

Cases Count: 76

**Case Number: 231443** 

Gender: F

**Data Entry Date**: 02/08/2007 **Weight (kg)**: 62

Hospitalisation : Age :

Onset Date : DOB : 01/01/1971

Outcome: Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

Convulsion

Preferred Term Severity Report Description Treatment

Subdural haematoma Caused or prolonged had a fit and had a severe

inpatient head injury described as hospitalisation severe intracranial bleed

and hematoma

Caused or prolonged

inpatient hospitalisation

Medicine details:

Zeldox (Suspected) Reason: Unspecified psychosis

80 Milligram 2 times Oral

**Batch**: **Started**: 03/07/2007 **Stopped**: 25/07/2007 0

ZYPREXA (Suspected) Reason :

5 Milligram Daily Oral

Batch: Started: 01/07/2007 Stopped:

AMITRIPTYLINE HYDROCHLORIDE (Other drug) Reason :

150 Milligram

Batch: Started: Stopped: 0

EFEXOR-XR (Other drug) Reason :

250 Milligram

Batch: Started: Stopped: 0

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**Hospitalisation:** 

# **Public Case Detail**

**Cases Count: 76** 

Case Number: 231666

Gender: M

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

**Age:** 15Y

Onset Date: 01/01/2002

Outcome:

DOB:

misci bate : 0 mo m2002

Causality: Causality possible

Unknown

**Information:** Clare Masters

Newspaper Reporter The Dailt Telegraph.

Reaction:

Preferred Term Severity Report Description Treatment

Weight increased Excessive weight gain. Weight ballooning from

Weight ballooning from 60 kilograms to 100 kilograms

Medicine details:

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number : 231813** 

Gender: U

Data Entry Date: 10/08/2007

Weight (kg): 70

**Hospitalisation:** 

Age:

Onset Date: 10/07/2007

**DOB**: 15/05/1953

Outcome:

Causality: Causality possible

Death

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Death Death found dead at home on

couch.

Medicine details:

OLANZAPINE (Suspected) Reason :

2.5 Milligram Daily

**Started**: 23/05/2007

Stopped:

**DIAZEPAM (Other drug)** 

Reason:

ENDEP (Other drug)

Reason:

50 Milligram

Batch :

Batch:

Started:

Started:

Stopped:

Stopped:

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Cases Count: 76

**Case Number: 231907** 

Gender: M

**Data Entry Date**: 13/08/2007

Weight (kg): 92

**Hospitalisation:** 

Age:

Onset Date :

**DOB**: 01/12/1989

Outcome :

Causality: Causality possible

Not yet recovered

Information:

Reaction:

**Preferred Term** 

Severity Report Description

**Treatment** 

Hypothermia

Hypothermia noted by patient. Remains so at

Reduced dose of Zypresa

lower dose of Zyprexa.

Medicine details:

ZYPREXA (Suspected)

Reason:

2.5 Gram

Daily

Batch:

Temperature

Started: 02/05/2007

Stopped:

**Laboratory Investigations:** 

Type

Range

Date Tested Result

**Details** 

Recorded temp for 2.5 mg Zyprexa:

7am - 35.7, 6pm - 37.0

Recorded temp for 1.5 mg Zyprexa:

7am - 34.9

Never above 36 degrees in the morning

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Cases Count: 76

not respond well, recommenced

on Zyprexa.

Gender: M

Case Number: 232352

**Data Entry Date**: 22/08/2007 **Weight (kg)**: 0

Hospitalisation: Age: 34Y

Onset Date: 24/07/2007 DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Caused or prolonged Agitated state. Patient Switched to Ziprasidone but did

inpatient became obese. Diabetes

hospitalisation mellitus non-insulin-dependent.

Intentional overdose.

Caused or prolonged patient received zyprexia

Intentional overdose Caused or prolonged patient received zyprexia inpatient 20mg orally daily for the

inpatient 20mg orally daily for the hospitalisation treatment of schizophrenia

beginning on an unspecified date, but the patient routinely took more olanzapine than he was

prescribed on his own accord (approx 25-30mg

daily).

Obesity Caused or prolonged

inpatient hospitalisation

Type 2 diabetes mellitus Caused or prolonged

inpatient hospitalisation

Medicine details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 25 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 76

Case Number: 232668

Gender: M

**Data Entry Date:** 29/08/2007

Weight (kg): 0

**Hospitalisation:** 

Age: 39Y

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information: Medical condition: Bipolar disorder and family history of diabetes.

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Diabetes mellitus

Patient developed diabetes Olanzapine discontinued.

0

mellitus and slight weight

Started on amisulpride.

gain.

Weight increased

Medicine details:

**ZYPREXA (Suspected)** 

Reason: Unspecifid affective psychosis

Batch:

Started:

Stopped:

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Cases Count: 76

Case Number: 233012 Gender: M

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

Hospitalisation: Age: 54Y

Onset Date : DOB :

Outcome: 15/06/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Agranulocytosis Patient experienced

Treated with filgrastim, IV antibiotics (ceftazidime &

gentamycin).

Medicine details:

**OLANZAPINE (Suspected)**Reason: Unspecifid affective psychosis

25 Milligram Daily Oral

agranulocytosis,

Batch: Started: Stopped: 22/05/2007

Risperdal Consta (Suspected) Reason :

Injection 25 Milligram Fortnightly Intramuscular

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

RISPERIDONE (Suspected) Reason: Unspecifid affective psychosis

Tablet 1 Milligram Daily Oral

Batch: Started: Stopped: 23/05/2007

NEXIUM (Other drug) Reason :

Batch: Started: Stopped:

NORFLOXACIN (Other drug) Reason : Prophylaxis

Batch: Started: Stopped:

PHYTOMENADIONE (Other drug) Reason :

Batch: Started: Stopped:

PROPRANOLOL HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped: 0

SPIRONOLACTONE (Other drug) Reason :

Batch: Started: Stopped:

THIAMINE (Other drug) Reason :

Batch: Started: Stopped:

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Laboratory Inves	tigations :			
Туре	Range	Date Tested	Result	Details
White blood cells		08/05/2007	6.0	
White blood cells		22/05/2007	4.1	
White blood cells		23/05/2007	3.0	
White blood cells		25/05/2007	2.8	
White blood cells		26/05/2007	3.8	
White blood cells		28/05/2007	5.9	
White blood cells		30/05/2007	16.8	
White blood cells		04/06/2007	4.8	
White blood cells		07/06/2007	3.6	
White blood cells		09/06/2007	5.9	
White blood cells		10/06/2007	12.0	
White blood cells		15/06/2007	6.4	
Neutrophils		08/05/2007	2.38	
Neutrophils		22/05/2007	0.62	
Neutrophils		23/05/2007	0.3	
Neutrophils		25/05/2007	0.03	
Neutrophils		26/05/2007	0.08	
Neutrophils		28/05/2007	0.00	
Neutrophils		30/05/2007	3.19	
Neutrophils		04/06/2007	1.41	
Neutrophils		07/06/2007	0.00	
Neutrophils		09/06/2007	0.06	
Neutrophils		10/06/2007	1.56	
Neutrophils		15/06/2007	3.59	
Platelets		08/05/2007	126	
Platelets		22/05/2007	93	
Platelets		23/05/2007	85	
Platelets		25/05/2007	115	
Platelets		26/05/2007	94	
Platelets		28/05/2007	106	
Platelets		30/05/2007	117	
Platelets		04/06/2007	-	
Platelets		07/06/2007	94	
Platelets		09/06/2007	87	
Platelets		10/06/2007	79	
Platelets		15/06/2007	90	

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Cases Count: 76

**Case Number: 233800** 

Gender: M

**Data Entry Date: 26/09/2007** Weight (kg): 88

Age:

**Hospitalisation: Onset Date:** 

**DOB**: 01/12/1989

Outcome: 12/09/2007

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Weight increased Weight gain Ceased Olanzapine

Medicine details:

**ZYPREXA (Suspected)** Reason: Unspecified psychosis

Tablet 2.5 Milligram Daily Oral

Batch: Started: 02/05/2007 Stopped: 16/08/2007

ARIMA (Other drug) Reason:

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result **Details** 

Other data 07/05/2007 87kg Other data 07/06/2007 90.4kg Other data 21/06/2007 91.5kg

Other data 16/08/2007 9.35kg (ceased

olanzapine)

Other data 12/09/2007 88kg

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Cases Count: 76

**Case Number : 234007** 

Gender: M

**Data Entry Date**: 04/10/2007

Weight (kg): 0

**Hospitalisation:** 

**Age:** 30Y

iospitalisation .

DOB:

Onset Date: 14/11/2006 Outcome: 07/12/2006

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description
Neuroleptic malignant

**Treatment** 

Hydration with saline,

bromocriptine, benztropine.

Neuroleptic malignant syndrome

Caused or prolonged inpatient

hospitalisation

syndrome due to zuclopenthixol. Started fortnightly Clopixol depot end of July. Presented to ED complaining of rigidity, drooling, tremor. Given benztropine. On 20/11

found on floor unable to move. Catatonic state, unable to move arms and legs, difficulty in talking. Rhabdomyolysis. Mild

renal impairment.

