcer whilst on Nexium

hospitalisation 40mg daily.

Mobic and sertraline ceased. Nexium dose increased.

Medicine details:

MOBIC (Suspected) Reason :

Tablet 15 Milligram Daily Oral

Batch: Started: Stopped: 0

SERTRALINE HYDROCHLORIDE (Suspected) Reason :

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 67 of 107



Cases Count: 98

Case Number: 242845

Gender: F

Data Entry Date: 11/07/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/05/2007

DOB: 21/01/1975

Outcome:

Recovered

Causality: Causality probable

Information:

Reaction: **Preferred Term**

Report Description

Treatment

down to 25mg.

Gradually reduced the dose

Menorrhagia

By the second menstrual cycle on higher dose she

realised her periods were getting heavier, with noticeable clotting. By October 2007 she was expereincing very heavy periods (requiring tampon and pad) and continuous

spotting and bleeding in-between cycles.

Metrorrhagia

Medicine details:

ZOLOFT (Suspected) Reason: Depression

Severity

Tablet 75 Milligram Daily Oral Batch: Started: 15/05/2007 **Stopped:** 15/01/2008

Laboratory Investigations:

Type Range Date Tested Result **Details**

Haemoglobin Patient had blood tests showing low Hb

and 2 x pap smears were normal

PUTRAN02 Page 68 of 107



Cases Count: 98

Case Number: 242883

Gender: F

Data Entry Date: 14/07/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date :

DOB: 05/07/1984

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Serotonin syndrome

Caused or prolonged

Patient was hospitalised for serotonin syndrome.

Tramadol was discontinued.

inpatient hospitalisation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

1 Dose Unspec As necessary

Batch:

Started:

Stopped:

TRAMADOL HYDROCHLORIDE (Suspected)

Reason: Migraine

Batch : Started :

Stopped:

FENTANYL (Other drug)

Reason: Migraine

Patch, dermal

Batch:

12.5 Microgram Per hour

Transdermal

RISPERIDONE (Other drug)

Stopped :

Reason: Unspecified schizophrenia

Batch :

Started :

Started:

Stopped:

PUTRAN02 Page 69 of 107



Cases Count: 98

Case Number: 243316

Gender: F

Data Entry Date: 30/07/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 12/05/2008

DOB: 03/08/1925

Outcome:

Causality: Causality possible

Recovered

.....

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dizziness and chest pain. Ceased tramadol and sertraline.

Dizziness Chest pain

Medicine details:

SERTRALINE HYDROCHLORIDE (Interaction) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped: 12/05/2008

TRAMADOL HYDROCHLORIDE (Interaction) Reason : Osteoarthritis

Tablet 200 Milligram Daily Oral

Batch: **Started**: **Stopped**: 12/05/2008

METOPROLOL TARTRATE (Other drug) Reason :

50 Milligram Daily Oral

Batch: Started: Stopped:

RABEPRAZOLE SODIUM (Other drug) Reason :

20 Milligram Daily Oral

Batch: Started: Stopped:

TRAVOPROST (Other drug) Reason :

1 Dose Unspec Daily Intraocular

Batch: Started: Stopped:

PUTRAN02 Page 70 of 107



Cases Count: 98

Case Number: 243659

Gender: F

Data Entry Date: 11/08/2008

Weight (kg): 60

Hospitalisation: Admitted to hospital

Age:

5

Onset Date: 07/05/2008

DOB: 13/10/1931

Outcome :

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description

Treatment

Inappropriate antidiuretic hormone secretion

Caused or prolonged

Suspected SIADH

inpatient hospitalisation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason : Pain

Tablet 50 Milligram Daily

Batch: **Started**: 02/05/2008 **Stopped**: 07/07/2008

CALTRATE (Other drug) Reason :

600 Milligram Daily Oral

Batch: Started: Stopped:

COLOXYL WITH SENNA (Other drug) Reason :

Batch: Started: Stopped:

