



# Public Case Detail

Cases Count: 20

**Case Number : 232664**

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

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 99U

**DOB :**

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Orthostatic hypotension		Postural hypotension	

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 20

**Case Number : 233191**

**Data Entry Date :** 10/09/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 30Y

**Outcome :**

**DOB :**

Death

**Causality :** Causality possible

**Information:** report to company by a coronial psthologist. Stated not to be an overdose

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Arrhythmia	Death	death from cardiac arrhythmia	

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Case Number : 233683**

**Data Entry Date :** 21/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 06/05/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	Creatine kinase high, ecg abnormal, Tachycardia, White blood cell count increased and neutrophils increased.	
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>AMISULPRIDE (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started : 21/12/2005</b> <b>Stopped :</b>
<b>PIMOZIDE (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>QUETIAPINE (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				28 Mar 2006 - CK ranged from 621 - 728 (ref 0 - 270)
Electrocardiography				ECG on 5 May 2006 showed increased sinus rate of approximately 115 bpm. Pulse varied from 87 - 122 bpm.
White blood cells				WBC ranged from 11.5 - 17.7 x 10 <sup>9</sup> /L (ref 4.0 - 11.0)

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils				Neutrophils were $13.00 \times 10^9/L$ (ref 1.8 - 7.5)

# Public Case Detail

Cases Count: 20

**Case Number : 234879**

**Data Entry Date :** 30/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 84

**Onset Date :** 01/01/2005

**Age :**

**Outcome :** 30/10/2007

**DOB :** 01/04/1941

Recovered

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tardive dyskinesia	Incapacity/disability	Tardive dyskinesia/ Parkinsonism secondary to Amisulpride	Amisulpride weaned.
Parkinsonism	Incapacity/disability		

<b>Medicine details :</b>			
<b>AMISULPRIDE (Suspected)</b>		<b>Reason :</b> Unspecifid affective psychosis	
Tablet	400 Milligram	2 times	Oral
<b>Batch :</b>	<b>Started :</b> 01/01/2003	<b>Stopped :</b> 26/10/2007	0

## Case Number : 237502

Data Entry Date : 04/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/12/2007

Age :

DOB : 22/06/1959

Outcome :

Causality : Causality possible

Recovered

**Information:** White blood cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Patient experienced a severe tonic-clonic seizure lasting approximately 3 minutes including myoclonic activity and loss of consciousness. She had another complex partial seizure in the right side of her face lasting approximately 2 minutes.	Clopine ceased
Complex partial seizures			

### Medicine details :

<b>AMISULPRIDE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/10/2007	<b>Stopped :</b>	
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	750 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/09/2007	<b>Stopped :</b> 19/12/2007	0
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ATORVASTATIN (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CHLORPROMAZINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>OMEPRAZOLE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b> Unspecified psychosis		
	2.2 Gram	Daily	
<b>Batch :</b>	<b>Started :</b> 01/10/2007	<b>Stopped :</b>	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				The patient was noted to a clozapine level of 660.
Haemoglobin				HB 107

# Public Case Detail

Cases Count: 20

**Case Number : 240117**

**Data Entry Date :** 17/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** Patient was on Solian for four years but three weeks ago he picked up his script from a different pharmacy and had the above reaction.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Tried to kill himself twice and then tried to kill his wife.	
Physical assault			

## Medicine details :

<b>SOLIAN (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>



# Public Case Detail

Cases Count: 20

**Case Number : 240190**

**Data Entry Date :** 21/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/02/2008

**Age :** 29Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Rash		Rash on trunk-chest, back, bottom.	Amisulpride and lamotrigine ceased. Celestone M ointment.

