

Case Number : 232065

Data Entry Date : 16/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 84Y

Outcome : 12/08/2007

DOB :

Recovered with sequelae

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Psychosis, due to lithium dose increase or addition of other antipsychotics (not specified).	

Medicine details :

LITHIUM CARBONATE (Suspected)	Reason :
Tablet	750 Milligram Daily
Batch :	Started : 01/08/2007 Stopped : 05/08/2007
AROPAX (Other drug)	Reason :
Tablet	20 Milligram Daily
Batch :	Started : Stopped :
BETALOC (Other drug)	Reason :
Tablet	50 Milligram 2 times
Batch :	Started : Stopped :
COLGOUT (Other drug)	Reason :
Tablet	500 Microgram Daily
Batch :	Started : Stopped :
DI-GESIC (Other drug)	Reason :
Tablet	2 3 times
Batch :	Started : Stopped :
MADOPAR (Other drug)	Reason :
Tablet	62.5 Milligram Daily
Batch :	Started : Stopped :
OROXINE (Other drug)	Reason :
Tablet	150 Microgram Daily
Batch :	Started : Stopped :
Ostevit D (Other drug)	Reason :
Tablet	1000 Unit Daily
Batch :	Started : Stopped :
PLAVIX (Other drug)	Reason :
Tablet	75 Milligram Daily
Batch :	Started : Stopped :

Medicine details :

TEMAZEPAM (Other drug)

Reason :

Tablet 10 Milligram Daily

Batch :

Started :

Stopped :

ZYLOPRIM (Other drug)

Reason :

Tablet 200 Milligram Daily

Batch :

Started :

Stopped :

ZYPREXA (Other drug)

Reason :

Tablet 5 Milligram Daily Oral

Batch :

Started :

Stopped : 0

Public Case Detail

Cases Count: 23

Case Number : 232364

Data Entry Date : 22/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 43Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: the reporting healthcare practitioner suspected that the event may be due to lithium overdose but was unsure.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Patient experienced acute renal failure.	

Medicine details :

CLOZAPINE (Suspected)

Reason :

Tablet

200 Milligram Daily

Oral

Batch :

Started :

Stopped :

LITHIUM CARBONATE (Suspected)

Reason :

Batch :

Started :

Stopped :

Case Number : 233948

Data Entry Date : 02/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 23Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: The patient underwent pre-clozapine investigations, including an electrocardiogram, echocardiograph, full blood count, hepatic and renal function tests, creatine kinase and troponin I, a CT scan of the brain and electroencephalograph, all of which were normal. Varambally S, Howpage P. Acute myocarditis associated with clozapine. Australian Psychiatry; Aug 2007, 15(4): 343-346.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, chest pain, heart rate increased, tachycardia, chest discomfort, body temperature increased, troponin increased, blood creatine phosphokinase increased, C-reactive protein increased, dyspnoea, white blood count increased.	All psychiatric medications were ceased. He was placed on low doses of bisoprolol and ramipril by the cardiac team.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Body temperature increased	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected) Reason : Unspecified schizophrenia

12.5 Milligram Daily

Batch : Started : Stopped : 0

FLUOXETINE HYDROCHLORIDE (Suspected) Reason : Depression

Batch : Started : Stopped :

LITHIUM CARBONATE (Suspected) Reason : Depression

Batch : Started : Stopped :

OLANZAPINE (Other drug) Reason :

15 Milligram

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Heart Rate				Heart rate 160/min
Temperature				Body temperature 38.4
Troponin				Troponin I 10.37 (range up to 0.1).
Creatine phosphokinase				Creatine kinase 259 (range up to 171).
C-Reactive Protein				C-Reactive protein 43.2 (range up to 5.0).