OXYCONTIN (Other drug) Reason :

40 Milligram Daily Oral

Batch: Started: Stopped:

PARACETAMOL (Other drug) Reason :

1 Gram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 71 of 107



Cases Count: 98

Gender: F

Case Number: 244165

Data Entry Date: 26/08/2008 Weight (kg): 60

Hospitalisation: Age:

DOB: 28/02/1935 Onset Date: 15/02/2008

Causality: Causality possible Outcome:

Recovered

Information: Background - Lewy body dementia

Reaction:

Preferred Term Severity **Report Description Treatment**

Hyponatraemia Life threatening Severe hyponatraemia

requiring ICU for 2-3 days.

Medicine details:

KARVEA (Suspected) Reason:

Started: Stopped: Batch:

ZOLOFT (Suspected) Reason:

Batch: Started: Stopped:

PUTRAN02 Page 72 of 107



Cases Count: 98

Case Number: 244226

Gender: M

Data Entry Date: 28/08/2008

Weight (kg): 27

Hospitalisation:

Age:

Onset Date: 28/06/2008

DOB: 22/12/1999

Outcome: 29/06/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Severity

Report Description

Treatment

Preferred Term Rash pruritic

itchy rash

Zoloft reduced

Medicine details:

ZOLOFT (Suspected)

Reason: Anxiety neurosis

Daily

Oral

Batch:

Started: 03/04/2008

50 Milligram

Stopped:

Contin

PUTRAN02 Page 73 of 107



Cases Count: 98

Case Number: 244381

Gender: F

Data Entry Date: 04/09/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Depression

After patient being maintained on Zoloft 100mg for depression, her

100mg for depression, her symptome reappeard when changed to Eleva within 2/12 of the change.

Therapeutic response unexpected with drug

substitution

Medicine details:

Eleva 100 (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: 26/05/2008 **Stopped:** 16/07/2008

NUROFEN PLUS (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

PHENERGAN (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 74 of 107



Cases Count: 98

Case Number: 244430

Gender: F

Data Entry Date: 08/09/2008

Weight (kg): 0

Hospitalisation:

Age: 83Y

Onset Date: 21/06/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Hyponatraemia

Hyponatraemia.

Medicine details:

ZOLOFT (Suspected)

Reason:

......

Daily

Batch :

Started :

Severity

Stopped :

PANAMAX (Other drug)

Reason:

6 Dose Unspec Daily

1 Dose Unspec Daily

50 Milligram

Batch :

Started :

Stopped:

VITAMIN D NOS (Other drug)

Reason:

Stopped :

Batch :

Started:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Sodium

21/06/2008 127

PUTRAN02 Page 75 of 107



Cases Count: 98

Case Number: 244671

Gender: F

Data Entry Date: 16/09/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Panic reaction

Caused or prolonged

inpatient

hospitalisation

felt sick, indigestion, sweating, felt like a tremor in the body and felt as if she would pass out. Fainting occurred at the hospital.ECG and blood

Dry mouth, feeling panicky,

tests were fine. Felt washed out and no

appetite.

Anorexia

Caused or prolonged

inpatient

hospitalisation

Dry mouth

Caused or prolonged

inpatient

hospitalisation

Dyspepsia

Caused or prolonged

inpatient

hospitalisation

Fatigue

Caused or prolonged

inpatient

hospitalisation

Hyperhidrosis

Caused or prolonged

inpatient

hospitalisation

Nausea

Caused or prolonged

inpatient

hospitalisation

Presyncope

Caused or prolonged

inpatient

hospitalisation

Syncope

Caused or prolonged

inpatient

hospitalisation

Tremor

Caused or prolonged

inpatient

hospitalisation

Medicine details:

ZOLOFT (Suspected)

Reason: Anxiety neurosis

25 Milligram

Started: 26/08/2008 Batch:

Stopped:

O

PUTRAN02 Page 76 of 107

Medicine detai	ls:		
DIDROCAL (Other drug)		Reason :	
Batch :	Started :		Stopped :
ETIDRONATE DISODIUM	(Other drug)	Reason :	
Batch :	Started :		Stopped:
FISH OIL NOS (Other drug	g)	Reason :	
Batch :	Started :		Stopped:
LOSEC (Other drug)		Reason :	
Batch :	Started :		Stopped:

PUTRAN02 Page 77 of 107



Cases Count: 98

Case Number: 244674 Gender: F

Data Entry Date: 17/09/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date : DOB : 10/03/1942

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Compulsive shopping Compulsive shopping, anxiety aggravated, racing

thoughts, visual disturbance, pain eye

Anxiety
Eye pain

Toobyobron

Tachyphrenia

Visual impairment

Ме	dic	ine	det	ails	•
----	-----	-----	-----	------	---

ZOLOFT (Suspected) Reason :

200 Milligram Daily

Batch: Started: Stopped:

ASPIRIN (Other drug) Reason :

Batch: Started: Stopped:

ATACAND (Other drug) Reason :

Batch: Started: Stopped:

BUSCOPAN (Other drug) Reason :

Batch: Started: Stopped:

DIAZEPAM (Other drug) Reason :

15 Milligram

Batch: Started: Stopped:

FEMARA (Other drug) Reason :

Batch: Started: Stopped:

LARGACTIL (Other drug) Reason :

25 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 78 of 107

Medicine details :							
PANADOL (Other drug)		Reason :					
Batch :	Started :		Stopped :				
RIVOTRIL (Other drug)		Reason :					
Tablet	1.5	Microgram	Oral				
Batch :	Started :		Stopped :				
SOMAC (Other drug)		Reason :					
Batch :	Started :		Stopped :				
ZOMETA (Other drug)		Reason :					
Batch :	Started :		Stopped :				

PUTRAN02 Page 79 of 107



Cases Count: 98

Case Number: 244894

Gender: F

Data Entry Date: 26/09/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 09/11/1971

Outcome: 11/09/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyspnoea Shortness of breath, chest burning, hypertension

Agitation

Chest pain
Hypertension

Throat tightness

Medicine details:

AMCAL COLD & FLU (Suspected) Reason :

Batch: Started: Stopped: 10/09/2008 0

ZOLOFT (Suspected) Reason :

100 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 80 of 107



Cases Count: 98

Case Number: 244954

Gender: F

Data Entry Date: 30/09/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 24/08/2008 DOB: 07/08/1922

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia patient was admitted in A&E with critically low

sodium serum level of 118

mmol/L.

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: **Started**: 24/08/2008 **Stopped**: 25/09/2008 0

Laboratory Investigations:

Type Range Date Tested Result Details

Sodium 25/09/2008 118mmol/L

PUTRAN02 Page 81 of 107



Cases Count: 98

Case Number : 245166

Gender: M

Data Entry Date : 03/10/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/02/2007

DOB: 24/05/1948

Outcome: 15/02/2007

Causality: Causality possible

Death

Information: Current Condition: Overweight, hypertensive, smoker.

Reaction:

Death

Preferred Term Severity

Report Description Treatment

The reporter stated that the

patient was deceased and that he had died on 15/02/2007. Follow up received from the coroner

on 04/09/2008.

Arrhythmia Death
Drug level increased Death
Hyperhidrosis Death

Medicine details:

CLOZARIL (Suspected)

Reason:

Tablet

700 Milligram

Daily

Oral

Batch :

Started: 15/02/1996

Stopped:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason:

100 Milligram

Daily

Batch :

Started:

Death

Stopped:

Laboratory Investigations:

Type

Range Date Tested Result

Details

Other data

Toxicology report revealed high level of

clozapine which was capable of being

toxic

Serum drug level

19/02/2008 0

0.5 mg/l Sertraline level

Serum drug level

19/02/2008 3.9 mg/l

Clozapine level

Serum drug level

19/02/2008 2.9 mg/l

Desmethyl clozapine

PUTRAN02 Page 82 of 107



Cases Count: 98

Case Number: 245182

Gender: F

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

Age: 16Y **Hospitalisation:**

Onset Date: DOB:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment** Patient experienced Ceased Zoloft

Suicidal behaviour Caused or prolonged inpatient

hospitalisation

excessive bleeding, psychosis, high blood pressure, severe diarrhoea, sweating, tremors, violent, aggressive and suicidal

behaviour, serotonin

syndrome.

