

# Public Case Detail

Cases Count: 104

**Case Number : 231494**

**Data Entry Date :** 03/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 23Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		abnormal movements suspected of being tardive dyskinesia	

**Medicine details :**

<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>EFEXOR-XR (Other drug)</b>		<b>Reason :</b>	
Capsule	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 232155**

**Data Entry Date :** 17/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Vision blurred			

**Medicine details :**

RISPERDAL (Suspected)	Reason :
Batch :	Started :
	Stopped :

## Case Number : 232662

**Data Entry Date :** 29/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 06/08/2007  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 09/05/1924  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	EPSE - Parkinsonism features, cogwheel rigidity, tremor at rest, mask-like face and low mobility.	Cease risperidone and venlafaxine, just observation.
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Masked facies	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>VENLAFAXINE HYDROCHLORIDE (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>AMIODARONE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b> Otr&nos disord of heart rhythm
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b> Chron isch heart dis no hyper
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>FRUSEMIDE (Other drug)</b>	<b>Reason :</b> Congestive heart failure
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>GLYCERYL TRINITRATE (Other drug)</b>	<b>Reason :</b> Chron isch heart dis no hyper
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Medicine details :

**METOPROLOL TARTRATE (Other drug)**

**Reason :** Chron isch heart dis no hyper

**Batch :**

**Started :**

**Stopped :**

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**OMEPRAZOLE (Other drug)**

**Reason :** Other diseases of esophagus

**Batch :**

**Started :**

**Stopped :**

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**PERINDOPRIL (Other drug)**

**Reason :** Chron isch heart dis no hyper

**Batch :**

**Started :**

**Stopped :**

0

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**SIMVASTATIN (Other drug)**

**Reason :** Chron isch heart dis no hyper

**Batch :**

**Started :**

**Stopped :**

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**SLOW-K (Other drug)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

---

**TEMAZEPAM (Other drug)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

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**THYROXINE SODIUM (Other drug)**

**Reason :** Myxedema

**Batch :**

**Started :**

**Stopped :**

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# Public Case Detail

Cases Count: 104

**Case Number : 232837**

**Data Entry Date :** 31/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 30/09/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Dystonia		affecting the right hand	
Blepharospasm		bilateral	
Tardive dyskinesia			

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 104

**Case Number : 232838**

**Data Entry Date :** 31/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 37Y

**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>
Drug withdrawal syndrome		patient ceased treatment 5 weeks prior to event	
Parkinsonism		stiffness	
Convulsion			

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection	50 Milligram	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 232947**

**Data Entry Date :** 31/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 89

**Onset Date :** 21/08/2007

**Age :**

**DOB :** 21/06/1976

**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>
Galactorrhoea		Galactorrhoea	

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Manic-depression psycho,manic	
Tablet	3 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 02/08/2007	<b>Stopped :</b> 21/08/2007	
<b>SODIUM VALPROATE (Suspected)</b>		<b>Reason :</b> Manic-depression psycho,manic	
	1500 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Case Number : 233012**

Data Entry Date : 04/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 54Y

Outcome : 15/06/2007

DOB :

Recovered

Causality : Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis,	Treated with filgrastim, IV antibiotics (ceftazidime & gentamycin).

**Medicine details :**

<b>OLANZAPINE (Suspected)</b>	<b>Reason :</b> Unspecifid affective psychosis
25 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> 22/05/2007
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>
Injection 25 Milligram Fortnightly Intramuscular	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> 22/05/2007
<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b> Unspecifid affective psychosis
Tablet 1 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> 23/05/2007
<b>NEXIUM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>NORFLOXACIN (Other drug)</b>	<b>Reason :</b> Prophylaxis
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>PHYTOMENADIONE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>PROPRANOLOL HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> 0
<b>SPIRONOLACTONE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>THIAMINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>



## Laboratory Investigations :

Type	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	

# Public Case Detail

Cases Count: 104

**Case Number : 233350**

**Data Entry Date :** 13/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 9Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Self injurious behaviour		has grabbed a blunt knife on 5 occasions and attempted to cut himself	
Suicidal ideation		he talks often of wanting to die	

