

Cases Count: 87

Case Number: 231470

Gender: F

Data Entry Date: 02/08/2007 **Weight (kg)**: 60.2

Hospitalisation: Age:

Onset Date: 20/06/2007 **DOB**: 01/02/1927

Outcome: Causality: Causality possible

Not yet recovered

Information: Adverse reaction to haloperidol and metoclopramide.

On 25mg bd at time of admission 2/5/07, dosage incrementally increased in effect to

manage aggression.

Started:

Reaction:

Preferred Term Severity Report Description Treatment
Oedema peripheral Patient experienced limb Observation.

Oedema peripheral Patient experienced limb oedema involving hands

and feet after medication dosage increased.

Therapy regimen changed

SORBITOL (Other drug)

Batch:

Medicine details: QUETIAPINE (Suspected) Reason: Otr spec symp psychopathol nec **Tablet** 200 Milligram Daily Oral Batch: Started: 20/06/2007 Stopped: 0 **OMEPRAZOLE** (Other drug) Reason: Started: Stopped: Batch: SINEMET (Other drug) Reason: Batch: Started: Stopped: **SODIUM VALPROATE (Other drug)** Reason: Started: Stopped: Batch:

Reason:

Stopped:

PUTRAN02 Page 1 of 96



Cases Count: 87

Case Number: 232545

Gender: M

Data Entry Date: 27/08/2007

Weight (kg): 0

Hospitalisation: Required a specialist consultation

Age: 32Y

Onset Date: 22/05/2007

DOB:

Outcome : Causalit

Causality: Causality possible

Recovered

Information:

Reaction:

Priapism

Preferred Term Severity Report Description Treatment

Priapism lasting 9+ hours. Surgically reduce priopism.

Requiring surgical intervention.

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 300 Milligram Daily Oral

Batch: **Started**: **Stopped**: 22/05/2007

PUTRAN02 Page 2 of 96



Cases Count: 87

Case Number: 232642

Gender: F

Data Entry Date: 28/08/2007

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 18/07/2007

DOB: 30/01/1977

Outcome: 18/07/2007

Causality: Causality possible

Unrelated death

Information: History of obesity.

Reaction:

Preferred Term Severity Report Description Treatment

Sudden death Death Patient died a sudden

death.

Medicine details:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 200 Milligram Daily Oral

Batch: **Started**: 17/07/2007 **Stopped**: 18/07/2007

SEROQUEL (Suspected) Reason :

Tablet Oral

Batch: Started: Stopped:

PUTRAN02 Page 3 of 96



Cases Count: 87

Age:

Case Number: 233391

Gender: F

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

Hospitalisation: Required a visit to the doctor

Onset Date: 02/09/2007 **DOB**: 29/08/1976

Outcome: Causality: Causality possible

Recovered

Information: 1st time use of quetiapine.

Reaction:

Preferred Term Severity Report Description Treatment

Oculogyric crisis - patient's Benztropine

eyes appeared to roll back in head. Patient also walking very hunched over at this time; unaware of this when questioned later.

Posture abnormal

Medicine details:

SEROQUEL (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 25 Milligram As necessary Oral

Batch: **Started**: 31/08/2007 **Stopped**: 0

LUVOX (Other drug) Reason : Depression

Tablet 200 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

PUTRAN02 Page 4 of 96



Cases Count: 87

Age:

Case Number: 233558

Se Number . 253556 Gender: F

Data Entry Date: 19/09/2007 **Weight (kg)**: 80

Onset Date: 20/08/2007 DOB: 23/02/1968

Outcome: Causality: Causality possible

Not yet recovered

Hospitalisation: Required a visit to the doctor

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Oedema peripheral
Patient developed oedema
of the feet and ankles
causing pain on walking

and unable to wear her

own shoes.

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecifid affective psychosis

Tablet 600 Milligram Daily Oral

Batch: **Started**: 15/04/2005 L TERM **Stopped**: 05/09/2007

PUTRAN02 Page 5 of 96



Cases Count: 87

Age:

Case Number : 233657

Hospitalisation: Admitted to hospital

Gender: F

Data Entry Date: 20/09/2007 **Weight (kg)**: 0

Onset Date : DOB : 19/07/1976

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tachycardia - Tachycardia - Low Magnesium

- Low Magnesium
- Low Potassium

- Prolonged QT interval

Electrocardiogram QT

prolonged Hypokalaemia

Hypomagnesaemia

Medicine details:

SEROQUEL (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 6 of 96



Cases Count: 87

Case Number: 233659

Gender: M

Data Entry Date: 20/09/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: The patient is a smoker, has transient ischaemic attck and high blood pressure.

Reaction:

Preferred Term Severity **Report Description**

Treatment

Ischaemic cardiomyopathy

Medicine details:

SEROQUEL (Suspected)

Reason:

Daily

Oral

Batch:

Started: 15/01/2007

400 Milligram

Stopped:

HALOPERIDOL (Other drug)

Reason:

Batch:

Started:

L TERM

Stopped:

PUTRAN02 Page 7 of 96



Cases Count: 87

Case Number: 233683

Gender: M

Data Entry Date: 21/09/2007 Weight (kg): 0

Hospitalisation: Age:

DOB: 06/05/1981 **Onset Date:**

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

increased

Preferred Term Severity **Report Description**

Treatment Blood creatine phosphokinase Caused or prolonged Creatine kinase high, ecg

> inpatient abnormal, Tachycardia, hospitalisation White blood cell count increased and neutrophils

increased.

Electrocardiogram abnormal Caused or prolonged

> inpatient hospitalisation

Caused or prolonged Neutrophil count increased

> inpatient hospitalisation

Tachycardia Caused or prolonged

> inpatient hospitalisation

White blood cell count

increased

Caused or prolonged

inpatient hospitalisation

Medicine details:

AMISULPRIDE (Suspected) Reason:

Started: 21/12/2005 Stopped: Batch:

PIMOZIDE (Suspected) Reason:

Batch: Started: Stopped:

QUETIAPINE (Suspected) Reason:

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Creatine 28 Mar 2006 - CK ranged from 621 -

phosphokinase 728 (ref 0 - 270)

Electrocardiography ECG on 5 May 2006 showed increased sinus rate of approximately 115 bpm.

Pulse varied from 87 - 122 bpm.

White blood cells WBC ranged from 11.5 - 17.7 x 10^9/L

(ref 4.0 - 11.0)

PUTRAN02 Page 8 of 96 **Laboratory Investigations:**

Туре Range Date Tested Result Details

Neutrophils were 13.00 x 10^9/L (ref 1.8 - 7.5) Neutrophils

PUTRAN02 Page 9 of 96



Cases Count: 87

Case Number : 233711

Gender: F

Data Entry Date: 21/09/2007 **Weight (kg)**: 0

Hospitalisation: Age: 24Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urinary retention - Urinary bladder retention

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified schizophrenia

Tablet 300 Milligram Daily Oral

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

LITHIUM CARBONATE (Other drug) Reason : Unspecified schizophrenia

250 Milligram Daily Oral

Batch: Started: Stopped: 0

SERTRALINE HYDROCHLORIDE (Other drug) Reason: Unspecified schizophrenia

150 Milligram Daily Oral

Batch: Stopped: 0

PUTRAN02 Page 10 of 96



Cases Count: 87

Case Number: 233995

Gender: F

Data Entry Date: 04/10/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 24/08/2007 **DOB**: 25/04/1920

Outcome: 11/09/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Medicine details:

AVAPRO (Suspected) Reason: Essential benign hypertension

150 Milligram Daily Oral

Batch: Started: L TERM Stopped: 28/08/2007

SEROQUEL (Suspected) Reason: Unspecified psychosis

125 Milligram Daily Oral

Batch: Started: L TERM Stopped:

PUTRAN02 Page 11 of 96



Cases Count: 87

Case Number: 234625

Gender: F

Data Entry Date: 22/10/2007

Weight (kg): 0

Hospitalisation:

Age: 16Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Life threatening	Patient admitted to Mental health facility after reaction to Zoloft. Intentionally overdosed on Fluoxetine and Quetiapine.	In care.
Self injurious behaviour	Life threatening	cutting herself, throwing herself against the walls while an inpatient	
Aggression	Life threatening	patient developed severe levels of aggression and violence	
Diarrhoea	Life threatening		
Headache	Life threatening		
Hyperhidrosis	Life threatening		