Aggression Caused or prolonged

inpatient

hospitalisation

Haemorrhage Caused or prolonged

inpatient hospitalisation

Caused or prolonged Hypertension

> inpatient hospitalisation

Psychotic disorder Caused or prolonged

> inpatient hospitalisation

Serotonin syndrome Caused or prolonged

inpatient

hospitalisation

Medicine details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

Tablet Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 83 of 107



Cases Count: 98

Case Number : 245251

Gender: F

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

Hospitalisation: Admitted to hospital **Age**:

Onset Date : DOB : 01/11/1980

Outcome: Causality: Causality possible

Recovered

Information: Patient had no problems during delivery or after delivery. the pregnancy outcome was

2 oct 2008 by induced vaginal delivery with gestational age at birth reported as 38 weeks +1. A full term live birth resulted in a normal newborn, a male with Apgar score

at 1 min of 6, 5min 8.

Reaction:

Preferred Term Severity Report Description Treatment

Uterine disorder Caused or prolonged Developed irritable uterus,

inpatient having ongoing

hospitalisation contractions and constant

discomfort. Has not progressed to labour.

Discomfort Caused or prolonged

inpatient

hospitalisation
Caused or prolonged

Drug exposure during

pregnancy

inpatient hospitalisation

Labour onset delayed Caused or prolonged

inpatient hospitalisation

Medicine details:

ZOLOFT (Suspected) Reason: Depression

Tablet 50 Milligram Daily Oral

Batch: Started: 25/06/2008 Stopped: Contin

MAXOLON (Other drug) Reason :

Batch: Started: 15/04/2008 Stopped:

RANI 2 (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Ultrasound 23/05/2008: Ultrasound scan estimated date of confinement 18 October 2008 with normal anatomy and placenta. Not

with normal anatomy and placenta. No triple screen done as patient declined.

PUTRAN02 Page 84 of 107



Cases Count: 98

Case Number: 245348

Gender: M

Data Entry Date: 13/10/2008

Weight (kg): 78

Hospitalisation:

Age:

Onset Date: 05/08/2008

DOB: 25/03/1963

Outcome:

Causality: Causality possible

Unknown

Ulikilowi

Information:

Reaction:

Suicidal ideation

Preferred Term Severity Report Description Treatment

Life threatening

Suicidal thoughts and Recommenced Zoloft

ideation. Exhibited aggressive and impulsive behaviour, very out of

character.

Abnormal behaviour Life threatening
Aggression Life threatening
Withdrawal syndrome Life threatening

Medicine details:

ZOLOFT (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: **Started**: 30/06/2008 **Stopped**: 03/08/2008

PUTRAN02 Page 85 of 107



Cases Count: 98

Case Number: 245494

Gender: F

Age:

Data Entry Date: 16/10/2008 Weight (kg): 61

Hospitalisation: Required a visit to the doctor

Onset Date: 02/09/2008 **DOB**: 19/11/1921

Outcome: 08/09/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Swelling face Facial puffiness and Treated with promethazine 25mg/tds.

itching, maculopapular rash on chest and lower

Stopped:

abdomen.