<b>Medicine details :</b>			
<b>AMISULPRIDE (Suspected)</b>			
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/01/2008		<b>Stopped :</b> 25/02/2008
<b>Reason :</b> Unspecified psychosis			
<b>ATENOLOL (Other drug)</b>			
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/09/2005		<b>Stopped :</b>
<b>Reason :</b> Palpitation			
<b>LAMOTRIGINE (Other drug)</b>			
Tablet	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/04/2007		<b>Stopped :</b> 25/02/2008
<b>Reason :</b>			
<b>QUETIAPINE (Other drug)</b>			
Tablet	1.1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/01/2005		<b>Stopped :</b>
<b>Reason :</b> Unspecified psychosis			

# Public Case Detail

Cases Count: 20

**Case Number : 240341**

**Data Entry Date :** 23/04/2008

**Gender :** F

**Hospitalisation :** Hospitalisation prolonged

**Weight (kg) :** 0

**Onset Date :** 11/04/2008

**Age :** 30Y

**Outcome :**

**DOB :**

Recovered with sequelae

**Causality :** Causality possible

**Information:** hyperglycaemia and diabetes mellitus have been ruled out.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Life threatening	following intentional drug overdose of amisulpride, admitted to hospital in extremis.	conservative
Electrocardiogram QT prolonged	Life threatening	Electrocardiogram QT prolonged, extrapyramidal symptoms, hypotension.	
Hypotension	Life threatening		
Nephrogenic diabetes insipidus	Life threatening		

## Medicine details :

<b>SOLIAN (Suspected)</b>	<b>Reason :</b>
	400 Milligram 1 time Oral
<b>Batch :</b>	<b>Started :</b> 11/04/2008 <b>Stopped :</b>

# Public Case Detail

Cases Count: 20

**Case Number : 241084**

**Data Entry Date :** 22/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :** 12/05/2008

**DOB :**

Recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Anaphylactic reaction	Life threatening	Anaphylaxis with respiratory distress, laryngeal/pharyngeal oedema and widespread severe urticaria with eosinophilia and elevated CRP.	
Angioedema	Life threatening		
C-reactive protein increased	Life threatening		
Eosinophilia	Life threatening		
Respiratory distress	Life threatening		
Urticaria	Life threatening		

**Medicine details :**

<b>AMISULPRIDE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
<b>Batch :</b>	<b>Started :</b> 08/05/2008
	<b>Stopped :</b> 10/05/2008

# Public Case Detail

Cases Count: 20

**Case Number : 241244**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 27/02/1948

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tardive dyskinesia		slurred speech, tardive dyskinesia (slight movements of the tongue and movements of the facial musculature).	
Dysarthria			

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b> Paranoid type schizophrenia	
	400 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 20

## Case Number : 241328

**Data Entry Date :** 29/05/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 30/05/2004  
**Outcome :**  
 Unknown

**Gender :** F  
**Weight (kg) :** 60  
**Age :**  
**DOB :** 24/04/1941  
**Causality :** Causality probable

### Information:

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Arthralgia	Caused or prolonged inpatient hospitalisation		
Psoriasis	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
SOLIAN (Suspected)	Reason :		
Tablet	1 Dose Unspec	Oral	
<b>Batch :</b>	<b>Started :</b> 29/05/2004	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Magnetic Resonance Imaging				MRI revealed patch of osteoarthritis and slight osteoporosis enlarged joint on top of foot between leg and foot. Left foot.

# Public Case Detail

Cases Count: 20

**Case Number : 241329**

**Data Entry Date :** 29/05/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 55

**Onset Date :**

**Age :**

**DOB :** 28/06/1974

**Outcome :**

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Amenorrhoea		Acute amenorrhoea.	Solian ceased.

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b>	
Tablet	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 20

**Case Number : 242548**

Data Entry Date : 03/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/05/2008

Age :

DOB : 25/06/1960

Outcome : 30/05/2008

Causality : Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Patient experienced tremor, shuffling gait, cog wheel rigidity, extrapyramidal symptoms.	Ceased amisulpride, treated with benzotropine.
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Gait disturbance	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>AMISULPRIDE (Suspected)</b>	<b>Reason : Paranoia</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 15/05/2008</b>	<b>Stopped : 27/05/2008</b>	