Medicine details:

FLUOXETINE HYDROCHLORIDE (Suspected)

Reason:

1 Dose Unspec Daily

Started :

Life threatening

Life threatening

Stopped:

QUETIAPINE (Suspected)

Reason:

1 Dose Unspec Daily

Batch:

Batch:

Nausea

Suicide attempt

Started:

Stopped:

PUTRAN02 Page 12 of 96



Cases Count: 87

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 13 of 96



Cases Count: 87

Gender: F

Case Number: 234838

Data Entry Date: 26/10/2007 Weight (kg): 0

Hospitalisation: Required a specialist consultation Age: 55Y

Onset Date: 01/04/2007 DOB:

Outcome: 30/10/2007 Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Tardive dyskinesia Incapacity/disability - Dyskinesia tardive: none

getting progressively worse, especially

lip-smacking

Medicine details:

OLANZAPINE (Suspected) Reason:

Batch: Started: Stopped:

SEROQUEL (Suspected) Reason:

1.3 Gram Oral **Tablet**

Batch: Started: 01/10/2006 Stopped: 0

PUTRAN02 Page 14 of 96



Cases Count: 87

Case Number: 234932

Gender: M

Data Entry Date: 01/11/2007 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 49Y

Onset Date: 01/08/2007 **DOB**:

Outcome: 01/10/2007 Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Caused or prolonged - Agitation Seroqul stopped; diazepam inpatient - Catatonia started; fluvoxamine started;

hospitalisation - Jaw locked weekly ECT - Funny movements

Catatonia Caused or prolonged

inpatient

hospitalisation

Trismus Caused or prolonged

inpatient hospitalisation

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet Milligram Daily Oral

Batch: Started: 01/08/2007 Stopped:

PUTRAN02 Page 15 of 96



Cases Count: 87

Case Number: 235177 Gender: M

Data Entry Date: 12/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 32Y

Onset Date: 25/02/2004 **DOB**:

Outcome: Causality: Causality possible

Death

Information:

Reaction	•
· · · · · · · · · · · · · · · · · · ·	-

Preferred Term Severity Report Description Treatment

Completed suicide Weight decreased

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified schizophrenia

Batch: Started: L TERM Stopped: 0

DIAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 16 of 96



Cases Count: 87

Case Number: 235284

Gender: F

Data Entry Date: 14/11/2007 **Weight (kg)**: 80

Hospitalisation : Age :

Onset Date : DOB : 13/12/1968

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vomiting Caused or prolonged Baby born 20/9/07. Fully Ceased Quetiapine.

inpatient hospitalisation

breastfed. Mother took Quetiapine nocte. Baby projectile vomiting, admitted to hospital. Mother ceased drug marked decrease in babies vomiting. Drug had been

taken during late pregnancy.

Drug exposure via breast milk Caused or prolonged

inpatient hospitalisation

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecified psychosis

Tablet 300 Milligram Daily Oral

Batch: Started: 24/07/2007 Stopped: 29/10/2007

Escitalopram (Other drug) Reason : Depression

Tablet 20 Milligram Daily Oral

Batch: Started: 15/03/2007 Stopped:

PUTRAN02 Page 17 of 96



Cases Count: 87

Case Number: 235338

Gender: F

Data Entry Date: 15/11/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 62Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Neutropenia

Caused or prolonged

described as severe, requiring admission to ICU

inpatient

hospitalisation

Reason:

MIRTAZAPINE (Suspected)

Medicine details:

Oral

Batch:

Started:

Stopped:

SEROQUEL (Suspected)

Reason: Depression

Oral

Batch:

Started:

L TERM

Stopped:

PUTRAN02 Page 18 of 96



Cases Count: 87

Case Number: 235646

Gender: F

Data Entry Date: 26/11/2007

Weight (kg): 64

Hospitalisation:

Age:

Onset Date: 01/10/2007

DOB: 28/08/1972

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Tachycardia

Patient experienced the development of bursts of Reduced dosage to 100mg Seroquel

tachycardia with ventricular

ectopics.

Ventricular extrasystoles

Medicine details:

SEROQUEL (Suspected)

Reason:

Oral

Tablet

200 Milligram Started: 01/09/2007

Daily

Stopped: 21/10/2007

EFEXOR-XR (Other drug)

Reason:

375 Milligram

Batch:

Batch:

Started:

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Other data

QTc 0.22

PUTRAN02 Page 19 of 96



Cases Count: 87

Case Number: 235733

Gender: M

Data Entry Date: 28/11/2007

Weight (kg): 100

Hospitalisation: Required a visit to the doctor

Age:

Onset Date :

DOB: 12/06/1968

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Tardive dyskinesia

Oral facial tardive

dyskinesia.

Medicine details:

QUETIAPINE (Suspected)

Reason: Unspecified psychosis

Tablet

300 Milligram

Daily

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 20 of 96



Cases Count: 87

Case Number: 235749

Data Entry Date: 28/11/2007

Hospitalisation:

Gender: M

Weight (kg): 0

Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:						
Preferred Term	Severity	Report Description	Treatment			
Tachycardia						
Medicine details :						
SEROQUEL (Suspected)		Reason :				
Batch :	Started :	Stopped :	0			
HALOPERIDOL (Other drug)		Reason :				
Batch :	Started :	Stopped :				
TRIFLUOPERAZINE HYDROCH	ILORIDE (Other drug)	Reason :				
Batch :	Started :	Stopped :				

PUTRAN02 Page 21 of 96



Report Description

Cases Count: 87

Treatment

Case Number: 236227 Gender: F

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

Onset Date : DOB : 24/10/1949

Outcome : Causality : Causality probable

Recovered

Severity

Information:

Reaction:
Preferred Term

Neutropenia		Patient noted t neutrapenic on to hospital.	Seorquel ceased.	
Medicine details :				
SEROQUEL (Suspected)		Reason :		
Tablet	200 Milligr	am Daily		Oral
Batch :	Started :		Stopped:	15/11/2007
COLOXYL WITH SENNA (Other drug)	Reason :		
Batch :	Started :		Stopped :	
DIAZEPAM (Other drug)		Reason :		
Batch :	Started :		Stopped :	
GEMFIBROZIL (Other drug)		Reason :		
Batch :	Started :		Stopped :	
MAGNESIUM NOS (Other drug)		Reason :		
Batch :	Started :		Stopped :	
METOPROLOL TARTRATE (Other dr	rug)	Reason :		
Batch :	Started :		Stopped :	
RANITIDINE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
SODIUM VALPROATE (Other drug)		Reason :		
Batch :	Started :		Stopped :	

PUTRAN02 Page 22 of 96

Laboratory Investigations:

Type Range Date Tested Result Details

Neutrophils=1.48, dropping to 0.85).

Neutrophils=1.48, dropping to 0.85). Seroquel ceased and neutrophils recovered to 3.35, 3 days later.

PUTRAN02 Page 23 of 96



Cases Count: 87

Gender: F

Case Number: 236906

Data Entry Date: 11/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 60Y

Onset Date: 01/10/2007 DOB:

Outcome : Causality : Causality possible

Not yet recovered

Information:

Weight increased

Reaction :				
Preferred Term	Severity	Report Description	Treatment	
Fluid retention		Patient was changed from Efexor to Seroquel and Valpro by psychiatrist. Over the next 10 weeks developed significant weight gain - weight increased from 78 to 101kg. Fluid has built up from knees to toes, as well as fat deposition around abdomen. Weight gain has been disabling as patient already paraplegic and it affects her ability to move around. Already as a paraplegic aware of weight gain as a potential problem so very fastidious about types and amount of food she eats.	Lasix	

Medicine details: SEROQUEL (Suspected) Reason: Unspecifid affective psychosis Tablet 25 Milligram Daily Oral Batch: Started: S TERM Stopped: 0 VALPRO (Suspected) Reason: Unspecifid affective psychosis Tablet 1000 Milligram Daily Oral **S TERM** Batch: Started: Stopped: ACIMAX (Other drug) Reason: Batch: Started: Stopped: COVERSYL (Other drug) Reason: Batch: Started: Stopped: LIPITOR (Other drug) Reason: Started: Batch: Stopped:

PUTRAN02 Page 24 of 96

Medicine details :			
NEURONTIN (Other drug)		Reason:	
Batch :	Started :		Stopped :
PANAFCORT (Other drug)		Reason :	
Batch :	Started :		Stopped :
ROCALTROL (Other drug)		Reason :	
Batch :	Started :		Stopped :

PUTRAN02 Page 25 of 96



Cases Count: 87

Case Number: 237097

Gender: F

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

Hospitalisation: Admitted to hospital Age: Onset Date: 25/12/2007 **DOB**: 01/03/1979

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Angioedema

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Urticaria Patient experienced mild

inpatient anaphylaxis, urticarial rash hospitalisation and angioedema of mouth

with mild wheeze.