Aphasia Caused or prolonged

inpatient

hospitalisation

Catatonia Caused or prolonged

inpatient

hospitalisation

Drooling Caused or prolonged

inpatient

hospitalisation

Hypertonia Caused or prolonged

inpatient

hospitalisation

Muscle rigidity Caused or prolonged

inpatient

hospitalisation

Renal impairment Caused or prolonged

inpatient

hospitalisation

Rhabdomyolysis Caused or prolonged

inpatient

hospitalisation

Tremor Caused or prolonged

inpatient

hospitalisation

Medicine details:

CLOPIXOL DEPOT (Suspected) Reason: Unspecified schizophrenia

Injection 200 Milligram Fortnightly Intramuscular

**Batch**: **Started**: 26/07/2006 **Stopped**: 20/11/2006

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Medicine details:

OLANZAPINE (Suspected) Reason :

20 Milligram Daily

**Batch**: **Started**: 26/07/2006 **Stopped**: 20/11/2006

Laboratory Investigations :					
Туре	Range	Date Tested	Result	Details	
Creatine phosphokinase	(20-200)	20/11/2006	44446		
Creatine phosphokinase	(20-200)	21/11/2006	29404		
Creatine phosphokinase	(20-200)	21/11/2006	29086		
Creatine phosphokinase	(20-200)	21/11/2006	18850		
Creatine phosphokinase	(20-200)	22/11/2006	133302		
Creatine phosphokinase	(20-200)	22/11/2006	10507		
Creatine phosphokinase	(20-200)	23/11/2006	5988		
Creatine phosphokinase	(20-200)	24/11/2006	4178		
Creatinine				Cr 129.	

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Cases Count: 76

**Case Number : 234569** 

Gender: M

**Data Entry Date :** 18/10/2007

Weight (kg): 3.2

Hospitalisation:

Age:

Onset Date: 25/09/2007

**DOB**: 25/09/2007

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

**Report Description** 

**Treatment** 

Convulsion neonatal

Caused or prolonged inpatient

? seizure activity at 4.5 hours of age associated with back arching, cycling

Intravenous fluids commenced. Infant retrieved to Flinders Medical Centre Level Three NICU. 1 x dose of Intravenous

hospitalisation

and jitteriness.

Phenobarb given.

Drug exposure during

pregnancy

Caused or prolonged

inpatient

hospitalisation

Feeling jittery

Caused or prolonged

inpatient

hospitalisation

Opisthotonus

Caused or prolonged

inpatient

hospitalisation

Medicine details:

**EFEXOR (Suspected)** 

Reason:

1 time

1 time

Oral

Batch :

Tablet

Tablet

Started: 01/01/2004

Stopped :

**OLANZAPINE** (Suspected)

Reason:

Oral

Batch :

Started: 01/01/2004

Stopped:

**Laboratory Investigations:** 

Type Albumin Range

Date Tested Result

Details

MRI Of head performed 28/9/07, Study

within normal limits.

EEG performed. This is a normal EEG with the child in the sleeping state.

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Cases Count: 76

**Case Number: 234667** 

Gender: F

**Data Entry Date**: 23/10/2007

Weight (kg): 0

**Hospitalisation:** 

**Age:** 84Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neutrophil count decreased Neutrophil reduced Olanzapine was stopped.

Medicine details:

OLANZAPINE (Suspected) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details
Neutrophils 1.0
1.7
1.2
1.9

White blood cells 3.9 3.4

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Cases Count: 76

Case Number: 234774

Gender: U

2.5mg daily.

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

Hospitalisation: Age: 17Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood cholesterol increased The patient experienced Olanzapine was reduced to

obesity and high

cholesterol.

Obesity Caused or prolonged

inpatient hospitalisation

Medicine details:

ZYPREXA (Suspected) Reason :

Tablet 20 Milligram Daily Oral

**Batch**: **Started**: 15/05/2007 **Stopped**: 0

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Cases Count: 76

**Case Number : 234793** 

Gender: M

**Data Entry Date**: 25/10/2007 **Weight (kg)**: 146

Hospitalisation: Age: 28Y

**Onset Date**: 15/02/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: Medical condition: Schizoaffective disorder.

Reaction:

Preferred Term Severity Report Description Treatment

Weight increased The patient's weight was 118 kg in Feb 2007 and

146 kg at time of reporting.

Overdose

Medicine details:

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

25 Milligram Daily

Batch: Started: 01/02/2007 Stopped:

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

Risperdal Consta (Other drug) Reason :

Injection Intravenous

Batch: Started: Stopped:

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Cases Count: 76

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

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**Hospitalisation:** 

# **Public Case Detail**

Cases Count: 76

Case Number: 235404

Gender: F

**Data Entry Date:** 19/11/2007 Weight (kg): 0

Age:

**DOB**: 25/08/1926 **Onset Date:** 

Causality: Causality possible Outcome:

Not yet recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Caused or prolonged Parkinsonism Patient experienced Olanzapine ceased.

inpatient

worsening of drug induced hospitalisation Parkinsonism.

Medicine details:

**OLANZAPINE** (Suspected) Reason:

Stopped: Batch: Started:

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**Cases Count: 76** 

Case Number: 235416

Gender: F

**Data Entry Date**: 19/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 90Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Electrocardiogram QT Patient experienced prolonged prolonged QTC.

Medicine details:

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number : 235800** 

Gender: M

**Data Entry Date**: 30/11/2007 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 12/11/2007 DOB: 01/04/1966

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Oedema peripheral

Oedema. Patient had 3

day history of increasing

change to Ziprasidone.

swelling of feet initially, now hands swelling too. Complaining of pain in feet

& numbness.

Hypoaesthesia

Pain in extremity

Medicine details:

OLANZAPINE (Suspected) Reason :

20 Milligram Daily Oral

Batch: Started: 22/10/2007 Stopped:

ALPRAZOLAM (Other drug) Reason :

Tablet 6 Milligram Oral

Batch: Started: Stopped:

ATORVASTATIN (Other drug) Reason :

Tablet 40 Milligram Oral

Batch: Started: Stopped:

DOXEPIN HYDROCHLORIDE (Other drug) Reason :

Capsule 250 Milligram Oral

Batch: Started: Stopped:

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**Cases Count: 76** 

Case Number: 235821

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

Hospitalisation : Age :

**Onset Date**: 20/02/2007 **DOB**: 30/06/1983

Outcome: Causality: Causality possible

Unknown

Information: Other drug taken: biotin, calcium pantothenate and retinol palmitate. History:

primigravida and ex-smoker.

Reaction:

Preferred Term Severity Report Description Treatment

Premature separation of

placenta

Patient experienced premature separation placental. antepartum haemorrhage and drug

exposure during pregnancy.

Antepartum haemorrhage

Drug exposure during

pregnancy

#### Medicine details:

**ZYPREXA (Suspected)** Reason: Unspecifid affective psychosis

Tablet 5 Milligram Daily Oral

Batch: Started: 20/02/2007 Stopped:

ASCORBIC ACID (Other drug) Reason :

Batch: Started: Stopped:

CALCIUM CARBONATE (Other drug) Reason :

Batch: Started: Stopped:

COPPER(I) CHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

CYANOCOBALAMIN (Other drug) Reason :

Batch: Started: Stopped:

ELEVIT RDI (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

ERGOCALCIFEROL (Other drug) Reason :

Batch: Started: Stopped:

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Medicine details	:			
FOLIC ACID (Other drug)		Reason :		
Batch :	Started :		Stopped :	
IRON (Other drug)	2.11.11.11	Reason :		
Batch :	Started :		Stopped :	
MAGNESIUM NOS (Other dru	g)	Reason :		
Batch :	Started :		Stopped :	
MANGANESE CHLORIDE (Oti	her drug)	Reason :		
Batch :	Started :		Stopped :	
NICOTINAMIDE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
PYRIDOXINE HYDROCHLORI	DE (Other drug)	Reason :		
Batch :	Started :		Stopped :	
RETINOL (Other drug)		Reason :		
Batch :	Started :		Stopped :	
RIBOFLAVINE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
TEMAZE (Other drug)		Reason :		
TEMALE (Other drug)		Reason .	Oral	
Batch :	Started :		Stopped :	
TEMAZEPAM (Other drug)		Reason :		
Batch :	Started :		Stopped :	
THIAMINE (Other drug)		Reason :		
Batch :	Started :		Stopped :	
ZINC (Other drug)		Reason :		
Batch :	Started :		Stopped :	

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**Cases Count: 76** 

**Case Number : 236027** 

Gender: U

**Data Entry Date**: 07/12/2007

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Severity

Started:

Information:

Reaction:

**Preferred Term** 

Report Description

**Treatment** 

Drug exposure during

pregnancy

One previous pregnancy during which patient was on Zyprexa, but the infant

on Zyprexa, but the infa had no complications.

Medicine details:

**ZYPREXA (Suspected)** 

Reason:

n Daily

Batch :

5 Milligram

Stopped:

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Cases Count: 76

**Case Number : 236029** 

Gender: U

**Data Entry Date**: 07/12/2007 **Weight (kg)**: 0

**Hospitalisation**: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

**Information:** The mother was continuing with olanzapine at the time of the initial report. The outcome

of the cysts on the brain was not repoted.