<b>Medicine details :</b>			
<b>LOVAN (Suspected)</b>		<b>Reason :</b>	
	20 Milligram	1 time	Oral
<b>Batch :</b>	<b>Started :</b> 15/09/2006	<b>Stopped :</b>	0
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>	
			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 104

**Case Number : 233707**

**Data Entry Date :** 21/09/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :** 99u  
**DOB :**  
**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Injection site pain	Caused or prolonged inpatient hospitalisation	Pt experienced following AEs: injection site pain, lack of efficacy, constant diarrhoea, anxiety, gynecomastia, lack of efficacy and admission to hospital  Concomittant meds: Axit tablets were switched to Eleva time unknown.  Pt. was not responding well to Risperdal Consta and Eleva treatment and was hospitalised against his will (Pt. stated "feeling fine and didn't need hospitalising"). Pt. was discharged from hospital. He complained about the Risperdal Consta needle size ("started self injecting")and also lost 6 kilos in 2 weeks, therefore stopped injecting the drug. Pt. was off medication when reporting this AE.	
Drug ineffective	Caused or prolonged inpatient hospitalisation		
Injection site reaction	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>Axit (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>

## Medicine details :

Eleva 100 (Other drug)

Reason :

Batch :

Started :

Stopped :

# Public Case Detail

Cases Count: 104

**Case Number : 233781**

**Data Entry Date :** 25/09/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 29/08/2007

**Age :**

**DOB :** 09/12/1985

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Hyperprolactinaemia			

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	1 Milligram	2 times	Oral
<b>Batch :</b>	<b>Started :</b> 28/08/2007	<b>Stopped :</b> 03/09/2007	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Prolactin				Serum Prolactin 823 (71-566)

# Public Case Detail

Cases Count: 104

**Case Number : 233895**

**Data Entry Date :** 02/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/09/2007

**Age :** 47Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

**Medicine details :**

Risperdal Consta (Suspected)

**Reason :**

Injection

Milligram

Cyclical

Intramuscular

**Batch :**

**Started :** 29/08/2007

**Stopped :**

## Case Number : 233917

Data Entry Date : 02/10/2007

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age :

DOB : 02/12/1990

Outcome :

Causality : Causality possible

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Raised LFT's	

#### Medicine details :

<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Bilirubin		09/03/2007	9	
Bilirubin		05/04/2007	13	
Bilirubin		15/04/2007	7	
SAP = ALP		09/03/2007	45	
SAP = ALP		05/04/2007	170	
SAP = ALP		15/06/2007	97	
GGT = SGGT = GGTP		09/03/2007	29	
GGT = SGGT = GGTP		05/04/2007	181	
GGT = SGGT = GGTP		15/04/2007	120	
ALT = SGPT		09/03/2007	18	
ALT = SGPT		05/04/2007	358	
ALT = SGPT		15/04/2007	32	
AST = SGOT		09/03/2007	186	
AST = SGOT		05/04/2007	106	
AST = SGOT		15/04/2007	20	

# Public Case Detail

Cases Count: 104

**Case Number : 234022**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 15Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality probable

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Somnolence		Admitted with 1st episode psychosis, commenced on risperidone. Became quite drowsy, disorientated, obtunded, then developed bed-sores to heel and ear whilst in this condition.	Meds changed to olanzapine, valproate and biperiden.
Depressed level of consciousness			
Disorientation			

**Medicine details :**

<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b>
	1 Dose Unspec Daily
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>



# Public Case Detail

Cases Count: 104

**Case Number : 234071**

**Data Entry Date :** 05/10/2007

**Gender :** M

**Hospitalisation :** Hospitalisation prolonged

**Weight (kg) :** 0

**Onset Date :** 29/08/2007

**Age :** 84Y

**Outcome :**

**DOB :**

Death

**Causality :** Causality possible

**Information:** Case to be reviewed by Hospital Deaths Committee. review requested 30/10/07

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Caused or prolonged inpatient hospitalisation	Thrombocytopenia	
Thrombocytopenia	Death	Thrombocytopenia: Admitted secondary to a situational crisis at home; awaiting placement Risperidone 0.5mg once daily for agitation (on a background of dementia) Thrombocytopenia was noted on routine blood examination Risperidone ceased on 21/09/07 Incidentally, Mr RC was also receiving Clexane but it was commenced on 15/09/07 (subsequent to reduction in platelet count); this too was stopped on 21/09/07 No further investigations	Risperidone ceased on 21/09/07; Clexane too was stopped on 21/09/07