Caused or prolonged inpatient

hospitalisation

Caused or prolonged Wheezing

inpatient

hospitalisation

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecified psychosis

Tablet 200 Milligram Daily Oral

Batch: Started: 19/12/2007 Stopped: 26/12/2007

PUTRAN02 Page 26 of 96



Cases Count: 87

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 27 of 96



Cases Count: 87

Case Number : 237292

Gender: F

Data Entry Date: 24/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 40Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation	consumer report: Bowel Bleeding - Weight increase	
Increased appetite	Caused or prolonged inpatient hospitalisation	cravings for high calorie foods and Coke	
Weight increased	Caused or prolonged inpatient hospitalisation	weight gain over 5 months from 52kg to 91 kg	

Medicine details :					
SEROQUEL (Suspected)		Re	ason : Unspe	cifid affective psychosis	
		100 Milligram	Daily	Oral	
Batch :	Started :			Stopped :	
EFEXOR (Other drug)		Re	ason :		
				Oral	
Batch :	Started :			Stopped :	
OXAZEPAM (Other drug)		Re	ason :		
Batch :	Started :			Stopped :	

PUTRAN02 Page 28 of 96



Hospitalisation:

Public Case Detail

Cases Count: 87

Case Number: 237429

Gender: F

Data Entry Date: 30/01/2008 Weight (kg): 68

Age:

Onset Date: 15/11/2007 **DOB**: 24/02/1926

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Hepatic function abnormal Elevated LFTs. Quetiapine ceased.

inpatient

hospitalisation

Medicine details:

QUETIAPINE (Suspected) Reason:

25 Milligram

Batch: Started: 01/11/2007 Stopped: 01/01/2008

AMLODIPINE (Other drug) Reason:

5 Milligram

Batch: Started: Stopped:

ATORVASTATIN (Other drug) Reason:

40 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 29 of 96



Cases Count: 87

Case Number : 237533

Gender: M

Data Entry Date: 04/02/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Chest pain - Chest pains

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet 1000 Milligram Oral

Batch: Started: Stopped: 0

SODIUM VALPROATE (Other drug) Reason :

1500 Milligram Oral

Stopped:

Batch: Started:

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason :

75 Milligram Oral

Batch: Started: Stopped:

PUTRAN02 Page 30 of 96



Cases Count: 87

Case Number: 237535

Gender: F

Data Entry Date: 04/02/2008

Weight (kg): 0

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome:

Causality: Causality certain

Recovered

Information: Cert:Rechall

Reaction:

Preferred Term

Severity

Report Description

- Weight increase

Treatment

Weight increased

Increased appetite

Medicine details:

SEROQUEL (Suspected)

Reason:

50 Milligram

Daily

Oral

Batch:

Tablet

Started: 13/11/2007

Stopped: 13/12/2007

0

PUTRAN02 Page 31 of 96



Cases Count: 87

Case Number : 237780

Gender: F

Data Entry Date: 11/02/2008

Weight (kg): 0

Hospitalisation:

Age: 48Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Gingival swelling

Medicine details:

SEROQUEL (Suspected)

Reason :

400 Milligram

Daily

Oral

Batch :

Started:

Stopped:

PUTRAN02 Page 32 of 96



Cases Count: 87

Case Number : 237831

Gender: M

Data Entry Date: 12/02/2008

Weight (kg): 80

Hospitalisation:

Age:

Onset Date: 03/11/2007

DOB: 20/03/1968

Outcome:

Causality: Causality possible

Death

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Sudden death Death Sudden unexplained

death.

Medicine details:

DIAZEPAM (Suspected) Reason: Unspecified schizophrenia

Tablet 10 Milligram Daily Oral

Batch: Started: L TERM Stopped:

QUETIAPINE (Suspected)Reason: Unspecified schizophrenia

Tablet 900 Milligram Daily Oral

Batch: Started: L TERM Stopped:

PUTRAN02 Page 33 of 96



Cases Count: 87

Case Number: 237915

Gender: F

Data Entry Date: 14/02/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital Age: 85Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information: patient has many concurrent medical conditions and medications,

Author: Landau J, Lu K, Choo C and Greenberg P. Title: Medicinal mishap: neutropenia with quetiapine

Journal: Australian prescriber

Date: 2008 Vol.: 31 Issue: 1 Page(s): 10-11

Reaction:

Preferred Term Severity Report Description Treatment

Leukopenia

Neutropenia

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecified psychosis

400 Milligram Oral

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

White blood cells

Neutrophils

PUTRAN02 Page 34 of 96



Cases Count: 87

Case Number: 237966 Gender: F

Data Entry Date: 15/02/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date : DOB : 22/01/1972

Outcome : Causality : Causality probable

Recovered

Information:

Reaction :				
Preferred Term	Severity F	Report Description	Treatment	
Leukopenia				
Neutropenia				
Medicine details :				
SEROQUEL (Suspected)	Re	eason: Depression		
	150 Milligram	Daily	Oral	
Batch :	Started: 05/12/2007	Stoppe	d : 09/01/2008	

Reason:

Batch: Started: Stopped:

EFEXOR (Other drug) Reason :

Batch: Started: Stopped:

Escitalopram (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

White blood cells

DIAZEPAM (Other drug)

Neutrophils

PUTRAN02 Page 35 of 96



Cases Count: 87

Case Number: 238203

Gender: F

Age:

Data Entry Date: 22/02/2008 Weight (kg): 0

Hospitalisation:

Onset Date : DOB : 28/06/1952

Outcome : Causality : Causality possible

Unknown

Information: Seroquel re-introduced at a lower dose and the adverse event did not recur

Reaction:					
Preferred Term Generalised oedema	Severity	1	Report Descripti moderate general oedema		
Medicine details :					
SEROQUEL (Suspected)		Re	eason :		
		200 Milligram	Daily	Oral	
Batch :	Started :		S	stopped :	

LOVAN (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

NOTEN (Other drug) Reason :

50 Milligram

Batch: Started: Stopped:

PUTRAN02 Page 36 of 96



Cases Count: 87

Case Number: 238495

Gender: M

Data Entry Date: 03/03/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 14/02/2008

DOB: 22/04/1948

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

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

White blood cell count decreased

White cell count decreased.

Medicine details:

QUETIAPINE (Suspected)

Reason: Manic-depression psycho, manic

Tablet

400 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

White blood cells

WBC decreased 30-36.

PUTRAN02 Page 37 of 96



Cases Count: 87

Gender: F

Stopped: 09/01/2008

Case Number: 238556

Data Entry Date: 29/02/2008 **Weight (kg)**: 59

Hospitalisation: Age:

Onset Date: 08/01/2008 **DOB**: 22/01/1972

Outcome: 18/01/2008 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neutropenia and Ceased Quetiapine

leucopenia secondary to

Quetiapine.

Leukopenia

Batch:

Medicine details:

QUETIAPINE (Suspected)

Tablet

Reason: Depression

Oral

EFEXOR (Other drug) Reason :

Batch: Started: Stopped:

Started: 05/12/2007

Lexapro (Other drug) Reason :

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 38 of 96



Cases Count: 87

Case Number: 238740

Gender: F

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

Hospitalisation: Treated in Accident/Emergency Depar

Age: 99u

Onset Date: DOB:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder heard voices, was feeling Cogentin

restless and overwhelmed, felt like passing out,

couldnt speak properly and was slurring words.
Fluctuating from being calm to emotional to being

very aggressive.