Reaction:

Cerebral cyst

Preferred Term Severity Report Description Treatment

Cysts on brain. Mother received Olanzapine, for an unspecified treatment beginning approximately two years from the initial

two years from the initial report (15 Nov 2007). The mother's compliance was questionable. Because of the questionable compliance, it was

Drug exposure in utero.

unknown if the foetus was exposed at conception or during which trimesters of the pregnancy. The expected date of delivery was reported as the end of

March 2008.

Drug exposure during

pregnancy

**Medicine details:** 

ZYPREXA (Suspected) Reason :

5 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Other data

On an unknown date, a scan was performed that showed the foetus had cysts on the brain. It was not known if the scan for the infant was verified by an

HCP.

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Cases Count: 76

Gender: M

**Case Number : 236085** 

**Data Entry Date**: 10/12/2007 **Weight (kg)**: 60

Hospitalisation: Age:

Onset Date : DOB : 05/04/1990

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

**Epistaxis** 

Preferred Term Severity Report Description Treatment

This patient had recurrent nose bleeds whilst on fluoxetine 40mg/day. He had been on fluoxetine, as well as olanzapine to 10mg/day, for about 2 months prior to the suspected adverse reaction. The patient decided to stop both medications on his own, and the nose bleeds stopped. He has since been started on sertraline to 75mg/day (and been on this for about 4 weeks), without a recurrence of nose bleeds. The reason for commencing an SSRI was to treat a depressive syndrome. I believe the possibility of an emerging psychosis was considered, although I do not believe that he is psychotic. This patient was treated as an outpatient throughout the course of this incident, with presentations to the

**Medicine details:** 

FLUOXETINE HYDROCHLORIDE (Suspected) Reason : Depression

40 Milligram 1 time Oral

**Emergency Department.** 

Batch: Started: Stopped: 10/11/2007

OLANZAPINE (Suspected) Reason: Unspecified psychosis

10 Milligram Daily Oral

Batch: Started: Stopped:

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Laboratory Investigations :

Туре Range Date Tested Result Details

Other data

I did not collect FBC during time of reaction, though I asked that his GP request FBD and coagulation studies.

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Cases Count: 76

**Case Number : 236895** 

Gender: M

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

Hospitalisation: Age:

**Onset Date**: 10/12/2007 **DOB**: 15/10/1964

Outcome: 10/12/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia Dystonic reaction of neck

muscles.

Medicine details:

OLANZAPINE (Suspected) Reason: Unspecified psychosis

20 Milligram Daily

Batch: Started: 05/12/2007 Stopped:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Otr spec symp psychopathol nec

Injection 150 Milligram 1 time

Batch: Started: 06/12/2007 Stopped:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason: Prophylactic inoculation and vaccination

Injection 350 Milligram Fortnightly

Batch: Started: 06/12/2007 Stopped:

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

40 Milligram Daily

Batch: Started: 05/12/2007 Stopped:

LITHIUM CARBONATE (Other drug) Reason :

Tablet 1.5 Gram Oral

Batch: Started: 05/12/2007 Stopped:

SODIUM VALPROATE (Other drug) Reason :

2 Gram

Batch: Started: 05/12/2007 Stopped:

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Cases Count: 76

**Case Number : 237066** 

Gender: F

**Data Entry Date:** 18/01/2008 Weight (kg): 50

Hospitalisation: Admitted to hospital Age:

Onset Date: 01/01/2008 **DOB**: 03/01/1991

Outcome: Causality: Causality possible

Not yet recovered

Information: Prolonged hospitalisation and absence from productive with 1 year detention in

psychiatric units. Patient has a known history of adverse reactions to many

pharmacological medications (GP) yet treaters psychiatrics in 07 have ignored this and follow of ongoing high doses ( Zyprexa reached 30mg ). Psychiatrists will not alter treatment. Child had history of: pre-natral brain damage, epilepsy, hypoglyceamic. Family has history of breast cancer. High use of multiple drugs on top of Zyprexa from Jan to Dec 07 and ongoing in detention in psychiatric facilities. Psychiatrists will not

respond to requests to cease.

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Suicide attempt Patient attempted suicide Life threatening cutting arms, collapsing, (often absent longer than 15 mins, itchy rash over

body, involuntary shaking and fine tremors,

hallucinations-delirium and

akathisia.

Akathisia Life threatening

Delirium Life threatening

Hallucination Life threatening

Intentional self-injury Life threatening

Loss of consciousness Life threatening

**Pruritus** Life threatening

Rash Life threatening

Tremor Life threatening

Medicine details:

Batch:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet As necessary Oral

Started: 15/07/2007 Batch: Stopped: Ongoing.

**EPILIM (Suspected)** Reason: Other&unspecified epilepsy

> 1 Gram Daily

Stopped:

Started .

ZYPREXA (Suspected) Reason: Unspecified psychosis

> 10 Milligram Daily

Started: 15/01/2007 Batch: Stopped:

PUTRAN02 Page 27 of 89 Medicine details: Abilify (Other drug) Reason: Unspecified psychosis 10 Milligram Daily Tablet Oral Started: Batch: Stopped: Reason: Specific disorders of sleep **TEMAZEPAM (Other drug)** 1 Dose Unspec Daily Tablet Oral Batch: Started: Stopped: VALIUM (Other drug) Reason : Otr spec symp psychopathol nec Tablet As necessary Oral Stopped: Batch: Started:

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Cases Count: 76

**Case Number : 237110** 

Gender: M

**Data Entry Date**: 21/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 69Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: patient is overweight and has a history of familial hypercholesterolaemia

Reaction:

Preferred Term Severity Report Description Treatment

Blood cholesterol increased Caused or prolonged

inpatient

hospitalisation

Patient receiving Efexor XR for approximately 12

years experiencd triglycerides increased and

triglycerides increased ar cholesterol increased,

pancreatitis.

Blood triglycerides increased Caused or prolonged

inpatient

hospitalisation

Pancreatitis Caused or prolonged

inpatient

hospitalisation

Medicine details:

CARBAMAZEPINE (Suspected) Reason :

400 Milligram

Batch: Started: Stopped:

EFEXOR-XR (Suspected) Reason:

450 Milligram Daily Oral

Batch: Started: Stopped:

ZYPREXA (Suspected) Reason :

5 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result **Details Biochemistry** 3.9-5.5 mmol/L 04/01/2008 29.7 cholesterol **Biochemistry** 3.9-5.5 mmol/L 06/01/2008 31.9 cholesterol **Biochemistry** 0.5-1.5 mmol/L 04/01/2008 107 **Triglycerides** 0.5-1.5 mmol/L 06/01/2008 **Biochemistry** 86.2 **Triglycerides** 

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**Cases Count: 76** 

**Case Number : 237847** 

Gender: F

**Data Entry Date**: 12/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 27Y
Onset Date: DOB:

Outcome: 11/11/2007 Causality: Causality possible

Death

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Incontinence Death Patient experienced incontinence, was

hospitalised, completed

suicide.

Completed suicide Death Hospitalisation Death

Medicine details:

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 76** 

**Case Number: 238541** 

Gender: F

Data Entry Date: 03/03/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 65Y

Onset Date: 15/02/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

**Report Description** 

**Treatment** 

Cerebrovascular accident

Stroke on left side of brain.

Cerebrovascular accident

**Medicine details:** 

ZYPREXA (Suspected)

 $\textbf{Reason:} \ \textbf{Unspecifid affective psychosis}$ 

15 Milligram

Daily

Oral

Batch:

Started: 15/10/2007

Stopped:

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Cases Count: 76

Case Number: 238661 Gender: M

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

Hospitalisation: Age: 64Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug interaction Confusion and agitation when recieving other meds

with Clofen.

Agitation

Confusional state

**PHENERGAN** (Interaction)

Medicine details :					
CLOFEN (Interaction)		Reason :			
Tablet					
Batch :	Started :	L TERM	Stopped :	0	
NEURONTIN (Interaction)		Reason :			
Batch :	Started :		Stopped :		
OLANZAPINE (Interaction)		Reason :			

Reason:

Stopped:

Batch : Started :

Batch: Started: Stopped: 0

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Cases Count: 76

Age:

**Case Number : 239352** 

Hospitalisation: Admitted to hospital

Gender: F

**Data Entry Date**: 31/03/2008 **Weight (kg)**: 95

Onset Date: 04/03/2008 DOB: 01/11/1952

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depressed mood Caused or prolonged

inpatient hospitalisation Gradual worsening of depressed mood over the past six weeks, to the point of feeling suicidal and at risk of harming herself.