## Medicine details :

<b>PANTOPRAZOLE (Suspected)</b>	<b>Reason :</b> No reason given		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b> 1 Dose Unspec Daily		
<b>Batch :</b>	<b>Started :</b> 23/08/2007	<b>Stopped :</b>	0
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLEXANE (Other drug)</b>	<b>Reason :</b> No reason given		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 21/09/2007	0

## Medicine details :

DIGOXIN (Other drug)

Reason :

Batch :

Started :

Stopped :

FRUSEMIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

PARACETAMOL (Other drug)

Reason :

Batch :

Started :

Stopped :

SPIRONOLACTONE (Other drug)

Reason :

Batch :

Started :

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Platelets		23/08/2007	130	
Platelets		29/08/2007	100	
Platelets		14/09/2007	76	
Platelets		17/09/2007	65	
Platelets		18/09/2007	52	
Platelets		20/09/2007	37	

# Public Case Detail

Cases Count: 104

## Case Number : 234146

Data Entry Date : 09/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 84Y

Outcome :

DOB :

Causality : Causality possible

Not yet recovered

**Information:** Risperdal initiated during admission in hospital due to lithium toxicity and dehydration.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		neutropenia	Risperdal was stopped.

### Medicine details :

<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecifid affective psychosis	
Tablet	0.5 Milligram	2 times	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 234517**

**Data Entry Date :** 17/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Diarrhoea	Caused or prolonged inpatient hospitalisation	Patient experienced diarrhoea, anxiety, gynecomastia, lost 6 kilos in 2 weeks.	
Anxiety	Caused or prolonged inpatient hospitalisation		
Gynaecomastia	Caused or prolonged inpatient hospitalisation		
Weight decreased	Caused or prolonged inpatient hospitalisation		

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

# Public Case Detail

Cases Count: 104

**Case Number : 234539**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 25/08/1926

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** This report is a duplicate of 234546

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Heart attack, joint stiffness, gout and fall.	Haloperidol dosed reduced and ceased.
Fall			
Gout			
Joint stiffness			

## Medicine details :

<b>HALOPERIDOL (Suspected)</b>		<b>Reason :</b>	
Tablet	2 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
Tablet	0.1 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 234745**

**Data Entry Date :** 24/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 06/08/2006

**Age :**

**DOB :** 31/07/1923

**Outcome :** 06/08/2006

**Causality :** Causality possible

Death, maybe drug

**Information:** History of smoking, hypertension, dementia and stroke.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Death	Patient's behaviour changed he became unco-operative and difficult, within a few weeks barely rousable. He could not wake to feed himself, physio impossible, jerky movements, impaired ability move, became dehydrated, had difficulty in swallowing and worsening dementia.	Drug not stopped.
Dehydration	Death		
Depressed level of consciousness	Death		
Dysphagia	Death		

## Medicine details :

**RISPERIDONE (Suspected)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 104

**Case Number : 234867**

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

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :** 33Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Abdominal distension	Caused or prolonged inpatient hospitalisation		
Appendicitis	Caused or prolonged inpatient hospitalisation		
Body temperature fluctuation	Caused or prolonged inpatient hospitalisation		
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>	
	25 Milligram	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 235045**

**Data Entry Date :** 06/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** concurrent condition include marijuana and alcohol abuse

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Systemic lupus erythematosus		the patient's lupus symptoms re-presented	

## Medicine details :

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection	50 Milligram		Intramuscular
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>



# Public Case Detail

Cases Count: 104

## Case Number : 235199

**Data Entry Date :** 12/11/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 29/10/2007  
**Outcome :** 30/10/2007  
 Recovered