Aggression

Dysarthria

Emotional disorder

Hallucination, auditory

Insomnia

Presyncope

Restlessness

Speech disorder

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified psychosis

400 Milligram Daily

Batch: Started: 15/01/2003 Stopped:

Zeldox (Suspected) Reason: Unspecified psychosis

Capsule 80 Milligram Daily Oral

Batch: Started: 22/02/2008 Stopped:

LOVAN (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 39 of 96



Cases Count: 87

Case Number: 238745

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

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tardive dyskinesia Patient treated for three years with Seroquel, and

for the latter 3 months with dexamphetamine, developed tardive

dyskinesia when Seroquel

was stopped.

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet 600 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

DEXAMPHETAMINE SULPHATE (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 40 of 96



Cases Count: 87

Case Number: 239105

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

Hospitalisation: Age: 62Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

			-		
ப	ea	\sim t	-	-	
т.					
	-u	UL	. •		

Preferred Term Severity Report Description Treatment

Hepatic steatosis - Fatty Infiltration

Hepatic function abnormal

Hepatic steatosis

Medicine details:

SEROQUEL (Suspected) Reason :

Batch: Started: Stopped:

SOMAC (Other drug) Reason :

Batch: Started: Stopped: 0

PUTRAN02 Page 41 of 96



Cases Count: 87

Case Number : 239168

Gender: M

Data Entry Date: 20/03/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Drug dependence

Caused or prolonged inpatient

hospitalisation

Felt addicted to it,

Patient admitted himself to a private hospital to detox off

Seroquel.

Medicine details:

SEROQUEL (Suspected)

Reason: Anxiety neurosis

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 42 of 96



Cases Count: 87

Case Number : 239170

Gender: M

Data Entry Date: 20/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood glucose fluctuation Diabetes, Blood sugar level fluctuation

Diabetes mellitus

Medicine details :

SEROQUEL (Suspected) Reason :

Tablet 1.2 Gram Oral

Batch: Started: Stopped:

PUTRAN02 Page 43 of 96



Cases Count: 87

Case Number: 239730

Gender: F

Data Entry Date: 08/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 78Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Pt suffers from paranoid schizphrenia.

Reaction:

Preferred Term Severity Report Description Treatment

Anticholinergic syndrome - Anticholinergic Side

Effects

Medicine details:

QUETIAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 44 of 96



Cases Count: 87

Case Number: 239767 Gender: U

Data Entry Date: 10/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

	4 .	
ロヘつ	0+10h	
rea	ction	-

Preferred Term Severity Report Description Treatment

Psychotic disorder Reporter had a patient who

became psychotic when using combinations of quetiapine and aripiprazole and withdrawing from

Efexor.

Medicine details:

Aripiprazole (Suspected) Reason :

Batch: Started: Stopped:

EFEXOR (Suspected) Reason :

Batch: Started: Stopped:

QUETIAPINE (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 45 of 96



Hospitalisation:

Public Case Detail

Cases Count: 87

Case Number: 239991

Gender: F

Data Entry Date: 15/04/2008 **Weight (kg)**: 68

Age:

Onset Date: 15/08/2007

DOB: 22/05/1952

Outcome :

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neutropenia Neutropenia Reduced Seroquel

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet 200 Milligram Daily Oral

Batch: Started: 15/06/2006 Stopped:

PROZAC (Other drug) Reason :

40 Milligram

Batch: Started: 15/08/2006 Stopped:

PUTRAN02 Page 46 of 96



Cases Count: 87

Case Number: 240588

Gender: F

Data Entry Date: 05/05/2008 Weight (kg): 51

Hospitalisation: Admitted to hospital Age: 30Y

Onset Date: 14/04/2008 DOB:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment** Caused or prolonged Mania

inpatient hospitalisation Manic episode. SAMe ceased

Medicine details:

EPILIM (Interaction) Reason: Unspecifid affective psychosis

> 2 Gram Daily

Batch: Started: Stopped:

SAMe Nos (Interaction) Reason: Depression

> 800 Milligram Daily

Batch: Started: 04/04/2008 Stopped: 07/04/2008

SEROQUEL (Interaction) Reason: Unspecifid affective psychosis

Tablet 300 Milligram Daily

Batch: Started: Stopped:

PUTRAN02 Page 47 of 96



Cases Count: 87

Gender: F

Case Number: 240855

Data Entry Date: 14/05/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: DOB: 06/03/1973

Outcome: Causality: Causality possible

Recovered

Information: Current condition smoker, hypothyroidism, drug dependance cannabis abuse.

Reaction: **Preferred Term** Severity **Report Description Treatment** Neutropenia Patient experienced Ceased Clozaril neutropenia hallucinatory and delusional symptomatology, anxiety, mood swings icrease in challenging behaviours. Abnormal behaviour Anxiety Delusion Hallucination

Mood swings Medicine details: **CLOZARIL** (Suspected) Reason: Unspecified schizophrenia **Tablet** Oral **Stopped:** 15/11/2006 Batch: Started: **QUETIAPINE (Suspected)** Reason: Started: Stopped: Batch: **SODIUM VALPROATE (Suspected)** Reason: Anxiety neurosis 4.5 Milligram Daily Oral Started: 04/04/2008 Batch: Stopped: FISH OIL NOS (Other drug) Reason: Started: Batch: Stopped: LITHIUM CARBONATE (Other drug) Reason: Started: Stopped: Batch: LORAZEPAM (Other drug) Reason: Started: 15/04/2008 Batch: Stopped: **MULTIVITAMINS (Other drug)** Reason: Batch: Started: 15/04/2008 Stopped:

PUTRAN02 Page 48 of 96

Medicine details:

OLANZAPINE (Other drug) Reason :

Batch: Started: 08/04/2008 Stopped:

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

 Neutrophils
 09/11/2006
 1.0

 Neutrophils
 10/11/2006
 1.0

PUTRAN02 Page 49 of 96



Cases Count: 87

Gender: F

Case Number: 241058

Data Entry Date: 21/05/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 12/03/2008 **DOB**: 08/07/1969

Outcome : Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pitting oedema	Caused or prolonged inpatient hospitalisation	Bilateral pitting oedema of legs, mixed affective state with rapid cycling, dose was increasd due to high levels of agitation.	
Agitation	Caused or prolonged inpatient hospitalisation		
Mental status changes	Caused or prolonged inpatient hospitalisation		

Medicine details :						
SEROQUEL (Suspected)		Rea	ason : Unspe	cifid affective psychosis		
		150 Milligram	Daily	Oral		
Batch :	Started :			Stopped :	0	
DIAZEPAM (Other drug)		Rea	ason :			
Batch :	Started :			Stopped :		
LAMISIL (Other drug)		Rea	ason :			
Batch :	Started :			Stopped :		
LITHIUM CARBONATE (Other dr	ug)	Rea	ason :			
Batch :	Started :			Stopped :		
Lyrica (Other drug)		Rea	ason :			
Batch :	Started :			Stopped :		
MERSYNDOL (Other drug)		Rea	ason :			
	.					
Batch :	Started :			Stopped :		
OLANZAPINE (Other drug)		Rea	ason :			
Details :	Ctontod			Ctannad .		
Batch :	Started :			Stopped :		

PUTRAN02 Page 50 of 96

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

PUTRAN02 Page 51 of 96



Cases Count: 87

Case Number: 241176

Gender: M

Data Entry Date: 26/05/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality probable

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant Life threatening Neuroleptic Malignant

syndrome Syndrome

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet 300 Milligram Daily Oral

Batch: Started: Stopped: 0

CARBAMAZEPINE (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 52 of 96



Cases Count: 87

Case Number : 241219

Data Entry Date: 27/05/2008 **Weight (kg)**: 0

Hospitalisation: Age: 81Y

Onset Date: 02/11/2007 DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Erythema Skin rash for 6/52. It was itchy. Diffuse macular erythema on arm, thigh,

back. Desquamating scales thigh. Some scales

on scalp.

kin rash for 6/52. It was Elocon and Dermeze cream. chy. Diffuse macular Seroquel and Zyprexa ceased.