Case Number : 235290

Data Entry Date : 14/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 60

Onset Date : 24/10/2007

Age :

Outcome : 30/10/2007

DOB : 30/09/1952

Recovered

Causality : Causality possible

Information: She has had previous acute organic brain disorder/syndrome secondary to Cabaser in past.i

Reaction :

Preferred Term	Severity	Report Description	Treatment
Mental disorder due to a general medical condition	Caused or prolonged inpatient hospitalisation	Patient has Parkinson's disease and history of stable bipolar disorder. She was seen by her psychiatrist the week preceding the study commencement, and had her dose of Lithium increased. She commenced placebo rivastigmine on 23/10/07. She developed what has been diagnosed as an "acute organic brain syndrome" secondary to Litium toxicity.	Lithium was temporarily ceased.

Medicine details :

LITHIUM CARBONATE (Suspected)		Reason : Unspecifid affective psychosis	
Tablet	1 Gram	Daily	Oral
Batch :	Started :	Stopped : 24/10/2007	
RIVASTIGMINE (Suspected)		Reason :	
Capsule	3 Milligram	Daily	Oral
Batch :	Started : 23/10/2007	Stopped : 24/10/2007	
CABASER (Other drug)		Reason :	
	1 Dose Unspec	Daily	
Batch :	Started :	Stopped :	
MADOPAR (Other drug)		Reason : Paralysis agitans	
	1 Dose Unspec	Daily	
Batch :	Started :	L TERM	Stopped :
SYMMETREL (Other drug)		Reason : Paralysis agitans	
Capsule	200 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

Public Case Detail

Cases Count: 23

Case Number : 235737

Data Entry Date : 28/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/06/2007

Age :

DOB : 01/08/1967

Outcome :

Causality : Causality possible

Recovered

Information: Patient was consuming approximately 10Lit of coke per day.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Diabetic hyperosmolar coma	Life threatening	? Lithium induced nephrogenic diabetes insipidus. ? Ziprasidone induced hyperglycaemia. (? Psychogenic polydipsia). Hyperosmolar non-ketotic coma?	Rehydration and treated with insulin infusion.
Hyperglycaemia	Life threatening		
Nephrogenic diabetes insipidus	Life threatening		

Medicine details :

LITHIUM CARBONATE (Suspected)		Reason :	
Tablet	1.5 Gram	Daily	Oral
Batch :	Started :	L TERM	Stopped : 05/06/2007 0
Ziprasidone (Suspected)		Reason : Diabetes mellitus	
Capsule	160 Milligram	Daily	Oral
Batch :	Started :		Stopped : 05/06/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum glucose				Blood glucose = 63mmol/L
Sodium				Na + = 152mmol/L.

Public Case Detail

Cases Count: 23

Case Number : 236769

Data Entry Date : 08/01/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Thinking abnormal	Caused or prolonged inpatient hospitalisation	"I felt my brain was BLOCKED. I couldn't think straight or creatively". Severe chest pain leading to collapse.	Lithium stopped. Now on Epilim.
Chest pain	Caused or prolonged inpatient hospitalisation		
Poverty of thought content	Caused or prolonged inpatient hospitalisation		
Thought blocking	Caused or prolonged inpatient hospitalisation		

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason : Unspecifid affective psychosis	
Tablet		Oral	
Batch :	Started :	L TERM	Stopped : 0

Public Case Detail

Cases Count: 23

Case Number : 237529

Data Entry Date : 04/02/2008
Hospitalisation : Admitted to hospital
Onset Date : 21/12/2007
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 30/05/1969
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug eruption	Caused or prolonged inpatient hospitalisation	Herpetiform rash on trunk. Confluent maculopapular rash on arms.	
Rash maculo-papular	Caused or prolonged inpatient hospitalisation		
Rash vesicular	Caused or prolonged inpatient hospitalisation		

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason : Unspecifid affective psychosis	
Batch :	Started :	S TERM	Stopped : 0
ATENOLOL (Other drug)		Reason : Essential benign hypertension	
		25 Milligram Daily	
Batch :	Started :	S TERM	Stopped :
MIRTAZAPINE (Other drug)		Reason : Unspecifid affective psychosis	
		45 Milligram Daily	
Batch :	Started :	L TERM	Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Skin biopsy				Confirmed reaction to lithium on skin biopsy