**Gender :** F  
**Weight (kg) :** 50  
**Age :**  
**DOB :** 07/09/1988  
**Causality :** Causality possible

**Information:** Patient used "Rainbow Herbal" for the first time with this drug.

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Dystonia	Caused or prolonged inpatient hospitalisation	Patient had a dystonic reaction, started on 29/10/07 and on 30/10/07. Had stiffening of her face, hands, legs with locked jaw.	Treated with Cogentin.
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Trismus	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>	<b>Reason :</b> Unspecified psychosis		
Injection	0.5 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	29/10/2007

# Public Case Detail

Cases Count: 104

**Case Number : 235357**

**Data Entry Date :** 16/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/08/2007

**Age :** 34Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased		weight gain (30kg) within a 2 month period	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection			Intramuscular
<b>Batch :</b>	<b>Started : 20/08/2007</b>	<b>Stopped :</b>	

## Case Number : 235493

Data Entry Date : 21/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 70

Onset Date :

Age : 47Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation	Patient experienced an increased QT interval, was anxious, tense, somewhat flat.	Ceased venlafaxine and started on Ziprazidone.
Anxiety	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b>
	6 Milligram Daily
<b>Batch :</b>	<b>Started :</b> 06/09/2007 <b>Stopped :</b>
<b>VENLAFAXINE HYDROCHLORIDE (Suspected)</b>	<b>Reason :</b>
	375 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
	500 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SIMVASTATIN (Other drug)</b>	<b>Reason :</b>
	40 Milligram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 235522**

**Data Entry Date :** 21/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 14/12/2006

**Age :**

**Outcome :** 19/12/2006

**DOB :** 19/10/1935

Recovered

**Causality :** Causality possible

**Information:**

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

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b>		
	0.5 Milligram 2 times		
<b>Batch :</b>	<b>Started :</b> 01/06/2006	<b>Stopped :</b> 14/12/2006	
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>		
	100 Milligram Daily		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>COLOXYL WITH SENNA (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>GLICLAZIDE (Other drug)</b>	<b>Reason :</b>		
	30 Milligram Daily		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
	1 Gram 3 times		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>OXAZEPAM (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

## Case Number : 235558

**Data Entry Date :** 22/11/2007

**Gender :** F

**Hospitalisation :** Hospitalisation prolonged

**Weight (kg) :** 69

**Onset Date :** 03/09/2007

**Age :** 47Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** The patient had experienced QT prolongation and episodes of bradycardia and atrial fibrillation prior to Zeldox and this was thought to be due to venlafaxine.

The patient had been previously hospitalised for catatonia and alcohol excess in 2002.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Anxiety		Anxiety, agitated, pain flank, foot cramps, faint, QT interval prolonged, tardive dyskinesia, back pain, cogwheel rigidity, suicidal ideation, tiredness, insomnia, nightmares, weight gain, shaking, vomiting, dizzy	Zeldox stopped; added benztropine, aripiprazole, diazepam, nortrytiline
Electrocardiogram abnormal		Anxiety, agitated, pain flank, foot cramps, faint, QT interval prolonged, tardive dyskinesia, back pain, cogwheel rigidity, suicidal ideation, tiredness, insomnia, nightmares, weight gain, shaking, vomiting, dizzy	Zeldox stopped
Tardive dyskinesia		tongue flicking	
Bradycardia			
Cogwheel rigidity			
Dizziness			
Electrocardiogram QT prolonged			
Fatigue			
Flank pain			
Insomnia			
Muscle spasms			
Nightmare			
Suicidal ideation			
Tremor			
Vomiting			
Weight increased			

## Medicine details :

RISPERIDONE (Suspected)

Reason :

2 Milligram

Oral

Batch :

Started : 03/09/2007

Stopped :

Zeldox (Suspected)

Reason :

Oral

Batch :

Started : 31/08/2007

Stopped : 10/10/2007

EFEXOR (Other drug)

Reason :

Batch :

Started :

Stopped :

METFORMIN HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

SERTRALINE HYDROCHLORIDE (Other drug)

Reason :

25 Milligram

Batch :

Started :

Stopped :