# Public Case Detail

Cases Count: 20

**Case Number : 242867**

**Data Entry Date :** 14/07/2008

**Gender :** M

**Hospitalisation :** Required a specialist consultation

**Weight (kg) :** 0

**Onset Date :**

**Age :** 23Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Restlessness		Significant restlessness	

<b>Medicine details :</b>			
<b>AMISULPRIDE (Suspected)</b>		<b>Reason :</b>	
	500 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
_____	_____	_____	



# Public Case Detail

Cases Count: 20

**Case Number : 243044**

**Data Entry Date :** 21/07/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/06/2008

**Age :**

**Outcome :**

**DOB :** 21/03/1979

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blood prolactin increased		6 times normal limits	
Amenorrhoea			
Galactorrhoea			
Hallucination, auditory			

<b>Medicine details :</b>			
<b>SEROQUEL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<hr/>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 20

**Case Number : 243124**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/05/2008

**Age :**

**DOB :** 12/06/1959

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Depression		Agressive symptoms meeting criteria for modarate severity major depressive episode within days of starting Solian.	Solian stopped.

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/05/2008	<b>Stopped :</b> 18/06/2008	0
<b>HALOPERIDOL (Other drug)</b>		<b>Reason :</b> Unspecified psychosis	
	0.1 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 20/04/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 20

**Case Number : 245487**

**Data Entry Date :** 16/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 10/09/2008

**Age :**

**DOB :** 16/03/1984

**Outcome :** 10/09/2008

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Oculogyric crisis		Oculogyric crisis and dystonia.	Patient already in hospital.
Dystonia			

<b>Medicine details :</b>			
<b>SOLIAN (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/09/2008	<b>Stopped :</b> 10/09/2008	

# Public Case Detail

Cases Count: 20

**Case Number : 245742**

**Data Entry Date :** 22/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Death

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Renal failure acute		Renal failure acute	
Drug level increased			

<b>Medicine details :</b>			
<b>AMISULPRIDE (Suspected)</b>		<b>Reason :</b>	
Tablet			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 20

**Case Number : 246160**

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

**Gender :** M

**Weight (kg) :** 74

**Hospitalisation :**

**Age :** 65Y

**Onset Date :** 05/10/2008

**DOB :**

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** History of depression, anxiety, paranoia, obsessive compulsive disorder.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		High blood pressure, raised potassium, unsteady gait, rigidity.	
Hypertension			
Muscle rigidity			
Tachycardia			

## Medicine details :

**SOLIAN (Suspected)**

**Reason :**

500 Milligram Daily

**Batch :**

**Started :** 15/09/2008

**Stopped :** 06/10/2008

**Case Number : 246165**

**Data Entry Date :** 12/11/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 11/06/2008

**Age :**

**DOB :** 11/03/1933

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** Recent suspected NMS secondary to risperidone 0.5mg. (Admitted 05/05 -08/05/08)

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Lower oral intake, lower mobility, fever.	Ceased amisulpride and simvastatin, given antipyretics, IV fluids.
Blood creatine phosphokinase increased			
Cogwheel rigidity			
Neuroleptic malignant syndrome			

## Medicine details :

<b>AMISULPRIDE (Suspected)</b>	<b>Reason :</b>		
	200 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 15/05/2008	<b>Stopped :</b>	11/06/2008
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>		
	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CALTRATE (Other drug)</b>	<b>Reason :</b>		
	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CHOLECALCIFEROL (Other drug)</b>	<b>Reason :</b>		
	1		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>DONEPEZIL HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
	10 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Escitalopram (Other drug)</b>	<b>Reason :</b>		
	20 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
	1 Gram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	11/06/2008
<b>Novomix 30 (Other drug)</b>	<b>Reason :</b>		
	16 Unit	Daily	Subcutaneous
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Medicine details :</b>		
<b>SIMVASTATIN (Other drug)</b>	<b>Reason :</b>	
	40 Milligram	Daily
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 11/06/2008

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				Febrile 38.1C, MSU (-), BCs (-), CK peaked @7211 on 12/06/08.

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: AMISULPRIDE, SOLIAN