Pruritus

Rash maculo-papular

Batch:

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 25 Milligram Daily Oral Batch: Started: 23/08/2008 Stopped: 02/09/2008

COLOXYL WITH SENNA (Other drug) Reason: Constipation

Tablet 4 Dose Unspec Daily Oral

L TERM 0 Batch: Started: Stopped:

L TERM

Reason: Myxedema

DONEPEZIL HYDROCHLORIDE (Other drug) Reason: Unspecified psychosis

Tablet 5 Milligram Daily Oral

Batch: Started: L TERM Stopped:

PERINDOPRIL (Other drug) Reason: Essential benign hypertension

2.5 Milligram Daily Oral Tablet

THYROXINE SODIUM (Other drug)

Started:

Oral **Tablet** 25 Microgram Daily

Batch: Started: L TERM Stopped:

PUTRAN02 Page 86 of 107



Cases Count: 98

Case Number: 245840

Data Entry Date: 27/10/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Mood altered Experienced change in mood and was almost

suicidal.

Suicidal ideation

Medicine details:

Champix (Suspected) Reason: Smoker

1 Milligram Daily

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 87 of 107



Cases Count: 98

Case Number: 245862

Gender: M

Data Entry Date: 27/10/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 88Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: History of stroke.

R	ea	CÍ	tic	n	•

Reaction:		
Preferred Term Dizziness	Severity Caused or prolonged inpatient hospitalisation	Report Description Experienced giddiness and double vision and his health has progressively worsened. He now has conjunctivitis, diarrhoea, swelling of ankles, weakness and a rash mainly on his arms. He has also had a CAT scan which has shown mesenteric adenopathy with associated mucosal changes in small bowel with most likely diagnosis of small bowel lymphoma. His blood tests have shown low albumin, high
Aspartate aminotransferase increased	Caused or prolonged inpatient	globulin and high aspartate aminotransferase (AST).
Asthenia	hospitalisation Caused or prolonged inpatient hospitalisation	
Conjunctivitis	Caused or prolonged inpatient hospitalisation	
Diarrhoea	Caused or prolonged inpatient hospitalisation	
Diplopia	Caused or prolonged inpatient hospitalisation	
General physical health deterioration	Caused or prolonged inpatient hospitalisation	
Globulins increased	Caused or prolonged inpatient hospitalisation	
Joint swelling	Caused or prolonged	

Treatment

PUTRAN02 Page 88 of 107

inpatient hospitalisation Reaction:

Rash

Preferred Term Severity Report Description Treatment

Lymphadenopathy Caused or prolonged

inpatient

hospitalisation

Lymphoma Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient hospitalisation

Medicine details:

ZOLOFT (Suspected) Reason :

Tablet 50 Milligram Daily Oral

Batch: **Started**: 15/11/2007 **Stopped**: 0

CARTIA (Other drug) Reason :

Batch: Started: Stopped:

COVERSYL (Other drug) Reason :

Batch: Started: Stopped: 0

Laboratory Investigations:

Type Range Date Tested Result Details

Other data

Patient has also had a computed axial

tomography (CAT) scan which has shown mesenteric adenopathy with associated mucosal changes in small bowel with most likely diagnosis of small bowel lymphoma. His blood tests have shown low albumin, high globulin and high aspartate aminotransferase (AST).

PUTRAN02 Page 89 of 107



Cases Count: 98

Case Number: 245884 Gender: F

Data Entry Date: 29/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 42Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Retinal degeneration 18 months after starting olanzapine, the patient's

retina deteriorated rapidly.

Medicine details:

ZOLOFT (Suspected) Reason :

Batch: Started: Stopped: 0

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

Tablet 15 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 90 of 107



Cases Count: 98

Case Number: 245959

Gender: F

Data Entry Date: 05/11/2008 **Weight (kg)**: 70

Hospitalisation: Required a visit to the doctor Age:

Onset Date: DOB: 20/10/1976

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash erythematous Patient had been on Zoloft 3/12, developed a low grad

rash 1/52, increase rash after going on 150mg of

Zoloft with welts,

erythematous and urticarial

rash.