Gender: M

Pruritus

Rash macular Skin exfoliation

Medicine details:

SEROQUEL (Suspected) Reason : Otr spec symp psychopathol nec

25 Milligram Daily

Batch: Started: Stopped: 29/10/2007

ZYPREXA (Suspected) Reason: Otr spec symp psychopathol nec

10 Milligram Daily

Batch: Started: Stopped: 02/11/2007

CABASER (Other drug) Reason : Paralysis agitans

2 Milligram Daily

Batch: Started: Stopped:

COLOXYL WITH SENNA (Other drug) Reason : Constipation

2 Dose Unspec Daily

Batch: Started: Stopped:

LASIX (Other drug) Reason: Essential benign hypertension

20 Milligram Daily

Batch: Started: Stopped:

OSTELIN 1000 (Other drug) Reason :

1 Dose Unspec Daily

Batch: Started: Stopped:

OXAZEPAM (Other drug) Reason : Anxiety neurosis

7.5 Milligram Daily

Batch: Started: Stopped:

PUTRAN02 Page 53 of 96

Medicine details: RAMIPRIL (Other drug) Reason: Essential benign hypertension 1.3 Milligram Stopped: Batch: Started: Reason: Paralysis agitans SELEGILINE HYDROCHLORIDE (Other drug) 5 Milligram Daily Batch: Started: Stopped: SINEMET (Other drug) Reason: Paralysis agitans 3 Dose Unspec Daily Batch: Started: Stopped: SORBOLENE CREAM WITH GLYCERINE 10% (Other drug) Reason: 1 Dose Unspec Daily Batch: Started: Stopped:

PUTRAN02 Page 54 of 96



Cases Count: 87

Case Number: 241511

Gender: M

Data Entry Date: 03/06/2008

Weight (kg): 0

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Neuroleptic malignant syndrome

Caused or prolonged inpatient

- Neuroleptic Malignant

Syndrome

Mutism

hospitalisation

Caused or prolonged

inpatient

hospitalisation

Medicine details:

SEROQUEL (Suspected) Reason: Depression

Tablet 37.5 Milligram Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 55 of 96



Cases Count: 87

Case Number: 241559

Data Entry Date: 04/06/2008 **Weight (kg)**: 70

Hospitalisation: Age:

Onset Date: 21/05/2008 **DOB**: 25/11/1986

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neutropenia Caused or prolonged inpatient

hospitalisation

neutropenia: neutrophil Cease possible offending count on 21/05/2008 was medications and continue to 1.8 and on 24/05/08 was 1.

Gender: F

. Following cessation of valproate and quetiapine and addition of lithium, neutrophil count had returned to normal on

25/05/08

Medicine details:

EPILIM (Suspected) Reason :

 Tablet
 1.5 Gram
 Daily
 Oral

 Batch :
 Started : 30/03/2008
 Stopped : 24/05/2008

SEROQUEL (Suspected) Reason :

Tablet 1 Gram Daily Oral

Batch: **Started**: 30/03/2008 **Stopped**: 24/05/2008

PUTRAN02 Page 56 of 96



Cases Count: 87

Case Number: 241590

Gender: F

Data Entry Date: 04/06/2008

Weight (kg): 0

Hospitalisation:

Age: 58Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Weight increased

Patient gained 18kg over

Maxolon and diet.

two years and also had experienced vomiting.

Vomiting

Medicine details:

SEROQUEL (Suspected)

Reason:

Tablet

Daily

Oral

Batch:

Started :

1.2 Gram

Stopped:

PUTRAN02 Page 57 of 96



Cases Count: 87

Case Number: 241727

Gender: F

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

 Hospitalisation :
 Age :

 Onset Date : 31/03/2008
 DOB : 29/09/1950

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Caused or prolonged Seroquel commenced at Dose reduced again

inpatient 50mg TID and titrated to 200mg QID plus prn doses to manage high levels of anxiety and associated agitation. Also developed

moderate peripheral oedema due to the dose

increase.

Agitation Caused or prolonged

inpatient hospitalisation

Drug ineffective Caused or prolonged

inpatient

hospitalisation

Oedema peripheral Caused or prolonged

inpatient hospitalisation

Medicine details:

SEROQUEL (Suspected) Reason: Anxiety neurosis

Tablet 800 Milligram Daily Oral

Batch: **Started**: 31/03/2008 **Stopped**: 0

PUTRAN02 Page 58 of 96



Cases Count: 87

Case Number: 242151

Gender: F

Data Entry Date: 20/06/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 01/05/2008 **DOB**: 28/01/1980

Causality: Causality possible Outcome:

Unknown

Information: The patient had previously experienced increased prolactin levels with risperidone

Reaction:

Preferred Term Severity **Report Description Treatment**

Blood prolactin increased

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified schizophrenia

> 600 Milligram Daily Oral

Batch: Started: 04/02/2008 Stopped:

Laboratory Investigations:

Type Range Date Tested Result **Details**

5/5/08- prolactin level - 2500 Prolactin

MRI showed no abnormalities

PUTRAN02 Page 59 of 96



Cases Count: 87

Gender: F

stopped.

Case Number : 242396

Data Entry Date: 30/06/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**:

Onset Date: 10/06/2008 DOB: 13/06/1962

Outcome: 14/06/2008 Causality: Causality probable

Recovered

Information: Previous serotonin syndrome several years ago when commenced on amisulpride

(resolved when amisulpride ceased).

Reaction:

Preferred Term Severity Report Description Treatment

Hyperreflexia Caused or prolonged Hyper reflexia, ankle Ziprasidone & phenelzine

inpatient clonus, tremor, dilated hospitalisation pupils, tachycardia,

increasing agitation and restlessness, sweating.

Agitation Caused or prolonged

inpatient

hospitalisation

Clonus Caused or prolonged

inpatient hospitalisation

Hyperhidrosis Caused or prolonged

inpatient hospitalisation

Neuroleptic malignant

syndrome

Caused or prolonged inpatient

hospitalisation

....

Restlessness Caused or prolonged

inpatient hospitalisation

Tachycardia Caused or prolonged

inpatient

hospitalisation

Tremor Caused or prolonged

inpatient hospitalisation

Medicine details:

LAMOTRIGINE (Interaction) Reason: Unspecified schizophrenia

400 Milligram Daily

Batch: Started: L TERM Stopped: 0

LITHIUM CARBONATE (Interaction) Reason : Unspecified schizophrenia

675 Milligram Daily

Batch: Started: L TERM Stopped: 0

PHENELZINE SULPHATE (Interaction) Reason: Unspecified schizophrenia

90 Milligram Daily

Batch: Started: L TERM Stopped: 0

PUTRAN02 Page 60 of 96

Medicine details: **QUETIAPINE** (Interaction) Reason: Unspecified schizophrenia 100 Milligram Daily LTERM Batch: Started: Stopped: Reason: Unspecified schizophrenia Ziprasidone (Interaction) 160 Milligram Daily Batch: Started: 05/06/2008 **Stopped**: 12/06/2008 0 **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** Reason: 40 Milligram Daily L TERM Started: Stopped: Batch: **INDAPAMIDE HEMIHYDRATE (Other drug)** Reason: 40 Milligram Daily Started : Stopped: Batch: **LEVLEN ED (Other drug)** Reason: 40 Milligram Daily

L TERM

Stopped:

Batch:

Started:

PUTRAN02 Page 61 of 96



Cases Count: 87

Case Number: 242735

Gender: M

Data Entry Date: 09/07/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 46Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: Seroquel increased to 300mg bd on 29/02/08.

Reaction:

Preferred Term Severity **Report Description Treatment**

Seizure

Convulsion Caused or prolonged

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason:

Capsule 150 Milligram Oral Daily

Batch: Started: Stopped:

SEROQUEL (Suspected) Reason:

600 Milligram Oral **Tablet** Daily

Batch: Started: Stopped: 0

ANDROCUR (Other drug) Reason:

> 25 Milligram Daily Oral

Started: Stopped: Batch:

AUGMENTIN DUO FORTE (Other drug) Reason:

> 175 Milligram Daily Oral

Batch: Started: 10/06/2008 Stopped:

PARACETAMOL (Other drug) Reason:

> 1 Gram As necessary Oral

Batch: Started: Stopped:

PUTRAN02 Page 62 of 96



Cases Count: 87

Case Number: 242913

Gender: F

Data Entry Date: 14/07/2008

Weight (kg): 0

Hospitalisation:

Age: 39Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Somnolence Somnolence.