Medicine details:

ACETYLCYSTEINE (Suspected) Reason: Unspecifid affective psychosis

Batch: Started: Stopped:

EFEXOR (Suspected) Reason: Unspecifid affective psychosis

375 Milligram Daily

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Suspected) Reason : Unspecifid affective psychosis

Tablet 900 Milligram Daily Oral

Batch: Started: Stopped: 0

**VALIUM (Suspected)** Reason: Unspecifid affective psychosis

10 Milligram Daily

Batch: Started: Stopped:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

30 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 239575** 

Gender: M

Age:

**Data Entry Date:** 03/04/2008

Onset Date: 05/03/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

**DOB**: 02/05/1925

Outcome:

Recovered

Causality: Causality possible

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Neutropenia

Caused or prolonged inpatient

Neutropenia

Olanzapine and all other medications withheld

hospitalisation

Medicine details:

**OLANZAPINE (Suspected)** 

Reason:

Daily

Batch:

Started:

Reason:

Stopped:

Stopped:

**ASPIRIN** (Other drug)

100 Milligram

160 Milligram

90 Milligram

5 Milligram

Daily

Oral

Batch:

Started:

Reason:

Daily

Oral

Batch:

Started:

Stopped:

**GLICLAZIDE** (Other drug)

FRUSEMIDE (Other drug)

Reason:

Daily

Oral

Batch:

Started:

Stopped:

**IRBESARTAN** (Other drug)

Reason: 300 Milligram

Daily

Oral

Batch:

Started:

Stopped:

### **Laboratory Investigations:**

Type Range	e Date Tested	Result	Details
Neutrophils	05/03/2008	0,2	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	06/03/2008	0.8	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	07/03/2008	1.2	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	08/03/2008	1.4	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	09/03/2008	1.9	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	10/03/2008	2.4	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	11/03/2008	4.1	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	13/03/2008	4.7	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	14/03/2008	4.6	Neutrophilis on 11/02/08 had been 9.9
Neutrophils	15/03/2008	5.9	Neutrophilis on 11/02/08 had been 9.9

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**Cases Count: 76** 

Gender: F

Case Number: 239580

**Data Entry Date**: 03/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 30Y

Onset Date: 01/10/2007 DOB:

Outcome: Causality: Causality possible

After tapering this medication for 9 weeks I

Unknown

Information:

Drug withdrawal syndrome

Reaction:

Preferred Term Severity Report Description Treatment

ceased taking it, after
which I immediately
experienced a 'withdrawal'
period that began with
intense vomiting (up to 30
times a day for the first two
weeks) and included
vertigo, oscillopsia,
headaches and migraines,
a feeling of pressure and
pain in my head, teeth
grinding, insomnia,

dizziness, dry mouth, hot flushes and sweats (drenching my clothes and sheets), shivering, intolerance to reading, tv or computer, hypersensitivity to heat, sound, light, smell and movement, extreme exhaustion, sores on my body, inability to sit or stand without vomiting, extreme muscle fatigue, racing heart (around 160bpm resting, eventually decreasing to 95bpm), lowered blood pressure,

passing out and nausea. This lasted at a high intensity for 6 weeks, and then only eased slightly. I continued to experience these effects for about

three months after ceasing

Zyprexa.

#### Medicine details:

ZYPREXA (Suspected) Reason :

5 Milligram Daily Oral

Batch: Started: Stopped:

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Medicine details :			
EDRONAX (Other drug)		Reason:	
		8 Milligram Daily	
Batch :	Started :		Stopped:
LOGYNON ED (Other drug) Reason :			
Batch :	Started :		Stopped:

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Extreme redness and

Cases Count: 76

**Case Number: 239623** 

Gender: F

**Data Entry Date:** 07/04/2008 Weight (kg): 0

Hospitalisation: Admitted to hospital Age: 99u

DOB: Onset Date: 15/02/2008

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Caused or prolonged Erythema

inpatient

swelling of both legs from hospitalisation her ankles up to her knees.

Oedema peripheral Caused or prolonged

inpatient

hospitalisation

Medicine details:

**ZYPREXA (Suspected)** Reason: Unspecifid affective psychosis

**Tablet** Oral

Batch: Started: 15/02/2008 Stopped:

**SODIUM VALPROATE (Other drug)** Reason:

Batch: Started: Stopped:

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Cases Count: 76

Case Number: 239915

**Data Entry Date**: 14/04/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date : DOB : 20/11/1934

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Leukopenia Patient was neutropenic. Gentamicin and timentin given

for febrile neutopenia.

Febrile neutropenia

**Medicine details:** 

OLANZAPINE (Suspected) Reason : Otr spec symp psychopathol nec

5 Milligram Daily

Batch: Started: 23/02/2007 Stopped: 26/02/2007

ANUSOL (Other drug) Reason :

Batch: Started: Stopped:

**ENOXAPARIN (Other drug)** Reason : Prophylaxis

40 Milligram Daily

Batch: Started: Stopped:

FOLIC ACID (Other drug) Reason :

10 Milligram

Batch: Started: Stopped:

HALOPERIDOL (Other drug) Reason :

Batch: Started: Stopped:

LORAZEPAM (Other drug) Reason :

2 Milligram

Batch: Started: Stopped:

MULTIVITAMINS (Other drug) Reason :

Batch: Started: Stopped:

PANTOPRAZOLE (Other drug) Reason :

40 Milligram

Batch: Started: Stopped:

THIAMINE (Other drug) Reason :

100 Milligram

Batch: Started: Stopped:

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Laboratory Inve	stigations :			
Туре	Range	Date Tested	Result	Details
Neutrophils		13/02/2007	3.09	
Neutrophils		26/02/2007	0.75	
Neutrophils		26/02/2007	0.91	
Neutrophils		27/02/2007	1.42	
Neutrophils		28/02/2007	1.15	
Neutrophils		01/03/2007	1.11	
Neutrophils		02/03/2007	0.89	
Neutrophils		05/03/2007	0.92	
Neutrophils		09/03/2007	2.65	
White blood cells		13/02/2007	5.24	
White blood cells		26/02/2007	1.54	
White blood cells		26/02/2007	1.94	
White blood cells		27/02/2007	3.11	
White blood cells		28/02/2007	2.48	
White blood cells		01/03/2007	2.76	
White blood cells		02/03/2007	2.13	
White blood cells		05/03/2007	2.15	
Temperature		19/02/2007	36.9	
Temperature		20/02/2007	36.7	
Temperature		21/02/2007	36	
Temperature		22/02/2007	36.8	
Temperature		23/02/2007	36.5	
Temperature		24/02/2007	36.5 & 38	
Temperature		25/02/2007	36.5 & 38.5 & 38	
Temperature		26/02/2007	37 & 36.9	
Temperature		27/02/2007	37.2	
Temperature		28/02/2007	36	

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Cases Count: 76

**Case Number : 239978** 

Gender: M

**Data Entry Date:** 15/04/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 13/08/2007

**DOB**: 16/03/1980

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Pmhx: The patient had been admitted less than a month earlier for an attempted

suicide. After that admission he was discharged on 10 mg of Olanzapine.

and dystonia.

Discharged on the 14/8 and his CK was down to 6040.

Reaction:

**Preferred Term** 

Severity

**Report Description** Actue leg weakness. **Treatment** Olanzapine was ceased.

Neuroleptic malignant syndrome

Caused or prolonged inpatient hospitalisation

Hypertensive, tachycardic and febrile. Neck rigidity

Benztropine and IVT.

Dystonia Caused or prolonged

inpatient

hospitalisation

Hypertension

Caused or prolonged

inpatient

hospitalisation

Nuchal rigidity

Caused or prolonged

inpatient

hospitalisation

Pyrexia

Caused or prolonged

inpatient

hospitalisation

Tachycardia

Caused or prolonged

inpatient

hospitalisation

Medicine details:

**OLANZAPINE (Suspected)** 

Reason:

20 Milligram Daily

Batch:

Started:

Stopped:

Reason:

Batch:

Started:

Stopped:

**METHADONE HYDROCHLORIDE (Other drug)** 

FLUOXETINE HYDROCHLORIDE (Other drug)

Reason:

Creatine kinase MB

60 Milligram

40 Milligram

Batch:

Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result

CK was 12580 but had normal renal and

liver function

**Details** 

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Cases Count: 76

**Case Number : 240942** 

Gender: F

Data Entry Date: 15/05/2008

Weight (kg): 0

Hospital is at ion:

**Age:** 18Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

**Preferred Term** 

Report Description

**Treatment** 

Weight increased

Over a one year period gained 15kg and 20kg.

In March 2008 Olanzapine was discontinued and was switched

to risperidone.

Medicine details:

ZYPREXA (Suspected)

Reason: Unspecifid affective psychosis

10 Milligram

Daily

Oral

Batch:

Started: 15/04/2007

Severity

Stopped: 15/03/2008

**SODIUM VALPROATE (Other drug)** 

Reason:

Batch:

Started:

Stopped:

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Cases Count: 76

picked up for 36 hours masked

deteriorated and after a Code Blue event ended up in ICU

by other issues - patient

**Case Number: 241001** 

Gender: M

**Data Entry Date:** 16/05/2008

Weight (kg): 65

**Hospitalisation:** 

Age: 77Y

DOB:

Outcome: 21/03/2008

Causality: Causality possible

Death

Information:

Onset Date: 09/03/2008

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** Seriousness of reaction not

Depressed level of consciousness

Life threatening

Gradual onset of cluster of symptoms - non responsive, rigid limbs, tongue obstructing airway, respiratory depression leading to aspiration pneumonia - "extra pyramidal side effects" within 12/24 hours -?

neuroleptic malignant syndrome eventuating in lethal catatonia and subsequent death

Life threatening

Catatonia Death

Life threatening

Extrapyramidal disorder

Life threatening

Hypertonia Hypokinesia Life threatening Life threatening

Pneumonia aspiration

Life threatening

Life threatening

Respiratory depression

Medicine details:

ZYPREXA (Suspected)

Reason:

5 Milligram

Daily

Oral

Batch:

Tablet

Started: 08/03/2008

Stopped: 10/03/2008

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**Cases Count: 76** 

**Case Number: 241135** 

Gender: F

**Data Entry Date**: 23/05/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 26Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term
Weight increased

Severity

**Report Description** 

**Treatment** 

Weight gain between 15

Discontinued olanzapine.

and 20kg.