0

SIMVASTATIN (Other drug)

Reason :

Batch :

Started :

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data		20/08/2007	GGT 78 U/L Unk - 35 GLUCOSE 6.0 mmol/L 3.4 - 5.4	
Other data		21/08/2007	BLOOD PRESSURE 90/50 mmHg CALCIUM 2.44 mmol/L 2.13 - 2.63 corrected GLOMERULAR 72 ml/min FILTRATION RATE PHOSPHATE 1.54 mmol/L 0.8 - 1.4 HEART RATE 50 irregular QT INTERVAL 450 milliseconds	
Other data		23/08/2007	ANION GAP 22 mmol/L 10 - 20 GGT 69 U/L Unk - 35 SODIUM 148 mmol/L 135 - 145	
Other data		03/09/2007	QT INTERVAL 120 milliseconds	
Other data		05/10/2007	GGT 93 U/L Unk - 35	
Other data		09/10/2007	BLOOD PRESSURE 98/61 mmHg GLUCOSE "Good" HEART RATE 56 QT INTERVAL 482 milliseconds- Widening of QT interval	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data		10/10/2007	QT INTERVAL 470 milliseconds	

# Public Case Detail

Cases Count: 104

**Case Number : 235742**

**Data Entry Date :** 28/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 51Y

**Outcome :**

**DOB :**

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			
Breast cancer			

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
		6 Milligram	Daily
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLONAZEPAM (Other drug)</b>		<b>Reason :</b> Anxiety neurosis	
		4 Milligram	As necessary
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b>





# Public Case Detail

Cases Count: 104

**Case Number : 235817**

**Data Entry Date :** 03/12/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 9Y

**DOB :**

**Causality :** Causality possible

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dystonia		experienced forward tongue thrusting	
Asthenia			
Depressed mood			
Emotional distress			
Flat affect			
Personality change			
Weight increased			

### Medicine details :

RISPERDAL (Suspected)

**Reason :**

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 104

**Case Number : 235818**

**Data Entry Date :** 03/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased		from a size 16 to a size 24	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection			Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 235982**

**Data Entry Date :** 06/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**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>
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	the patient began shuffling around and then could not walk after 4 months of treatment, required a wheelchair. Could not turn over in bed, no pain accompanying the stiffness	
Abasia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>LITHIUM CARBONATE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SEROQUEL (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236001**

**Data Entry Date :** 06/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 70

**Onset Date :**

**Age :** 47Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Depressed mood		Patient had trouble sleeping,being tired, nightmares, agitated, pain in the right flank radiating to her back, cramps in foot, shaking, vomiting,dizzy, QT interval prolonge, depressed mood..	Ceased Ziprasidone, risperidone reduced.
Agitation			
Back pain			
Dizziness			
Electrocardiogram QT prolonged			
Fatigue			
Muscle spasms			
Nightmare			
Sleep disorder			
Tremor			
Vomiting			

**Medicine details :**

<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>		
Tablet	4 Milligram	Daily		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		
<b>Ziprasidone (Suspected)</b>		<b>Reason :</b>		
Capsule	40 Milligram	Daily		Oral
<b>Batch :</b>	<b>Started : 31/08/2007</b>	<b>Stopped :</b>		

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Electrocardiography				ECG-widening of QT interval to 482 msec,
QT interval		10/10/2007	470	

# Public Case Detail

Cases Count: 104

**Case Number : 236208**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 72

**Onset Date :** 19/11/2007

**Age :**

**DOB :** 25/05/1924

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Abnormal dreams		Very vivid unpleasant dreams. Reduced gait, feeling unbalanced.	
Balance disorder			
Gait disturbance			

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	0.5 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 15/11/2007	<b>Stopped :</b> 27/11/2007	
<b>PLAVIX (Other drug)</b>		<b>Reason :</b>	
	75 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SERC (Other drug)</b>		<b>Reason :</b>	
	8 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236247**

**Data Entry Date :** 13/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Muscle contracture		clenching sensation in arms and legs	
Dysarthria			
Dyspnoea			
Insomnia			
Musculoskeletal stiffness			
Nasal congestion			
Restless legs syndrome			
Tremor			
Vision blurred			