Medicine details:

SEROQUEL (Suspected) Reason :

Tablet Oral

Batch: Started: Stopped:

PUTRAN02 Page 63 of 96



Hospitalisation:

Public Case Detail

6 times normal limits

Cases Count: 87

Case Number: 243044

Gender: F

Data Entry Date: 21/07/2008 **Weight (kg)**: 0

Age:

Onset Date: 20/06/2008 **DOB**: 21/03/1979

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood prolactin increased

Amenorrhoea Galactorrhoea

Hallucination, auditory

SOLIAN (Suspected)

Medicine details:

SEROQUEL (Suspected) Reason: Unspecified psychosis

Oral

Batch: Started: Stopped:

Reason: Unspecified psychosis

Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 64 of 96



Cases Count: 87

Case Number : 243355

Gender: F

Data Entry Date: 31/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 21Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: Patient had no history of neuroleptic malignant syndrome.

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant

syndrome

Dose of Seroquel was All three medications Ceased increased to 800mg daily as the lower dose was not

effective. In addition pt was on Epilim and Lithium. Pt developed neuroleptic malignant syndrome

Medicine details:

EPILIM (Suspected) Reason: Unspecifid affective psychosis

Tablet Oral

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

Tablet Oral

Batch: Started: Stopped: 0

SEROQUEL (Suspected) Reason: Unspecifid affective psychosis

Tablet 800 Milligram Daily Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 65 of 96



Cases Count: 87

Case Number: 243685

Gender: M

Data Entry Date: 11/08/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date:

DOB: 10/05/1933

Outcome:

Causality: Causality probable

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description Increased Cardiac

Treatment

Cardiac enzymes increased

Caused or prolonged inpatient hospitalisation

Enzymes

Medicine details:

SEROQUEL (Suspected)

Reason:

Tablet

Oral

Batch:

Started:

Stopped: 0

PUTRAN02 Page 66 of 96



Cases Count: 87

Case Number: 243796

Gender: M

Data Entry Date: 13/08/2008

Weight (kg): 80

Hospital is at ion:

Age:

Onset Date: 04/07/2008

DOB: 10/08/1961

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Urine flow decreased

Patient complained of passing small amount of urine only seems to occur during middle of day.

Nil

Medicine details:

Duloxetine hydrochloride (Suspected)

Reason: Depression

Capsule

60 Milligram

Daily

Oral

Batch :

Batch:

Started: 02/07/2008

Started: 27/06/2008

QUETIAPINE (Suspected)

Reason :

Oral

Tablet

900 Milligram

Daily

Stopped :

LITHIUM CARBONATE (Other drug)

Reason:

Reason:

Batch :

Started :

Stopped:

Stopped:

SEREVENT ACCUHALER (Other drug)

Vitamins and Minerals Combination (Other drug)

Stopped :

THIAMINE (Other drug)

Batch:

Reason:

Reason:

Batch :

Started :

Started:

Stopped :

Batch :

Started:

Stopped:

PUTRAN02 Page 67 of 96



Cases Count: 87

Case Number: 243820

Gender: F

Data Entry Date: 14/08/2008

Weight (kg): 157

Hospitalisation: Required a visit to the doctor

Age: 49Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information: This lady gained a lot off weight (90kg-> 120 kg) on previous antipsychotics (Zyprexa

and Solian) and on Stilnox (she became a compulsive eater).

Reaction:

Preferred Term

Severity

Report Description

Treatment

Cease Seroquel

Weight increased

Patient gained a lot of weight despite dieting,

cannot lose weight.

Weight loss poor

٨	1	ec	ik	ci	ne	e d	le	tai	Is	
	, .	$\mathbf{\cdot}$	41	•		, ,	•	ш		

SEROQUEL (Suspected)

Reason:

900 Milligram

Batch:

Started:

LAMICTAL (Other drug)

Reason:

Daily

Daily

Batch:

Started:

Stopped:

Stopped:

RIVOTRIL (Other drug)

Reason:

2 Milligram

50 Milligram

Daily

Batch:

Started:

Stopped:

PUTRAN02 Page 68 of 96



Cases Count: 87

Gender: M

Case Number: 243948

Data Entry Date: 20/08/2008 **Weight (kg)**: 75

Hospitalisation: Age: 59Y

Onset Date: 16/08/2006 **DOB**:

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Accidental overdose	Life threatening	Massive overdose of quetiapine with profound shock resistant to aggressive saline loading. Paradoxical and severe worsening of hypotension after commencemnet of adrenaline infusion. No report of such recorded in MIMS for quetiapine. Dramatic resolution of shock when noradrenaline substituted for adrenaline	
Shock	Life threatening		

Medicine details:

ADRENALINE (Suspected) Reason :

Batch: Started: Stopped: 0

QUETIAPINE (Suspected) Reason : Hypotension

Tablet Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 69 of 96



Cases Count: 87

Case Number: 243988

Hospitalisation: Age: 59Y

Onset Date: 15/07/2008 DOB:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction: **Preferred Term** Severity **Report Description Treatment** Tardive dyskinesia Incapacity/disability Tardive Dyskinesia. Seroquel discontinued Abnormal involuntary movements were observed including acute dystonia and tongue protrusion. Also experienced collapse. Incapacity/disability Syncope Reason:

Medicine details: SEROQUEL (Suspected) Tablet 200 Milligram Daily Oral Batch: Started: **Stopped**: 03/08/2008 AVANZA (Other drug) Reason: Batch: Started: Stopped: **CORDILOX SR (Other drug)** Reason: Batch: Started: Stopped: SOLIAN (Other drug) Reason: Stopped: Batch: Started: 0

PUTRAN02 Page 70 of 96



Cases Count: 87

Case Number: 244247

Gender: F

Data Entry Date: 29/08/2008 **Weight (kg)**: 0

Age:

Hospitalisation :
Onset Date :

DOB: 21/01/1960

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Batch:

Preferred Term Severity Report Description Treatment

Dyspnoea Shortness of breath Seroquel stopped

Medicine details:

SEROQUEL (Suspected) Reason: Anxiety neurosis

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

ALPRAZOLAM (Other drug) Reason :

Started:

4 Milligram Oral

EFEXOR (Other drug) Reason : Anxiety neurosis

Oral

Stopped:

Batch: Started: Stopped:

PUTRAN02 Page 71 of 96



Cases Count: 87

Case Number : 244428

Gender: F

Data Entry Date: 08/09/2008

Weight (kg): 60

Hospitalisation:

Age: 56Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Page 72 of 96

Constipation

Caused or prolonged inpatient

hospitalisation

Severe constipation.

Picoprep/enema, disempted

bowel.

Medicine details:

QUETIAPINE (Suspected)

Reason: Unspecified psychosis

Tablet

800 Milligram

Daily

Oral

Batch :

Started :

, TED

Stopped: 11/08/2008

FLUPENTHIXOL DECANOATE (Other drug)

Reason: Unspecified psychosis

Injection

60 Milligram Daily

Batch :

Started :

L TERM

Stopped:

PUTRAN02



Cases Count: 87

Case Number : 244672

Gender: F

Data Entry Date: 16/09/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 01/08/2008 DOB: 07/11/1966

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hypersomnia during a severe depression as above, didn't bother

episode i was advised to take one 25mg Seroquel tablet. due to multiple past reactions to drugs, i took 1/2 of a tablet - 12.5mg. As i was home alone i didn't realise how much i was sleeping. the first night about 12 hours, 2nd night 14, and on the third night i slept for 20 hours straight. when i woke up i noticed my face was ashen, my tongue was grey and swollen. i had had another anaphylactic reaction but due to my state of mind, didn't bother seeking help, i simply went back to sleep it off although it did take a few more days to get rid of the drowsiness and some swelling around the eyes.

Pallor

Tongue discolouration

Tongue oedema

Medicine details:

SEROQUEL (Suspected) Reason: Depression

Tablet 12.5 Milligram Daily Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 73 of 96



Cases Count: 87

Case Number: 245232

Hospitalisation: Admitted to hospital Age:

Onset Date : DOB: 11/03/1933

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

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

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

hypotention.