Medicine details:

**ZYPREXA (Suspected)** 

 $\textbf{Reason:} \ \textbf{Unspecifid affective psychosis}$ 

Tablet

15 Milligram

Daily

Oral

Batch:

Started:

**Stopped**: 15/12/2007

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Cases Count: 76

**Case Number: 241141** 

Gender: M

**Data Entry Date: 23/05/2008** Weight (kg): 0

**Hospitalisation:** Age: 99u

Onset Date: 08/04/2008 DOB:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Tremor Caused or prolonged experiencing major

> inpatient extrapyramidal symptoms

hospitalisation including irregular gait, slow speech and tremor.

Extrapyramidal disorder Caused or prolonged

inpatient

hospitalisation

Speech disorder Caused or prolonged

inpatient

hospitalisation

Medicine details:

**OLANZAPINE** (Suspected) Reason:

> 20 Milligram Daily

Batch: Started: Stopped:

**DOTHEP (Other drug)** Reason:

150 Milligram

Batch: Started: Stopped:

LITHIUM CARBONATE (Other drug) Reason:

450 Milligram

Batch: Started: Stopped:

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Cases Count: 76

Elocon and Dermeze cream.

Seroquel and Zyprexa ceased.

Gender: M

**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.

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

Reason: On speciety

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:

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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: Stopped: Started: SORBOLENE CREAM WITH GLYCERINE 10% (Other drug) Reason: 1 Dose Unspec Daily Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 241220** 

Gender: M

**Data Entry Date: 27/05/2008** 

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Onset Date: 08/04/2008

Reaction:

Batch:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Fall

Caused or prolonged inpatient

hospitalisation

Seen in emergency after a fall the previous night.

Collagpse on the floor

during the night.

Medicine details:

**OLANZAPINE (Suspected)** Reason:

> 10 Milligram Daily

Started: Zeldox (Suspected) Reason:

> 80 Milligram Daily

Batch: Started: 28/03/2008 Stopped:

Stopped:

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**Cases Count: 76** 

**Case Number : 241476** 

Gender: M

**Data Entry Date**: 03/06/2008 **Weight (kg)**: 80

Age:

Hospitalisation :
Onset Date :

**DOB**: 25/02/1973

Outcome :

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Bradycardia Life threatening heart rate slowes down too much nearly causing heart

attack

Medicine details:

OLANZAPINE (Suspected) Reason :

Tablet 25 Milligram Daily Oral

Batch: Started: 04/05/1998 Stopped:

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Cases Count: 76

**Case Number: 241526** 

Gender: M

Age:

**Data Entry Date:** 03/06/2008 Weight (kg): 68

Hospitalisation: Admitted to hospital

**DOB**: 21/07/1979

Ceased Clopine

Onset Date: 06/05/2008

Causality: Causality possible

Not yet recovered

Information:

Outcome:

Reaction:

**Preferred Term Report Description** Severity **Treatment** 

Alanine aminotransferase

increased

Caused or prolonged

inpatient

hospitalisation

Aspartate aminotransferase

increased

Caused or prolonged

inpatient

hospitalisation

Medicine details:

**CLOZAPINE (Suspected)** Reason: Unspecified schizophrenia

125 Milligram

Daily

Oral

Batch: Started:

Stopped: Reason: Unspecified schizophrenia

Increased ALT and AST

**OLANZAPINE (Suspected)** 30 Milligram

Oral Daily

Batch: Started:

Stopped:

AMISULPRIDE (Other drug)

Started:

Stopped:

**DIAZEPAM (Other drug)** 

Batch:

Reason:

Reason:

Batch:

Started:

Stopped:

LORAZEPAM (Other drug)

Reason:

Batch:

Started:

Stopped:

THIAMINE (Other drug)

Reason:

Batch:

Started:

Stopped:

**Laboratory Investigations:** 

Range Date Tested Result **Details** Type

ALT = SGPT 11/04/2008 303 ?? May - ALT 509 ?? May - ALT 509 ALT = SGPT 28/04/2008 58 ALT = SGPT 06/05/2008 470 ?? May - ALT 509

AST = SGOT11/04/2008 99 AST = SGOT06/05/2008 199

PUTRAN02 Page 49 of 89 **Laboratory Investigations:** 

Туре Range Date Tested Result Details

GGT = SGGT = GGTP 28/04/2008 52

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Cases Count: 76

**Case Number: 241529** 

Gender: M

**Data Entry Date:** 03/06/2008

Weight (kg): 68

Hospitalisation: Admitted to hospital

Age:

Onset Date: 06/05/2008

**DOB**: 21/07/1979

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

**Preferred Term** 

**Report Description** Severity

**Treatment** 

Alanine aminotransferase increased

Caused or prolonged inpatient

Increased ALT and AST

Ceased Clozapine

Aspartate aminotransferase

Caused or prolonged

increased

inpatient

hospitalisation

hospitalisation

Medicine details:

**CLOPINE (Suspected)** Reason: Unspecified schizophrenia

100 Milligram

Oral

Batch:

Batch:

Started: 29/04/2008

Stopped:

**OLANZAPINE (Suspected)** 

Reason: Unspecified schizophrenia

30 Milligram

Daily

Daily

Oral

AMISULPRIDE (Other drug)

Reason:

Batch:

Started:

Started:

Stopped:

Stopped:

**DIAZEPAM (Other drug)** 

Reason:

Batch:

Started:

Started:

Stopped:

LORAZEPAM (Other drug)

Stopped:

THIAMINE (Other drug)

Reason:

Reason:

Batch:

Batch:

Started:

Stopped:

**Laboratory Investigations:** 

Range Date Tested Result Type Details

ALT = SGPT 11/04/2008 303 ?? May 08 - ALT 509 ALT = SGPT ?? May 08 - ALT 509 28/04/2008 58 ALT = SGPT 06/05/2008 470 ?? May 08 - ALT 509

AST = SGOT11/04/2008 99 AST = SGOT06/05/2008 199

PUTRAN02 Page 51 of 89 **Laboratory Investigations:** 

Type GGT = SGGT = GGTP Range Date Tested Result Details

28/04/2008 52

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Cases Count: 76

DOB:

**Case Number: 241868** 

**Gender**: F

**Data Entry Date**: 13/06/2008 **Weight (kg)**: 70

Hospitalisation: Age: 50Y

Outcome : Causality : Causality possible

Not yet recovered

Information:

Onset Date: 10/06/2008

Reaction:

Preferred Term Severity Report Description Treatment

Oedema peripheral Incapacity/disability One day after starting 5 mg cessation of medication, olanzapine, developed frusemide (self administered)

moderately severe peripheral oedema. Gradually resolving after stopping medication and taking one dose of

frusemide. Oedema mostly around feet but also noticed swollen fingers.

Medicine details:

OLANZAPINE (Suspected) Reason: Unspecifid affective psychosis

Tablet 10 Milligram Daily Oral

**Batch**: ?? **Started**: 09/06/2008 **Stopped**: 11/06/2008

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Cases Count: 76

Case Number: 242181

Gender: M

**Data Entry Date: 23/06/2008** 

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Severity

Age:

Onset Date: 23/06/2006

**DOB**: 15/07/1977

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** 

**Report Description** 

**Treatment** 

Abdominal pain upper

On drug trial. Developed stomach cramps and haematuria. ? URTI. Maculopapular rash.

Eosinophilia and microscopic haematuria.

Eosinophilia Haematuria

Medicine details:

**OLANZAPINE** (Suspected)

Reason: Unspecified psychosis

20 Milligram Daily

Batch:

Started: 31/03/2006

Stopped: 23/06/2008

**Laboratory Investigations:** 

Type

Other data

Range

Date Tested Result

**Details** 

Consultation: renal physician ->

interstitial nephritis, probably secondary

to Olanzapine.

Creatinine Normal

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Cases Count: 76

Case Number: 242201

Gender: F

**Data Entry Date: 24/06/2008** 

Weight (kg): 0

**Hospitalisation:** 

Age: 0Y

DOB:

**Onset Date:** Outcome:

Causality: Causality possible

Unknown

Information: Note set-up of Registry

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Drug exposure during

pregnancy

drug exposure via pregnancy: small foetus for

dates, small at birth, unresponsive to stimuli at

birth

Foetal growth retardation

Small for dates baby

Unresponsive to stimuli

Medicine details:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** 

Reason:

Daily

Oral

Batch:

Started: 01/08/2007

750 Milligram

20 Milligram

Stopped: 01/10/2007

**DILANTIN** (Suspected)

Reason:

Batch:

Started: 08/08/2007

Stopped: 15/08/2007

**OLANZAPINE (Suspected)** 

Reason:

Daily

Oral

Batch:

Started: 01/01/2007

**Stopped**: 12/02/2007

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**Cases Count: 76** 

Case Number: 242912 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

Depression suicidal Depression and suicidal.