Urticaria

Medicine details:

ZOLOFT (Suspected) Reason : Depression

Tablet 150 Milligram Daily Oral

Batch: **Started**: 15/05/2008 **Stopped**: 22/09/2008 0

PUTRAN02 Page 91 of 107



Cases Count: 98

Age:

Case Number: 246100

Gender: F

Data Entry Date: 10/11/2008 **Weight (kg)**: 77

Hospitalisation: Required a visit to the doctor

Onset Date: 14/09/2008 DOB: 22/02/1963

Outcome: 17/09/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentRash pruriticDeveloped rash on face,Prednisone

Developed rash on face, swelling of upper lip, red face, slight swelling of upper eyelids, itchy rash on lower left ribs, eczema like rash over right side of

body.

Lip oedema

Periorbital oedema

Therapy regimen changed

Medicine details:

ZOLOFT (Suspected) Reason : Depression

50 Milligram Daily

Batch: **Started**: 09/09/2008 **Stopped**: 16/09/2008

LEVLEN ED (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 92 of 107



Cases Count: 98

Case Number: 246111

Gender: M

Data Entry Date: 10/11/2008 **Weight (kg)**: 74

Hospitalisation: Age: 69Y

Onset Date: 01/09/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

hospitalisation

Information: Recent LRTI, increased chol, type 2 DM, hypotension, COPD, peptic ulcer disease.

Reaction: **Preferred Term** Severity **Report Description Treatment** Metabolic acidosis Caused or prolonged Metabolic acidosis, acute inpatient renal failure, tubule hospitalisation interstitial nephritis, hyponatremia. Caused or prolonged Hyponatraemia inpatient hospitalisation Caused or prolonged Nephritis interstitial inpatient hospitalisation Caused or prolonged Renal failure acute inpatient

Medicine details: **COVERSYL** (Suspected) Reason: Essential benign hypertension **Tablet** 5 Milligram Daily Oral Batch: Started: Stopped: 02/09/2008 **DIAFORMIN (Suspected)** Reason: Diabetes mellitus **Tablet** 3 Gram Daily Oral Batch: Started: **Stopped**: 01/09/2008 Eleva 100 (Suspected) Reason: 100 Milligram **Tablet** Oral Daily Batch: Started: Stopped: 01/09/2008 LOFENOXAL (Suspected) Reason: Diarrhea Tablet 3 Dose Unspec Daily Oral Batch: Started: Stopped: 01/09/2008 **SPIRACTIN (Suspected)** Reason: **Tablet** 25 Milligram Daily Oral Stopped: Batch: Started: 01/09/2008 **ASPIRIN** (Other drug) Reason: Started: Stopped: Batch:

PUTRAN02 Page 93 of 107

Medicine details :			
Ferrograd C (Other drug)		Reason:	
Batch :	Started :		Stopped:
RANI 2 (Other drug)		Reason :	
Batch :	Started :		Stopped:
VASOCARDOL (Other drug)		Reason :	
Batch :	Started :		Stopped:

PUTRAN02 Page 94 of 107



Cases Count: 98

Case Number: 246200 Gender: M

Data Entry Date: 12/11/2008 **Weight (kg)**: 0

Hospitalisation: Age: 55Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

v	Δ	2	r	tı	$\boldsymbol{\cap}$	n	•
	C	a	v	LI	v	n	

Preferred Term Severity Report Description Treatment

Anxiety exacerbation of anxiety, memory impaired, reflexes

decreased,

breathlessness, lethargy,

confusion

Dyspnoea Hyporeflexia Lethargy

Memory impairment

Medicine details:

Champix (Suspected) Reason :

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

15 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 95 of 107



Cases Count: 98

Case Number: 246352

Gender: F

Data Entry Date: 18/11/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date: 03/11/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Dizziness

Developed feeling chest tightness, felt faint and a

wave of nausea

Chest discomfort

Nausea

Syncope

Medicine details:

ZOLOFT (Suspected)

Reason:

150 Milligram

Batch:

Started:

Stopped:

PUTRAN02 Page 96 of 107



Cases Count: 98

Gender: M

Case Number: 246440

Data Entry Date: 21/11/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

~ 0	26	T I 4	nr	•	•
че	av	u	91		

Preferred Term Severity Report Description Treatment

Lichenoid keratosis Caused or prolonged

inpatient hospitalisation The patient received irbesartan for a long time. At the time of this report, the patient was recovering from lichenoid eruption but

new lesions were

appearing. The patient was

also taking sertraline

hydrochloride.