Neuroleptic malignant Caused or prolonged syndrome inpatient

inpatient hospitalisation

Orthostatic hypotension Caused or prolonged

inpatient hospitalisation

Medicine details :

ARICEPT (Interaction) Reason:

Tablet 10 Milligram Daily Oral

Batch: Started: 11/04/2008 Stopped:

Escitalopram (Interaction) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: 11/04/2008 Stopped:

SEROQUEL (Suspected) Reason :

Tablet 400 Milligram Daily Oral

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

PUTRAN02 Page 74 of 96



Cases Count: 87

Case Number : 245376

Gender: F

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

Hospitalisation : Age :

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

Outcome: 29/06/2008 Causality: Causality possible

Death, maybe drug

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

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

psychotic disorder.

Reaction:

Preferred Term Severity Report Description Treatment

Stillbirth - Drug Exposure during

pregnancy

- Stillbirth at 33/40 weeks

gestation

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

Pregnancy).

Drug exposure during

pregnancy

Intra-uterine death

Medicine details:

CIPRAMIL (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped: 0

SEROQUEL (Suspected) Reason: Unspecified psychosis

Tablet 1.2 Gram Daily Oral

Batch: Started: Stopped: 0

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

Batch: Started: Stopped: 0

Laboratory Investigations:

Type Range Date Tested Result Details

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

moving in utero, ultrasound revealed

fetal demise.

PUTRAN02 Page 75 of 96



Cases Count: 87

Age:

Case Number: 245384 Gender: M

Data Entry Date: 13/10/2008 **Weight (kg)**: 178

Hospitalisation :

Onset Date : DOB : 15/11/1974

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Somnolence

Weight increased from
110kg to 205kg while on
Zyprexa, gradually
developed gynecomastia
and sleep apnoea. Was
very drowsy a lot of the

time.

Gynaecomastia

Sleep apnoea syndrome

Weight increased

Medicine details:

RISPERDAL (Other drug)

SOLIAN (Other drug)

SEROQUEL (Suspected) Reason: Unspecified schizophrenia

Tablet 200 Milligram Daily Oral

Batch: Started: 01/06/2006 Stopped:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

Abilify (Other drug) Reason :

Batch: Started: Stopped:

Batch: Started: Stopped:

Batch: Started: Stopped:

STELAZINE (Other drug) Reason :

Batch: Started: Stopped:

Reason:

Reason:

PUTRAN02 Page 76 of 96



Cases Count: 87

Case Number: 245721

Gender: M

Data Entry Date: 21/10/2008

Weight (kg): 0

Hospital is at ion:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Weight increased

Weight increase from 75kg

to 100kg.

Medicine details:

SEROQUEL (Suspected)

Reason:

Tablet

Oral

Stopped:

Batch: Started:

PUTRAN02 Page 77 of 96



Cases Count: 87

Case Number: 246054 Gender: F

Data Entry Date: 07/11/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 30/09/2008 **DOB**: 21/03/1973

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction :				
Preferred Term	Severity	Report Description	Treatment	
Mania		Patient was becoming Manic, depressed with noticable dyskinetic movements of jaw and small movement of toes bilaterally.		
Depression				
Dyskinesia				
Medicine details :				
SEROQUEL (Suspected)		Reason :		
Batch :	Started :	Stopped :		

Medicine details :				
SEROQUEL (Suspected)	Re	ason :		
Batch :	Started :	Stopped :		
Zeldox (Suspected)	Reason: Unspecifid affective psychosis			
	80 Milligram	Daily Ora	al	
Batch :	Started : 26/08/2008	Stopped :	0	
Cymbalta (Other drug)	Re	ason :		
Batch :	Started :	Stopped :		
OXYCONTIN (Other drug)	Re	ason :		
Batch :	Started :	Stopped :		
QUILONUM SR (Other drug)	Re	ason :		
Batch :	Started :	Stopped :		

PUTRAN02 Page 78 of 96



Cases Count: 87

Case Number: 246055

Gender: M

Data Entry Date: 07/11/2008

Weight (kg): 0

Hospitalisation: Hospitalisation prolonged

Age: 38Y

Onset Date: 05/11/2008

DOB:

DOD .

Outcome:

Causality: Causality possible

Unknown

Information: CTN re zolpidem use

Reaction:

Preferred Term Severity

Caused or prolonged

In hospital with agitation and acute anxiety patier

Report Description

Treatment seroquel and zolpidem stopped.

inpatient hospitalisation and acute anxiety ;patient complained of absences ,

then had a Grand mal

seizure

Medicine details:

Grand mal convulsion

SEROQUEL (Suspected) Reason: Anxiety neurosis

Tablet Oral

Batch: **Started**: 01/11/2008 **Stopped**: 05/11/2008 0

Zolpidem tartrate (Suspected) Reason :

Oral

Batch: **Started**: 01/11/2008 **Stopped**: 05/11/2008

EPILIM (Other drug) Reason :

500 Milligram Daily

Batch: Started: 01/11/2003 Stopped:

PUTRAN02 Page 79 of 96



Cases Count: 87

Gender: F

Case Number: 246089

Data Entry Date: 10/11/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 15/10/2008 **DOB:** 23/01/1983

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Amnesia Caused or prolonged

inpatient hospitalisation Memory loss, loss of coordination, chronic diarrhoea, twitching on right side of the body, hives which required hospitalisation. Following withdrawal of Seroquel, patient has experienced insomnia and is currently feeling suicidal due to lack

of sleep.

Coordination abnormal Caused or prolonged

inpatient

hospitalisation

Diarrhoea Caused or prolonged

> inpatient hospitalisation

Insomnia Caused or prolonged

> inpatient hospitalisation

Muscle twitching Caused or prolonged

> inpatient hospitalisation

Suicidal ideation Caused or prolonged

> inpatient hospitalisation

Urticaria Caused or prolonged

> inpatient hospitalisation

Caused or prolonged Withdrawal syndrome

inpatient

hospitalisation

Medicine details:

SEROQUEL (Suspected) Reason:

Oral

Ratch : Started: 15/05/2008 **Stopped**: 15/09/2008

PUTRAN02 Page 80 of 96



Cases Count: 87

Case Number: 246265

Gender: F

Data Entry Date: 14/11/2008

Information:

Weight (kg): 0

Hospitalisation:

Age: 31Y

Onset Date: 10/06/2008 DOB:

Outcome:

Causality: Causality possible

Unknown

Reaction:

Preferred Term Severity **Report Description**

Treatment

Anxiety

Caused or prolonged inpatient

Situation crisis- anxiety attack, tachycardia

Tachycardia

Caused or prolonged

inpatient

hospitalisation

hospitalisation

Medicine details:

SEROQUEL (Suspected)

Reason: Unspecified schizophrenia

Oral

0

Page 81 of 96

Tablet

Batch:

Started: 02/04/2008

Stopped: 10/06/2008

PUTRAN02



Cases Count: 87

Case Number : 246300

Gender: F

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

Hospitalisation: Admitted to hospital **Age**: 49Y

Onset Date: 06/05/2008 **DOB**:

Outcome: 06/05/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dysphagia Caused or prolonged Tingling and numbness to Ceased seroquel. Given

inpatient lips/mouth. (altered Cogentin. hospitalisation sensations). Also stiffness

of shoulders, difficulty

swallowing.

Arthralgia Caused or prolonged

inpatient hospitalisation

Hypoaesthesia oral Caused or prolonged

inpatient hospitalisation

Paraesthesia oral Caused or prolonged

inpatient hospitalisation

Medicine details :

SEROQUEL (Suspected) Reason: Unspecifid affective psychosis

100 Milligram 1 time

Batch: Started: Stopped:

CATAPRES (Other drug) Reason :

50 Microgram Daily

Batch: Started: Stopped:

LAMICTAL (Other drug) Reason :

100 Milligram Daily

Batch: Started: Stopped:

PROGYNOVA (Other drug) Reason :

2 Milligram Daily

Batch: Started: Stopped:

Seretide 250/25 MDI (Other drug) Reason :

2 Dose Unspec Daily

Batch: Started: Stopped:

TEMAZE (Other drug) Reason :

1 Dose Unspec As necessary

Batch: Started: Stopped:

PUTRAN02 Page 82 of 96

Medicine details :					
TRIPRIM (Other drug)	Reason :				
		300 Milligram	Daily		
Batch :	Started :			Stopped :	

PUTRAN02 Page 83 of 96



Cases Count: 87

Case Number: 246383

Gender: F

Data Entry Date: 19/11/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date:

DOB: 29/11/1982

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Spina bifida

Life threatening

Fell pregnant whilst on Epilim. Epilim ceased at 5.5 weeks pregnant. 19 week ultrasound showed severe spina bifida

myelomeningocoele. Pregnancy terminated.