**Medicine details:** 

OLANZAPINE (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 76

Case Number: 243006

Gender: F

**Data Entry Date**: 17/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 66Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information: Approx 12 days after all neuroleptics had been ceased the patient displayed waxy

flexibility and posturing. Became mute an uncooperative, was afebrile and CK remained within normal range. A diagnosis of catatonia was made. Lorazepam 1mg tds was commenced. Over the next week patient was discharged to a psycho-geriatric nursing

home.

Severity

#### Reaction:

Preferred Term

Neuroleptic malignant

syndrome

**Report Description** 

Treatment

Malignant Chlorpromazine and olanzaoine

ceased

Neuroleptic Malignant Syndrome, Pyrexia, Creatine Phosphokinase increased, Hypertonia, during the following 10

days, she had a

recurrence of persecutory delusions and she

remained agitated and fearful despite receiving olanzapine 15mg/day. Chlorpromazine 50mg at night was added to her rregimen. 48 hours after starting chlorpromazine, she became febrile and

exhibited increased muscle

tone and disturbance of consciousness.

Agitation

Altered state of consciousness

Fear

Hypertonia

Persecutory delusion

Pyrexia

#### Medicine details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

50 Milligram Daily

Batch: Started: Stopped: 0

**OLANZAPINE (Suspected)** Reason: Unspecified psychosis

Tablet 15 Milligram Daily Oral

Batch: Started: Stopped: 0

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Medicine details:

DONEPEZIL HYDROCHLORIDE (Other drug)

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Creatine INCREASED FROM 370 TO 1134 U/L

Creatine phosphokinase

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**Cases Count: 76** 

Gender: F

Case Number: 243134

**Data Entry Date**: 22/07/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date : DOB : 11/07/1970

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Bundle branch block This patient was on Tegretol and Zyprexa Tegretol treatment, dose discontinued.

Tegretol treatment, dose was 400 to 800mg for an unknown indication for a couple of years. The patient was diagnosed with "incomplete right block bundle of the heart" whilst on treatment with Tegretol. Patient also felt worsening

Patient also felt worsel ectopic beats.

Extrasystoles

Medicine details:

TEGRETOL (Suspected) Reason :

Tablet 400 Milligram Daily Oral

Batch: Started: Stopped: 27/06/2008

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 243149** 

Gender: F

**Data Entry Date**: 22/07/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: Reporter consumer. Patient also taking antipsychotics.

Reaction:

Preferred Term

Severity Report Description

Treatment

Pulmonary embolism

Pulmonary embolism and cardiac disorder.

Cardiac damage requiring a

pacemaker.

Cardiac disorder

Medicine details:

**ZUCLOPENTHIXOL DECANOATE (Suspected)** 

Reason:

Injection

Batch :

Started:

Stopped:

**ZYPREXA (Suspected)** 

Reason:

Injection, solution

20 Milligram

Daily

Intramuscular

Batch:

Started :

Stopped:

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Cases Count: 76

**Case Number: 243206** 

**Data Entry Date: 24/07/2008** 

Weight (kg): 60

Gender: M

**Hospitalisation:** 

Age:

Onset Date: 19/07/2008

**DOB**: 03/10/1923

Outcome: 20/07/2008

Causality: Causality possible

Recovered

Information:

Reaction:

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

and metaraminol.

ventilation, intravenous fluids

**Preferred Term** Hypothermia

Life threatening

Patient admitted to hospital Intubation/mechanical 3 weeks prior to adverse event. In the general ward

he was being treated for pneumonia, ? TB meningitis. On the 18/07 he was noted to be hypothermic. On the following morning, the patient was very agitated. Olanzapine 5mg was given at 11.30 am then at 1300.

(Total of 10mg). At 1530 the BP dropped acutely to 55/- GCS 6. Code Blue was called. Patient was intubed and transferred to

ICU,

Agitation Hypotension

Injection

Injection

Life threatening Life threatening

Medicine details:

OLANZAPINE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 10 Milligram 1 time Oral

Started: 19/07/2008 Stopped: 19/07/2008 Batch:

ACICLOVIR (Other drug)

Reason:

Reason:

600 Milligram 3 times Intravenous

Batch: Started: 17/07/2008 Stopped: 0

**BENZYLPENICILLIN** (Other drug)

4 times Intravenous

Batch: Started: 16/07/2008 Stopped: 0

2.4 Gram

ISONIAZID (Other drug) Reason:

Tablet 300 Milligram 1 time Oral

Batch: Started: 17/07/2008 Stopped:

RIFAMPICIN (Other drug) Reason:

Capsule 600 Milligram 1 time Oral

Batch: Started: 17/07/2008 Stopped:

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Cases Count: 76

Case Number: 243220 Gender: F

Data Entry Date: 25/07/2008 Weight (kg): 0

Hospitalisation: Age: 66Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentCatatoniaTwelve daysLorazepam

Catatonia

Twelve days
discontinuation of her
antipsychotic agents, she
exhibited symptoms of

catatonia.

Medicine details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

Batch: Started: Stopped:

**OLANZAPINE (Suspected)** Reason: Unspecified psychosis

Batch: Started: Stopped:

PUTRAN02 Page 62 of 89



Cases Count: 76

Case Number: 243301

Gender: F

**Data Entry Date: 29/07/2008** 

Weight (kg): 0

**Hospitalisation:** 

Age: 99u

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Unknown

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

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Abortion spontaneous

Multiple miscarriages while

taking Lovan and

olanzapine.

Drug exposure during

pregnancy

Medicine details:

LOVAN (Suspected)

Reason: Depression

20 Milligram

Daily

Oral

Batch:

Started: 15/09/1996

Stopped: 15/07/2008

0

**ZYPREXA (Suspected)** 

Reason:

Tablet Batch: 5 Milligram

Daily

Oral Stopped:

0

Started: 15/11/2004

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Cases Count: 76

**Case Number : 243543** 

Gender: M

**Data Entry Date**: 06/08/2008 **Weight (kg)**: 80

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

**Onset Date**: 17/06/2008 **DOB**: 09/02/1946

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash erythematous Rash started, started as Ceased Zyprexa, soap free blisters and pustules over washes.

blisters and pustules over abdomen, became widespread over trunk and

widespread over trunk an limbs, eczematous areas behindr knees, ongoing blisters around ankles, prurpuric patches over dependent areas, polymorphic drug reaction

polymorphic drug reaction

prob to olanzapine.

Blister

Drug eruption

Purpura

Medicine details:

**ZYPREXA (Suspected)** Reason: Unspecified psychosis

Tablet 20 Milligram Daily Oral

**Batch**: **Started**: 27/05/2008 **Stopped**: 20/06/2008

CLOPIXOL DEPOT (Other drug) Reason: Unspecified psychosis

Injection 200 Milligram Fortnightly Intramuscular

Batch: Started: 03/06/2008 Stopped:

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Cases Count: 76

IPPR, single dose of

phenobarbitone at 20mg/kg

**Case Number: 243564** 

Gender: M

**Data Entry Date**: 06/08/2008 **Weight (kg)**: 3.7

Hospitalisation: Age:

Onset Date: 24/06/2008 DOB: 24/06/2008

Outcome: 28/06/2008 Causality: Causality possible

Recovered

**Information:** 37 year old G3 P2 (now) woman whose blood group is A positive. She delivered at

Royal North Shore Hospital. She has a history of bipolar disorder. She conceived on

Epilim and Lexapro.

Neonatologists thought - not related to meconium, intrapartum hypoxia, no evidence of neonatal infection. Posibility that may be related to uterine hyperstimulation secondary

to IV Syntocinon but seems less likely due to normal blood gases.

Reaction:

Preferred Term Severity Report Description Treatment

Apgar score abnormal Was born at 17:13 hours with a birth weight of 3724

grams (55th centile). There was meconium stained liquor. Apgars were 2 at 1 minute, 3 at 5 minutes, 6 at 10 minutes and 8 at 15 minutes respectively, treated with intubation and suction below the cords. Was irritable, with

Was irritable, with increased tone, persistent high pitched cry, lip smacking and sucking

movements.

Hypoxic encephalopathy

Medicine details:

OLANZAPINE (Suspected) Reason :

2.5 Milligram Daily

Batch: Started: Stopped:

BENZYLPENICILLIN (Other drug) Reason :

1.2 Gram Intravenous

Batch: Started: Stopped:

SYNTOCINON (Other drug) Reason :

10 Unit

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

pH Arterial cord pH was 7.424 and the base

excess -5

Liver function tests LFT's were mildly elevated on day 1

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Laboratory Investigations :							
Туре	Range	Date Tested	Result	Details			
Other data				Intrapartum monitoring and cord gases were normal. Haematology (24/06/08) HB 172 g/l, Hct 49 WCC 16.5 x 10*9/L Platelets 234 x 10*9/L Biochemistry (26/06/08) Na 141 mmol/L, K 4.1 mmol/L, iCA 1.22 mmol/L, Creat 45 umol/L Last SBR (26/06/08) SBR 176 umol/L micromol/L			
Ultrasound				A head ultrasound on 26/06/08 showed no evidence of intraventricular haemorrhage or oedema			

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Cases Count: 76

**Case Number: 243887** 

Gender: F

Age:

**Data Entry Date**: 18/08/2008 **Weight (kg)**: 55

Hospitalisation: Required a visit to the doctor

Onset Date: 07/08/2008 DOB: 29/01/1920

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Grand mal convulsion Seizure grand mal,,(

previously on 2.5mg daily for 2 years-dose increased to 5mg daily in late June

Stopped:

2008).