٨	Λ	٦i	ci	ne	d	ata	ile	
I١	ИE	uı	G	пe	u	zla	HZ	٥.

AVAPRO (Suspected) Reason :

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 97 of 107



Cases Count: 98

Gender: M

Case Number : 246572

Data Entry Date: 25/11/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 26/07/2008 DOB: 23/08/1980

Outcome: 26/07/2008 Causality: Causality possible

Death

Information:

Reaction: **Preferred Term** Severity **Report Description Treatment** Depression Death Patient overdosed on medications available, led to patient being comatose and could not be resuscitated, patient was hospitalised on 26/07/08, died on the 26/07/08, patient had recently developed some depression symptoms, fluctuating paranod thoughts while under stress. Coma Death Completed suicide Death Intentional overdose Death Paranoia Death

Medicine details:

Stress

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 200 Milligram Daily Oral

Batch: Started: 12/04/2000 Stopped:

QUETIAPINE (Suspected) Reason :

Death

Batch: Started: Stopped:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

Batch: Started: 22/04/2008 Stopped:

PUTRAN02 Page 98 of 107



Cases Count: 98

Case Number: 246785

Gender: F

Data Entry Date: 03/12/2008

Weight (kg): 0

Hospital is at ion:

Age:

Onset Date: 21/10/2008

DOB: 30/03/1955

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

vaginal bleeding

drug ceased

Medicine details:

Vaginal haemorrhage

ZOLOFT (Suspected)

Reason:

50 Milligram

Daily

Batch:

Started: 20/10/2008

Stopped: 01/11/2008

0

PUTRAN02 Page 99 of 107



Cases Count: 98

Gender: F

Case Number: 246826

Weight (kg): 0 **Data Entry Date:** 04/12/2008

Hospitalisation: Hospitalisation prolonged Age:

DOB: 08/06/1972 Onset Date:

Causality: Causality possible Outcome:

Recovered with sequelae

Information:			
Reaction :			
Preferred Term	Severity	Report Description	Treatment
Rash pustular	Caused or prolonged inpatient hospitalisation	Developed pimple like rash on torso, heart palpitations, loose bowels, vomiting, swelling of lips and numbness in her left ankle. Diagnosed with anxiety. Dose of zoloft and oxazepam were doubled and she was transferred to another hospital where she developed seizures. After the initial seizure, she developed facial spasm, abnormal tongue movements which affected her speech, abnormal limb movements and complete numbness in the right side of her body. She also experienced breathing problems. A psychiatrist diagnosed her with serotonin syndrome.	
Convulsion	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Facial spasm	Caused or prolonged inpatient hospitalisation		
Hypoaesthesia	Caused or prolonged inpatient hospitalisation		
Lip swelling	Caused or prolonged inpatient hospitalisation		

PUTRAN02 Page 100 of 107 Reaction:

Preferred Term Severity Report Description Treatment

Caused or prolonged inpatient

hospitalisation

Serotonin syndrome Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient

Inpatient hospitalisation

Vomiting Caused or prolonged

inpatient hospitalisation

Medicine details:

Palpitations

Tongue paralysis

MURELAX (Interaction) Reason: Specific disorders of sleep

Batch: Started: Stopped: 0

ZOLOFT (Interaction) Reason : Depression

Batch: Started: Stopped: 0

PUTRAN02 Page 101 of 107



Cases Count: 98

Case Number: 246847

Gender: M

Data Entry Date: 05/12/2008

Weight (kg): 0

Hospitalisation:

Age: 68Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

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

Anxiety

3 days after dose was increased from 25mg to 50mg, experienced anxiety attack and verbalised

suicidal ideation

Suicidal ideation

Medicine details:

ZOLOFT (Suspected) Reason: Otr spec symp psychopathol nec

> 50 Milligram Daily

Batch: Started: Stopped:

PUTRAN02 Page 102 of 107



Cases Count: 98

Gender: M

Case Number: 247265

Data Entry Date: 19/12/2008 **Weight (kg)**: 0

Hospitalisation: Hospitalisation prolonged Age:

Onset Date : DOB : 01/12/2008

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug exposure during Caused or prolonged Mother switched from as above pregnancy Venlafaxine to Sertraline

during 3rd trimester of pregnancy. Baby born with persistant pulmonary hypertension (currently recovering in neonatal

ICU)

Reason:

Pulmonary hypertension Caused or prolonged

inpatient hospitalisation

hospitalisation

Medicine details:
SERTRALINE HYDROCHLORIDE (Suspected)

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 103 of 107



Cases Count: 98

Case Number: 247408

Gender: F

Data Entry Date: 24/12/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Drug withdrawal syndrome

drug withdrawal symptoms after taking Zoloft for 5.5 years, she reduced dose and developed dizziness and lightheadedness and

impaired general

functioning

Anxiety

Dizziness

Drug dependence

Stress

Medicine details :

ZOLOFT (Suspected)

Reason: Depression

Oral

Batch:

Started :

L TERM

Stopped:

PUTRAN02 Page 104 of 107



Cases Count: 98

Case Number: 247755

Onset Date: 01/10/2008

Gender: F

Age:

Data Entry Date: 16/01/2009 **Weight (kg)**: 80

Hospitalisation: Admitted to hospital

DOB: 26/06/1972

Outcome: Causality: Causality possible

Unknown

Information: Sertraline recently increased from 100mg.

Medication commenced 3/12 prior; dose increased approx 2/52 prior.

Request fro FI sent.

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion Life threatening Two witnessed seizures in Phenytoin commenced. the space of four hours; Sertraline discontinued.

prolonged post-ictal phase; nothing else on investigtion

to account for same.

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason : Depression

200 Milligram Daily

Batch: **Started**: 15/06/2008 **Stopped**: 02/10/2008

INDERAL (Other drug) Reason :

Milligram Daily

Willigram

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

Milligram Daily

Batch: Started: Stopped:

OXAZEPAM (Other drug) Reason :

30 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 105 of 107



Cases Count: 98

treated for Parkinson's disease

by another doctor

Gender: M

Case Number: 247899

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

Hospitalisation: Admitted to hospital Age: 83Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Constipation report by a carer. The patient was diagnosed as having Parkinson's disease, several months

after starting sertraline. (dosage, indication and duration of treatment unstated) While on Zoloft had constipation, sleeping difficulties, vision

disturbance, hands swelling, ankle swelling.

Insomnia

Oedema peripheral
Visual acuity reduced

Medicine details:

ZOLOFT (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 106 of 107



Cases Count: 98

Case Number: 247976

Gender: F

Data Entry Date: 27/01/2009 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug dependence Tried to stop treatment but found that she needed to

keep taking medication

Medicine details:

ZOLOFT (Suspected) Reason : Depression

Batch: Started: Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: SERTRALINE HYDROCHLORIDE, SERTRALINE HYDROCHLORIDE CT, SERTRALINE HYDROCHLORIDE SAS, SERTRALINE HYDROCHLORIDE TRIAL, ZOLOFT, ZOLOFT CT, ZOLOFT SAS, Xydep, Sertraline-DP 100, GenRx Sertraline, Eleva 100, Chem Mart Sertraline, Terry White Chemists Sertraline, Eleva 50, Concorz, Setrona, Sertraline Generic Health

PUTRAN02 Page 107 of 107