Meningomyelocele

Life threatening

Medicine details:

EPILIM EC 500 (Suspected)

Reason: Unspecifid affective psychosis

Tablet

1 Gram

Daily

Oral

Batch:

Started: 11/04/2008

Stopped: 03/06/2008

SEROQUEL (Suspected)

Tablet

Reason:

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 84 of 96



Cases Count: 87

Gender: F

Case Number: 246490

Data Entry Date: 24/11/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: DOB: 20/01/1973

Causality: Causality possible Outcome:

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Anxiety Worsening anxiety, drug Added Haloperidol

inpatient exposure during

hospitalisation pregnancy, worsening of

psychosis, dyskinesia.

Drug exposure during Caused or prolonged pregnancy

inpatient hospitalisation

Caused or prolonged Psychotic disorder

inpatient hospitalisation

Medicine details:

SEROQUEL (Suspected) Reason:

Tablet 800 Milligram Oral

Batch: Started: Stopped: 0

PUTRAN02 Page 85 of 96



Cases Count: 87

Case Number: 246492

Gender: F

Data Entry Date: 24/11/2008

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred TermTardive dyskinesia

Severity

Report Description

Treatment

Tardive dyskinesia

Medicine details:

SEROQUEL (Suspected)

Reason:

iveason

200 Milligram

Oral

Tablet Batch :

Started:

Stopped:

PUTRAN02 Page 86 of 96



Cases Count: 87

Case Number: 246506

Gender: F

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

Hospitalisation : Age :

Onset Date: DOB: 20/01/1973

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Given Haloperidol in Haloperdol ceased and

conjunction with Seroquel Seroquel increased to 800mg.

which led to dyskinesia.

Medicine details:

HALOPERIDOL (Suspected) Reason :

Tablet Oral

Batch: Started: Stopped: 0

SEROQUEL (Suspected) Reason :

Tablet

Batch: Started: Stopped:

PUTRAN02 Page 87 of 96



Cases Count: 87

Case Number : 246572

Mainlet (len)

Data Entry Date : 25/11/2008

Weight (kg): 0

Gender: M

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

Stress Death

Medicine details:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 200 Milligram Daily Oral

Batch: Started: 12/04/2000 Stopped:

QUETIAPINE (Suspected) Reason :

Batch: Started: Stopped:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

Batch: Started: 22/04/2008 Stopped:

PUTRAN02 Page 88 of 96



Cases Count: 87

Case Number: 246587

Gender: M

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

Hospitalisation : Age :

Onset Date : DOB : 04/03/1983

Outcome: Causality: Causality probable

Not yet recovered

Information: History of heroin dependence, drug dependence, drug abuse, social phobia and major

depression.

Reaction:

Preferred Term

Dysphemia

Severity

Incapacity/disability

Patient experienced a severe sorsening of his pre-existing stutter.

Treatment

Seroquel discontinued.

Medicine details	:	
SEROQUEL (Suspected)		Reason:
Tablet		Oral
Batch :	Started :	Stopped :
CATAPRES (Other drug)		Reason :
Batch :	Started :	Stopped :
DEPTRAN (Other drug)	rug) Reason : Depression	
Batch :	Started :	Stopped :
RIVOTRIL (Other drug)		Reason :
Batch :	Started :	Stopped :

PUTRAN02 Page 89 of 96



Cases Count: 87

Case Number: 246808 Gender: M

Data Entry Date: 03/12/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Schizophrenia Had been taking Seroquel IR with good effect.

Switched to equivalent dose with Seroquel XR and experienced severe

relapse with hallucinations

and self harm

Hallucination

Self injurious behaviour

Medicine details:

Seroquel XR (Suspected) Reason:

Batch: Started: Stopped:

PUTRAN02 Page 90 of 96



Cases Count: 87

Gender: F

Case Number: 247000

Data Entry Date: 09/12/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date : DOB : 30/03/1976

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Weight increased - Weight gain of 15 kg

Medicine details:

SEROQUEL (Suspected) Reason: Unspecifid affective psychosis

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped: 0

PROZAC (Other drug) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 91 of 96



Cases Count: 87

Case Number : 247210

Gender: M

Data Entry Date: 17/12/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 28/01/1974

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Left ventricular dysfunction

Left ventricular dysfunction, ejection fraction decreased, lymphocytosis,

neutrophilla, neuroleptic malignant syndrome, sinus tachycardia, hypertension,

blood cholesterol increased, blood trigycerides

increased.Blood glucose increased, treatment noncompliance.

Blood cholesterol increased

Blood glucose increased

Blood triglycerides increased

Ejection fraction decreased

Hypertension

Lymphocytosis

Neuroleptic malignant

syndrome

Neutrophilia

Sinus tachycardia

Treatment noncompliance

Medicine details:

CLOPINE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 600 Milligram
 Daily
 Oral

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

SEROQUEL (Suspected) Reason:

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Cholesterol Blood cholesterol high 7.1.
Serum glucose Blood glucose high 5.7

PUTRAN02 Page 92 of 96

Laboratory Investigations:

Type Range Date Tested Result Details

Blood pressure 140/90

Usal blood pressure.

Triglyceride High 6.8

Echocardiogram 29/03/2005 Low normal LV contraction

with impaired relaxation.

02/06/2008 Mild global LV systolic

dysfunction.

Heart Rate 115 high

Patient normal ranged 88bpm-112bpm.

PUTRAN02 Page 93 of 96



Cases Count: 87

Case Number: 247297

Gender: F

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

Hospitalisation: Age: 30Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: The reporter's comments were as follows: Seroquel was considered suspect as the

patient was sensitive to increase and decrease of drug dose.

Reaction:

Preferred Term Severity Report Description Treatment

Sinus tachycardia

Medicine details:

SEROQUEL (Suspected) Reason: Unspecifid affective psychosis

800 Milligram Daily Oral

Batch: Started: Stopped:

LITHIUM CARBONATE (Other drug) Reason :

Oral

Batch: Started: Stopped:

PUTRAN02 Page 94 of 96



Cases Count: 87

Case Number: 247313

Gender: F

Data Entry Date: 22/12/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 24/12/1959

Outcome: 30/10/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depression Caused or prolonged Admitted to acute psych

inpatient ward with increase in hospitalisation depression with Bipolar

disorder.

Medicine details:

ACETYLCYSTEINE (Suspected) Reason: Unspecifid affective psychosis

Injection 2.2 Gram Daily

Batch: Started: 14/10/2008 Stopped:

PARNATE (Suspected) Reason : Unspecifid affective psychosis

Tablet 20 Milligram Daily Oral

Batch: Started: 15/07/2008 Stopped:

SEROQUEL (Suspected) Reason : Unspecifid affective psychosis

Tablet 100 Milligram Daily Oral

Batch: Started: 15/07/2008 Stopped:

PUTRAN02 Page 95 of 96



Onset Date:

Public Case Detail

Cases Count: 87

Case Number : 247816

Gender: F

Age:

Data Entry Date: 20/01/2009 **Weight (kg)**: 60

Hospitalisation: Required a visit to the doctor

DOB: 01/10/1954

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood triglycerides increased Triglycerides increased,

Ceased Seroquel

higher cholesterol.

Hypercholesterolaemia

Medicine details:

SEROQUEL (Suspected) Reason : Depression

 Tablet
 100 Milligram
 Daily
 Oral

 Batch :
 Started : 15/01/2008
 Stopped : 15/04/2008

Lexapro (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result **Details** Cholesterol 13/02/2006 5.7 Cholesterol 10/04/2008 9.5 Cholesterol 24/11/2008 8.5 Triglyceride 13/02/2006 5.1 Triglyceride 10/04/2008 14.9 24/11/2008 Triglyceride 6.1

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: ANATENSOL, ANATENSOL ENANTHATE FOR INJECTION, FLUPHENAZINE DECANOATE, FLUPHENAZINE ENANTHATE, FLUPHENAZINE HYDROCHLORIDE, FLUPHENAZINE NOS, MODECATE, NEULACTIL, PERICYAZINE, QUETIAPINE, SEROQUEL, Seroquel XR

PUTRAN02 Page 96 of 96