Medicine details:

ZYPREXA (Suspected) Reason :

5 Milligram Daily

**Started**: 20/06/2008

ALPRAZOLAM (Other drug) Reason : Anxiety neurosis

Tablet 250 Microgram Daily Oral

Batch: Started: L TERM Stopped:

PREDNISOLONE (Other drug) Reason : Otr mus rheum,fibrosit&myalgia

Tablet 1 Milligram Daily Oral

Batch: Started: L TERM Stopped:

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Cases Count: 76

Case Number: 244084

Gender: F

**Data Entry Date: 22/08/2008** 

Weight (kg): 64

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 16/07/2008

**DOB**: 24/08/1951

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Hepatic function abnormal

Skin rash, abnormal LFT's. Zyprexa ceased, topical agent

for skin reaction, regular blood

tests.

Rash

Medicine details:

**ZYPREXA (Suspected)** 

Reason: Unspecified psychosis

20 Milligram

Daily

Batch:

Started: 04/07/2008

**Stopped**: 18/07/2008

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Cases Count: 76

Case Number: 244085

Hospitalisation: Admitted to hospital

Gender: F

**Data Entry Date: 22/08/2008** Weight (kg): 35

Age:

Onset Date: 06/07/2008 **DOB**: 15/11/1971

Outcome: 07/07/2008 Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Caused or prolonged Dystonia Dystonic reaction Medication ceased, IMI

inpatient hospitalisation cogentin, oral cogentin

Medicine details:

**ZYPREXA (Suspected)** Reason: Otr spec symp psychopathol nec

> 10 Milligram Daily

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

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Cases Count: 76

Case Number: 244167

Gender: M

**Data Entry Date: 26/08/2008** 

Weight (kg): 88

Hospitalisation: Admitted to hospital

Age:

Onset Date: 05/01/2008

**DOB**: 17/05/1959

Outcome:

Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Blood cholesterol increased

Life threatening

Heart attack, high

cholesterol.

Myocardial infarction

Life threatening

Medicine details:

Reason: Unspecified schizophrenia

2.5 Milligram

Daily

Batch:

**ZYPREXA (Suspected)** 

Started: 15/01/1997

Stopped: 15/02/2008

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**Cases Count: 76** 

Case Number: 244397

Gender: F

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

Hospitalisation: Admitted to hospital Age:

**Onset Date**: 14/08/2008 **DOB**: 18/06/1938

Outcome: Causality: Causality possible

Unknown

Information: past history of TIA and tinnitus; continues herbal medicines. against doctor's advice

Reaction: **Preferred Term** Severity **Report Description Treatment** Convulsion Caused or prolonged seizure, tinnitus, insomnia, drug ceased. inpatient shakiness and collapse. hospitalisation Caused or prolonged Insomnia inpatient hospitalisation **Tinnitus** Caused or prolonged inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation

Medicine details: Zeldox (Suspected) Reason: Unspecifid affective psychosis Capsule Oral Batch: Started: 12/08/2008 Stopped: 0 **ZYPREXA (Suspected)** Reason: Unspecifid affective psychosis Started: Stopped: Batch: **HERBAL MEDICINES (Other drug)** Reason: Batch: Started: Stopped: **MELATONIN** (Other drug) Reason: Batch: Started: Stopped: **THYROXINE SODIUM (Other drug)** Reason: Batch: Started: Stopped:

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Cases Count: 76

**Case Number: 245077** 

Gender: F

Age:

**Data Entry Date**: 02/10/2008 **Weight (kg)**: 0

Hospitalisation :

Onset Date : DOB : 04/06/2004

Outcome: 01/09/2008 Causality: Causality certain

Recovered

Information: Cert(rechall)

Same symptoms recurred when restarteded Zyprexa.

Reaction:

Preferred Term Severity Report Description Treatment

Hypercalcaemia Caused or prolonged Hypercalcaemia

inpatient hospitalisation

Medicine details:

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped: 0

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Calcium When Zyprexa restarted Calcium

increased to 2.7, at height 3.2.

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Cases Count: 76

**Case Number : 245293** 

Gender: M

**Data Entry Date**: 09/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 75Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Past history of HSV infection.

Journal unk, Author: Singh D.

Title: Olanzapine and delirium: lesson from clinical practice.

Volume unk, Year Unk, Pages Unk.

Reaction:

Preferred Term Severity Report Description Treatment

Delirium Patient became febrile and developed tachycardia, became disorientated, agitated and his speeech

agitated and his speeech was incoherent. After withdrawal of olanzapine diagnosed of delirium was

made.

Patient became febrile and Olanzapine was cease and the developed tachycardia, patient was maintained on

oxazepam.

Agitation

Confusional state
Disorientation

Incontinence

Pyrexia

Tachycardia

Medicine details:

**ZYPREXA (Suspected)** Reason: Unspecified psychosis

5 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Chest X-ray Normal Haematology Normal Biochemistry Normal

Other data Nuclear magnetic resonance imaging,

bilateral hippocampal atrophy.

Mini mental status examination, on

admission 0/30.

Position emission tomogram hypoactivity over the parietal and

temporal lobes.

Mini over mental status examination.

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Cases Count: 76

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

time.

very drowsy a lot of the

Gynaecomastia

Sleep apnoea syndrome

Weight increased

Medicine details:

RISPERDAL (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:

SOLIAN (Other drug) Reason :

Batch: Started: Stopped:

STELAZINE (Other drug) Reason :

Batch: Started: Stopped:

Reason:

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Cases Count: 76

Gender: M

Case Number: 245480

**Data Entry Date**: 16/10/2008 **Weight (kg)**: 0

Hospitalisation : Age :

**Onset Date**: 04/08/2008 **DOB**: 03/02/1963

Outcome: Causality: Causality possible

Recovered

Information: Patient has an alcohol problem.

Reaction:

Preferred Term Severity Report Description Treatment

Sleep disorder Sleep disorder and hepatic Zyprexa switched.

function abnormal.

Hepatic function abnormal

Medicine details:

ZYPREXA (Suspected) Reason :

Tablet 5 Milligram Daily Oral

**Batch**: **Started**: 16/07/2008 **Stopped**: 25/08/2008 0

FLUOXETINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

THIAMINE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 76

**Case Number : 245523** 

Gender: F

**Data Entry Date**: 16/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 66Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

**Information:** The case was described in the article: Singh D, Forlano R, Athey R. Neuroleptic

malignant syndrme and catatonia in patient twith dementia. The Royal Australian and New Zeland College of Psychiatrists. 2008, 547-548. History of cognitive disorder and

delusion.

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant syndrome

The patient initially presented with cognitive impairment, persecutory delusions and hehavioural

disturbance.

Risperidone was withdrawn. Treated with chlorpromazine 50mg. Lorazepam 1mg/tds was commenced. Patient discharged to a psycho-geniatric nursing

home.

Catatonia Pyrexia

**Medicine details:** 

**ZYPREXA (Suspected)** Reason: Unspecified psychosis

Tablet 15 Milligram Daily Oral

Batch: Started: Stopped:

BENZTROPINE MESYLATE (Other drug) Reason :

Batch: Started: Stopped:

DONEPEZIL HYDROCHLORIDE (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

RISPERIDONE (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

White blood cells White blood cell count high, total white cells: mild increase. Blood creatine phosphokinase = 370 U/I, blood creatine phosphokinase = 1134 U/I and rose

from 370 U/I over the next 12 hours.

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Cases Count: 76

**Case Number: 245714** 

Gender: M

**Data Entry Date:** 21/10/2008 Weight (kg): 0

Hospitalisation: Admitted to hospital Age: 29Y

DOB: **Onset Date:** 

Outcome: Causality: Causality probable

Unknown

Both his father and two first cousins were known to have type two diabetes mellitus. Information:

> 24D Report Source Literature Journal: Internal Medicine Journal

Author: S Buchholz, A F Morrow, P L Coleman

Title: A typical antipsychotic-induced diabetes mellitus: an update on epidememiology

and postulated mechanism.

Volume: 38 Year: 2008 Pages: 602-606

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Diabetes mellitus Caused or prolonged

inpatient hospitalisation Patient was admitted in a semi-conscious state having collapsed at home. He reported general

malaise, polydypsia, polyurea and weight loss.

Olanzapine discontinued, oral hypoglycaemia agents.

Hyperglycaemic hyperosmolar

nonketotic syndrome

Caused or prolonged

inpatient

hospitalisation

**Medicine details:** 

**ZYPREXA (Suspected)** Reason: Unspecified schizophrenia

Batch: Started: Stopped:

**Laboratory Investigations:** 

Range Type Date Tested Result **Details** 

Serum glucose 68.8 mmol/L

Glycosylated 16.7%

haemoglobin (HbA1C)

Other data Body Mass Index: 24.8 kg/m2 Urine analysis: Mildly positive for

ketone, and there was evidence of

kidney failure.