Public Case Detail

Cases Count: 23

Case Number : 238757

Data Entry Date : 10/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 22Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		electrocardiogram QT interval abnormal: corrected QTc >500ms	Zeldox ceased

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
Zeldox (Suspected)		Reason :	
Capsule	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0
QUETIAPINE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
QT interval				QTc greater than 500ms

Case Number : 239203

Data Entry Date : 25/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 64Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term

Drug interaction

Severity

Caused or prolonged inpatient hospitalisation

Report Description

In Sep/Oct 2007, the patient's Lithium levels increased to 0.8 (unit and reference range unspecified). The patient's renal function decreased (unspecified). In late 2007 the patient developed hypothyroidism. On an unspecified date the patient experienced parkinsonian syndrome, cognitively "dull", "catatonic" with arms hanging down and open mouth. Suspected Lithium toxicity. The Lithium was discontinued (date unspecified) and the risperidone was decreased to 0.5mg daily and the valproate continued (dose unspecified). The patient's lithium level was 3 (value unspecified) (normal reference range unspecified) prior to cessation. On an unspecified date (late 2007 or early 2008) the patient fell over and was hospitalised with renal failure. The lithium level dropped to 1 but, the patient remained "Parkinsonian" It was suspected that the patient was experiencing encephalopathy due to a suspected drug interaction between lithium and risperidone.

Treatment

Lithium was withdrawn, risperidone was reduced.

Fall

Caused or prolonged inpatient hospitalisation

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hypothyroidism	Caused or prolonged inpatient hospitalisation		
Parkinsonism	Caused or prolonged inpatient hospitalisation		
Renal failure	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		
Toxic encephalopathy	Caused or prolonged inpatient hospitalisation		

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason :	
		1 Gram	Daily
Batch :	Started :	Stopped :	
RISPERDAL (Suspected)		Reason : Unspecifid affective psychosis	
		1 Milligram	Daily
Batch :	Started :	Stopped :	0
SODIUM VALPROATE (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Serum drug level	Lithium			Lithium level was 3 (value unspecified) (normal range unspecified) prior to cessation (date unspecified). Lithium level dropped to 1 (value unspecified) (normal range unspecified) (date unspecified)>

Public Case Detail

Cases Count: 23

Case Number : 239352

Data Entry Date : 31/03/2008
Hospitalisation : Admitted to hospital
Onset Date : 04/03/2008
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 95
Age :
DOB : 01/11/1952
Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 23

Case Number : 240070

Data Entry Date : 16/04/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age : 46Y

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hyperparathyroidism		Hyperparathyroidism, nephrolithiasis and renal cyst.	Ceased Lithium
Nephrolithiasis			
Renal cyst			

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason :	
Batch :	Started :	L TERM	Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Calcium				Calcium levels were found to be raised (2.63 mmol/L, normal range 2.10-2.60). Increased urinary calcium excretion. Calcium levels normalised after Lithium was ceased.
Other data	1.6-6.9			Raised parathyroid hormone (PTH) of 13 pmol/L PTH remained elevated at 9.7 after Lithium was ceased.
Ultrasound				Renal ultrasound revealed small calculi.

Case Number : 240325

Data Entry Date : 23/04/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 2.88

Onset Date : 09/02/2008

Age :

DOB : 09/02/2008

Outcome :

Causality : Causality possible

Not yet recovered

Information: Secretariat comment: F/N.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pulmonary valve stenosis	Caused or prolonged inpatient hospitalisation	Baby born to a mother taking lithium for bipolar disorder. Diagnosed with critical pulmonary valve stenosis. Duct dependent and requires cardiac surgery at hospital.	
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Pulmonary valve stenosis congenital	Caused or prolonged inpatient hospitalisation		

Medicine details :

LITHIUM CARBONATE (Suspected)		Reason :	
Tablet	450 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
FLUOXETINE HYDROCHLORIDE (Other drug)		Reason :	
	40 Milligram		Oral
Batch :	Started :	Stopped :	
FOLIC ACID (Other drug)		Reason :	
	5 Milligram		Oral
Batch :	Started :	Stopped :	
MULTIVITAMINS (Other drug)		Reason :	
	1 Dose Unspec		Oral
Batch :	Started :	Stopped :	
THYROXINE SODIUM (Other drug)		Reason :	
Tablet	100 Microgram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 242396

Data Entry Date : 30/06/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 10/06/2008

Age :

Outcome : 14/06/2008

DOB : 13/06/1962

Recovered

Causality : Causality probable

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 inpatient hospitalisation	Hyper reflexia, ankle clonus, tremor, dilated pupils, tachycardia, increasing agitation and restlessness, sweating.	Ziprasidone & phenelzine stopped.
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

Medicine details :

QUETIAPINE (Interaction)

Reason : Unspecified schizophrenia

100 Milligram Daily

Batch :

Started :

L TERM

Stopped :

Ziprasidone (Interaction)

Reason : Unspecified schizophrenia

160 Milligram Daily

Batch :

Started : 05/06/2008

Stopped : 12/06/2008 0

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)

Reason :

40 Milligram Daily

Batch :

Started :

L TERM

Stopped :

INDAPAMIDE HEMIHYDRATE (Other drug)

Reason :

40 Milligram Daily

Batch :

Started :

Stopped :

LEVLEN ED (Other drug)

Reason :

40 Milligram Daily

Batch :

Started :

L TERM

Stopped :

Public Case Detail

Cases Count: 23

Case Number : 243355

Data Entry Date : 31/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 21Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information: Patient had no history of neuroleptic malignant syndrome.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Dose of Seroquel was increased to 800mg daily as the lower dose was not effective. In addition pt was on Epilim and Lithium. Pt developed neuroleptic malignant syndrome	All three medications Ceased

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

Case Number : 243368

Data Entry Date : 31/07/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 15/01/2008

Age :

DOB : 27/01/1965

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hypercalcaemia		Sweats, rapid pulse, leg cramps, constipation and blurred vision.	Lithium withdrawn.
Blood parathyroid hormone increased			
Constipation			
Heart rate increased			
Hyperhidrosis			
Muscle spasms			
Vision blurred			

Medicine details :

LITHIUM CARBONATE (Suspected)	Reason : Unspecifid affective psychosis
Tablet	900 Milligram Daily Oral
Batch :	Started : Stopped :
ACIMAX (Other drug)	Reason :
Batch :	Started : Stopped :
Adefin XL (Other drug)	Reason :
Batch :	Started : Stopped :
CARTIA (Other drug)	Reason :
Batch :	Started : Stopped :
COVERSYL PLUS (Other drug)	Reason :
Batch :	Started : Stopped :
LAMOTRIGINE (Other drug)	Reason :
Batch :	Started : Stopped :
MINIPRESS (Other drug)	Reason :
Batch :	Started : Stopped :

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

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Nuclear magnetic resonance				Nuclear medicine scan negative

Case Number : 243844

Data Entry Date : 15/08/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 15/02/2008

Age :

DOB : 12/11/1929

Outcome :
Recovered

Causality : Causality certain

Information: CERT

Reaction :

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Usual lithium levels (for years) 0.6mmol/L. Patient was noted to be experiencing diarrhoea, slurred speech, drowsiness, unsteady gait and persistent low grade nausea. It had been attributed to her history of reflux and new oxycontin. Lithium level when tested was 1.4mmol/L.	Ketoprofen tablets were ceased
Ataxia			
Dysarthria			
Nausea			
Somnolence			

Medicine details :

LITHICARB (Interaction) Reason : Unspecifid affective psychosis

2 Dose Unspec Daily

Batch :

Started :

Stopped :

ORUVAIL SR (Interaction) Reason : Pain

200 Milligram Daily

Oral

Batch :

Started : 15/01/2008

Stopped : 15/02/2008

ACIMAX (Other drug) Reason :

20 Milligram Daily

Batch :

Started :

Stopped :

KALMA (Other drug) Reason :