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Cases Count: 76

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:

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Cases Count: 76

Case Number: 246022

Gender: F

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

**Hospitalisation**: Admitted to hospital **Age**:

**Onset Date**: 18/10/2007 **DOB**: 25/02/1959

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Asthma

**Bronchitis** 

Preferred Term Severity Report Description Treatment

Cough Caused or prolonged Patient was hospitalised

inpatient due to bronchitis and hospitalisation bronchial obstructive

syndrome.

Caused or prolonged inpatient

hospitalisation

Bronchial obstruction Caused or prolonged

inpatient hospitalisation

. Caused or prolonged

inpatient

hospitalisation

Urticaria Caused or prolonged

inpatient hospitalisation

Medicine details:

OLANZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 15 Milligram Daily Oral

**Batch: Started:** 31/05/2007 **Stopped:** 04/06/2008

DIAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

EFEXOR-XR (Other drug) Reason :

Batch: Started: 19/09/2007 Stopped:

SODIUM VALPROATE (Other drug) Reason :

Batch: Started: 24/05/2007 Stopped:

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**Cases Count: 76** 

**Case Number : 246092** 

Gender: M

**Data Entry Date :** 10/11/2008

Weight (kg): 0

**Hospitalisation:** 

Age:

Onset Date: 16/09/2008

**DOB**: 04/08/1930

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description Treati

Treatment

Mania

Patient experienced manic symptoms and his

Duloxetine dose was decreased

creatinine clearance level

to 30mg on 16/09/2008.

was 32.

Creatinine renal clearance

decreased

**Medicine details:** 

Cymbalta (Suspected) Reason :

Capsule 60 Milligram Daily Oral

**Batch**: **Started**: 02/09/2008 **Stopped**: 15/09/2008 0

ZYPREXA (Suspected) Reason :

2.5 Milligram

Batch: Started: Stopped: Contin

Bicor (Other drug) Reason :

Batch: Started: Stopped:

CLOPIDOGREL (Other drug) Reason :

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Creatinine clearance Prior to taking Duloxetine creatinine

clearance levels:32

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**Cases Count: 76** 

Case Number: 246096

Gender: U

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

Hospitalisation : Age :

**Onset Date: DOB:** 16/08/1948

Outcome : Causality : Causality probable

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hypercalcaemia Developed hypercalcemia

Medicine details:

ZYPREXA (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 76

Gender: M

**Case Number : 246129** 

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

Hospitalisation: Age: 85Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

The patient was admitted to the hospital for treatment of depression. Upon admission, his drug therapy included doxepin, clonazepam, morphine, prednisolone, omeprazole, cisapride, and betaxalol eye drops. Doxepin was discontinued, and nefazodone was started on hospital day 6. The nefazodone dosage was slowly increased to 150mg twice daily by hospital day 17. Prednisolone was tapered and stopped on hospital day 20. Clonazepam was decreased to 0.5 mg twice daily on day 20, and was discontinued on day 25. Three doses of haloperidol were administered on days 26 and 27 for treatment of increased confusion and paranoia.

No specific treatmentwas administered and the fever, tachycardia, and rigidity resolved within two days. His mental state improved, although he remained confused.

CITATION: This case was described in the articles: Nyfort-Hansen K, Alderman C. Possible neuroleptic malignant syndrome associated with olanzapine. The annals of pharmacotherapy. 2000; 34:667. Stevens D L. associated between selective serotonin-reuptake inhibitors, second-generation antipsychotics and neuroleptic malignant syndrome. The annals of pharmacotherapy. 2008; 42: 1290-1297.

#### Reaction:

**Preferred Term** 

# Neuroleptic malignant syndrome

Severity

#### **Report Description**

85 year old caucasian male who experienced neuroleptic malignant syndrome. He received olanzapine. The patient has a history of rheumatoid arthritis, depression, peptic ulcer disease, glaucoma, and possible parkinson's disease. Olanzapine 10mg every night was started in hospital day 28. Two days after the addition of olanzapine to nefzodone, the patient was disoriented and hallucinating, and developed a fever of 38 degrees celsius. Over the next three days, he was confused and paranoid, became tachycardic (heart rate 100-110 beats/min), and developed urinary incontinence. Body temperature ranged from 37.5 to 38.5. Hyperreflexia, hypertonia, and clonus

#### **Treatment**

Intravenous ceftriaxone and erythromycin.

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were noted.

Medicine details :					
HALOPERIDOL (Suspected)	Re	Reason :			
Batch :	Started :			Stopped :	
	Started .			оторрец .	
ZYPREXA (Suspected)		10 Milligram	eason : Daily	Oral	
Batch :	Started :	10 Willingram	Bally	Stopped :	
BETAXOLOL HYDROCHLORIDE (Other drug)		Reason :			
Batch :	Started :			Stopped :	
CISAPRIDE (Other drug)		Re	eason :		
Batch :	Started :			Stopped :	
CLONAZEPAM (Other drug)		Re	eason :		
Batch :	Started :			Stopped :	
MORPHINE NOS (Other drug)		Re	eason:		
Batch :	Started :			Stopped :	
NEFAZODONE HYDROCHLORIDE (Other drug)		Re	eason :		
Batch :	Started :			Stopped :	
OMEPRAZOLE (Other drug)		Re	eason:		
Batch :	Started :			Stopped :	

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Lactate dehydrogenase was elevated at 289 U/L. Lactate

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Cases Count: 76

**Case Number: 246512** 

Gender: F

**Data Entry Date**: 25/11/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 38Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

**Report Description** 

**Treatment** 

Blood prolactin increased

Since the beginning of treatment the patient experienced a prescribed overdose, after one week treatment, the patient's prolactin levels went up

and she started lactating

Zyorexa ceased.

Galactorrhoea

Overdose

Tablet

Medicine details:

**ZYPREXA (Suspected)** 

Reason:

40 Milligram

Daily

Oral

Batch :

Started:

STERM

Stopped:

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Cases Count: 76

**Case Number: 246879** 

Gender: M

**Data Entry Date:** 08/12/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

**Age:** 16Y

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Convulsion

Caused or prolonged

Patient experienced

Zyprexa discontinued.

inpatient

hospitalisation

Medicine details:

LOVAN (Suspected)

Reason:

seizures.

Batch:

Started:

Stopped:

Ongoing.

**ZYPREXA (Suspected)** 

Reason:

20 Milligram

1.3 Milligram

Batch:

Started:

Stopped:

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**Cases Count: 76** 

**Case Number: 247648** 

Gender: M

**Data Entry Date**: 12/01/2009 **Weight (kg)**: 0

Hospitalisation : Age :

**Onset Date: DOB:** 25/06/1937

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Parkinsonism Parkinsonian symptoms.

Extrapyramidal disorder

Medicine details:

OLANZAPINE (Suspected) Reason : Unspecified schizophrenia

Tablet 30 Milligram 1 time Oral

Batch : Started : Stopped :

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Cases Count: 76

Case Number: 247708

Gender: F

**Data Entry Date:** 14/01/2009

Weight (kg): 0

**Hospitalisation:** 

**Age:** 18Y

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** Polycystic ovaries Severity

**Report Description** 

**Treatment** 

Patient developed possible Zyprexa dose decreased to polycystic ovarian

2.5mg.

syndrome, elevated testosterone levels, facial

acne and weight

increased.

Acne

Blood testosterone increased

Weight increased

Medicine details:

**ZYPREXA (Suspected)** 

Reason:

10 Milligram

Daily

Batch:

Started: 15/03/2008

Stopped:

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Cases Count: 76

discontinued.

**Case Number: 247763** 

Gender: F

**Data Entry Date**: 19/01/2009 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Has had 3 miscarriages, all in the first trimester.

Reaction:

Preferred Term Severity Report Description Treatment

Abortion spontaneous Patient took oral Fluoxetine treatment was

olanzapine 5mg daily for the treatment of bipolar mood disorder beginning in Nov 2004 and fluoxetine 20 mg daily for the treatment of depression beginning in Sep 1996. On an unknown date in the first trimester, the patient

had a miscarriage.

Drug exposure during

pregnancy

**Medicine details:** 

LOVAN (Suspected) Reason : Depression

20 Milligram Daily

**Batch**: **Started**: 15/09/1996 **Stopped**: 15/07/2008

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

Tablet 5 Milligram Daily Oral

Batch: Started: 15/11/2004 L TERM Stopped:

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**Hospitalisation:** 

# **Public Case Detail**

**Cases Count: 76** 

Case Number: 247928

Gender: M

**Data Entry Date**: 22/01/2009 **Weight (kg)**: 60

Age:

Onset Date: 13/01/2009

**DOB**: 13/02/1936

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hepatic function abnormal ALT 299, GGT 472 Asymptomatic. Antipsychotic

rotation and LFT follow up -

resolved.

Medicine details:

OLANZAPINE (Suspected) Reason : Depression

Device, tablet 5 Milligram 1 time Oral

Batch: Started: 17/12/2008 Stopped: 13/01/2009

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: OLANZAPINE, ZYPREXA, Zyprexa Zydis, Zyprexa IM

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