1 Milligram Daily

Batch :

Started :

Stopped :

Lexapro (Other drug) Reason :

20 Milligram Daily

Batch :

Started :

Stopped :

OXYCONTIN (Other drug) Reason : Pain

10 Milligram Daily

Batch :

Started : 15/12/2007

Stopped :

Medicine details :			
PANAMAX (Other drug)	Reason :	6 Dose Unspec Daily	
Batch :	Started :	Stopped :	
VALPRO (Other drug)	Reason :	Unspecifid affective psychosis	
		1000 Milligram	Daily
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				Usual lithium levels 0.6 mmol/L. Lithium result 1.4 mmol/L.

Public Case Detail

Cases Count: 23

Case Number : 244638

Data Entry Date : 15/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/04/2007

Age :

DOB : 20/10/1960

Outcome :

Causality : Causality possible

Not yet recovered

Information: HIV +ve

Reaction :

Preferred Term	Severity	Report Description	Treatment
Nephrogenic diabetes insipidus		diabetes insipidus (nephrogenic)	ceased lithium therapy, switched to olanzapine therapy

Medicine details :

LITHIUM CARBONATE (Suspected)	Reason : Unspecifid affective psychosis
	750 Milligram
Batch :	Started :
	Stopped : 17/12/2007

Case Number : 244731

Data Entry Date : 18/09/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Recovered

Causality : Causality certain

Information: Concurrent medical conditions included hypomanic episode and hypertension. Patient had a family history of bipolar disorder in two first-degree relatives.
Parker G. Alert: Inaccurate Lithium Assay Results.
Aus & NZ Journal of Psychiatry. 2008; 42: 643-645
The author's considered the events were related to treatment with Lithium carbonate. The author's commented that "on further testing, they established that when a serum level was high, the assay (provided by an independent major pharmaceutical company) performs an 'automatic dilution' that can then generate a falsely low value...Thus, patients with high lithium levels and at risk of toxicity are, paradoxically, most likely to generate a spuriously low (and false) value, and therefore be at risk of inappropriate clinical management".

Reaction :

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	A patient who had experienced bipolar disorder for over 20 years and who had been euthymic for most of that period while highly compliant with lithium, had falsely low lithium levels reported over two periods, 6 years apart, and was actually lithium toxic on the most recent occasion. At that latter time the spuriously low lithium levels reported on the assay risked dispelling any clinical suspicion of lithium toxicity, although toxicity was later confirmed.	
Agitation	Caused or prolonged inpatient hospitalisation		
Anaemia	Caused or prolonged inpatient hospitalisation		
Blood creatinine increased	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Depressive symptom	Caused or prolonged inpatient hospitalisation		
Elevated mood	Caused or prolonged inpatient hospitalisation		
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation		
Laboratory test interference	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Stress	Caused or prolonged inpatient hospitalisation		
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine details :

LITHIUM CARBONATE (Suspected)

Reason : Depression

1 Gram Daily

Batch :

Started :

Stopped :

LISINOPRIL (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		03/08/2008	51 U/L	
Other data		01/09/2000	0.8 mmol/L	Blood lithium level
Other data		05/02/2008	1.9 mmol/L	Blood lithium level
Other data		09/02/2008	0.8 mmol/L	Blood lithium level
Other data		10/02/2008	0.8 mmol/L	Blood lithium level
Other data		11/07/2008	0.8 mmol/L	Blood lithium level
Other data		03/08/2008	1.1 mmol/L	Blood lithium level
Other data		06/03/2008	1.8 mmol/L	Blood lithium level
Other data		11/03/2008	1.8 mmol/L	Blood lithium level
Other data		18/03/2008	1.8 mmol/L	Blood lithium level
Creatinine		03/09/2008	125 micromol/L	
GGT = SGPT = GGTP		03/09/2008	121 U/L	

Public Case Detail

Cases Count: 23

Case Number : 245330

Data Entry Date : 10/10/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 85

Onset Date :

Age :

DOB : 14/12/1966

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuralgia		Painful feet, neuropathic pain, burning soles of feet, pain radiating into legs, including bone, muscular nerve pain.	Slow lithium withdrawal, anti-inflammatories.
Renal impairment			

Medicine details :

LITHIUM CARBONATE (Suspected)		Reason : Unspecifid affective psychosis	
Tablet	750 Milligram	Daily	Oral
Batch :	Started : 10/08/2006	Stopped :	
RABEPRAZOLE SODIUM (Other drug)		Reason :	
	20 Milligram	Daily	Oral
Batch :	Started : 21/01/2008	Stopped :	

Case Number : 245402

Data Entry Date : 14/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2008

Age :

DOB : 13/02/1947

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Patient experienced a fall and fractured her right arm, patient also has a history of lithium toxicity	Ceased Clopine
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 01/01/2002	Stopped : 22/07/2008	
LITHIUM CARBONATE (Suspected)		Reason : Depression	
Tablet	500 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
DOTHIEPIN HYDROCHLORIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				Lithium blood level: mildly toxic.

Case Number : 246499

Data Entry Date : 24/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 60Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: Included in the PI (attached)

The latter incident identified a serious problem, whereby it is likely that the particular assay risks generating spuriously low values when high serum levels of lithium are present-a so-called hook phenomenon, that has been described for some quantitative immunoassays.

There was a family history of bipolar disorder in two first-degree relatives.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Therapeutic agent toxicity		Lithium toxicity, developed mood elevation, stress and depressive symptoms, adverse experienced requiring surgery, mild anaemia, slightly elevated creatinine level at 125 umol/L, drug interaction, slight neutropenia. Patient also experienced agitation and confusion	
Agitation			
Anaemia			
Blood creatinine increased			
Confusional state			
Depressed mood			
Drug interaction			
Elevated mood			
Hepatic enzyme increased			
Memory impairment			
Neutropenia			

Medicine details :

LISINOPRIL (Interaction)	Reason : Essential benign hypertension
Tablet	20 Milligram Daily Oral
Batch :	Started :
	Stopped :
LITHIUM CARBONATE (Interaction)	Reason : Unspecifid affective psychosis
Tablet	1 Gram Daily Oral
Batch :	Started :
	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electroencephalograph				Shown a pattern consistent with lithium toxicity.
Creatinine	(40-120)	19/03/2008	125	
Liver function tests				Elevation of some liver enzymes.
ALT = SGPT				Level of 51 U/L exceeding the upper limit of 45 U/L, level of 121 U/L exceeding the upper limit of 121 U/L.

Case Number : 246886

Data Entry Date : 08/12/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age : 31Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: History of bipolar affective disorder, obesity and psoriatic arthropathy.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient experienced fever, tremor, lethargy, leukocytosis, platelets elevated, decreased haemoglobin levels and possible encephalopathic syndrome.	Treatment with Lithium and Olanzapine were discontinued.
Haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Plateletcrit increased	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine details :

LITHIUM CARBONATE (Suspected)	Reason :
900 Milligram Daily	
Batch :	Started : Stopped :
SODIUM VALPROATE (Suspected)	Reason :
Batch :	Started : Stopped :
ENOXAPARIN (Other drug)	Reason :
Batch :	Started : Stopped :
OLANZAPINE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				WBC = > 25
Platelets				Platelets elevated > 1000
Haemoglobin				Haemoglobin decreased = < 90

Public Case Detail

Cases Count: 23

Case Number : 247860

Data Entry Date : 21/01/2009

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 89

Onset Date :

Age :

DOB : 10/02/1962

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Renal impairment		Progressive renal impairment	Lithium ceased

Medicine details :			
LITHIUM CARBONATE (Suspected)		Reason : Unspecifid affective psychosis	
	1.2 Gram	Daily	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatinine				0.20
Glomerular filtration rate				23

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CAMCOLIT, LITHICARB, LITHIUM CARBONATE, PRIADEL, QUILONUM SR, TIMONIL, Lithicarb SR