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
		2 times	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<hr/>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<hr/>			

# Public Case Detail

Cases Count: 104

**Case Number : 236335**

**Data Entry Date :** 17/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Dystonia		jerky arm movements which the reporter describes as tardive dyskinesia	
Confusional state			

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection	50 Milligram	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236337**

**Data Entry Date :** 17/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2007

**Age :** 46Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blepharospasm			

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Injection	37.5 Milligram		Intramuscular
<b>Batch :</b>	<b>Started :</b> 15/07/2006	<b>Stopped :</b>	ongoing



# Public Case Detail

Cases Count: 104

**Case Number : 236537**

**Data Entry Date :** 27/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 20Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** patient reported to be intolerant of typical antipsychotics but had been ok taking oral risperidone

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pain in extremity		pain in limbs	
Back pain			
Hypokinesia			
Muscle spasms			

## Medicine details :

**Risperdal Consta (Suspected)**

**Reason :**

Injection

50 Milligram

Cyclical

Intramuscular

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 104

**Case Number : 236540**

**Data Entry Date :** 27/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** patient reported intolerant to typical antipsychotics but had been ok taking oral risperidone

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Back pain			
Hypokinesia			
Muscle spasms			
Pain in extremity			

## Medicine details :

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	50 Milligram	Cyclical	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236542**

**Data Entry Date :** 27/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** Patient is reported to be sensitive to typical antipsychotics. Patient had tolerated risperidone tablets previously.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pain in extremity		pain in limbs	
Back pain			
Hypokinesia			
Muscle spasms			

## Medicine details :

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	50 Milligram	Cyclical	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236543**

**Data Entry Date :** 27/12/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** patient intolerant of typical antipsychotics but had been ok taking oral risperidone

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pain in extremity		pain in limbs	
Back pain			
Hypokinesia			
Muscle spasms			

## Medicine details :

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	50 Milligram	Cyclical	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 236715**

**Data Entry Date :** 07/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 62.4

**Onset Date :** 05/02/2007

**Age :**

**Outcome :** 07/02/2007

**DOB :** 18/08/1997

Recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Rash macular	Caused or prolonged inpatient hospitalisation	Reported to be drowsy at school. Eyes rolled to back of his head, had blotchy red patches over his torso, face was 'burning', tongue was sticking out to one side, felt 'clammy'. Was on Sertraline and ceased abruptly.	All drugs ceased.
Eye rolling	Caused or prolonged inpatient hospitalisation		
Flushing	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>	
	2 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/02/2007	<b>Stopped :</b> 06/02/2007	
<b>SERTRALINE HYDROCHLORIDE (Suspected)</b>		<b>Reason :</b>	
	100 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 03/02/2007	



# Public Case Detail

Cases Count: 104

**Case Number : 236759**

**Data Entry Date :** 08/01/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :** 40Y

**DOB :**

**Causality :** Causality possible

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous			
Drug exposure during pregnancy			

### Medicine details :

Risperdal Consta (Suspected)		Reason :	
Injection			Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 237069**

**Data Entry Date :** 18/01/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Heart rate increased		consumer report : the day following risperdal consta injection patient experienced pulse increased, chest pain, small swelling inside mouth which is painful	
Chest pain			
Oral mucosal eruption			

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection			Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 237120**

**Data Entry Date :** 21/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Anger		moody and angry	
Hypoaesthesia		numbness of the arms legs and face	
Heart rate irregular		pounding and irregular heartbeat	
Blood glucose increased			
Rhinorrhoea			

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



# Public Case Detail

Cases Count: 104

**Case Number : 237131**

**Data Entry Date :** 21/01/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 35Y

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tardive dyskinesia			

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

# Public Case Detail

Cases Count: 104

**Case Number : 237168**

**Data Entry Date :** 22/01/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** The psychiatrist and the patient's husband both felt that the events where due to the patients underlying disease progression and unrelated to risperidone

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Dementia		a rapid decline in dementia symptoms over 2 years	

## Medicine details :

RISPERDAL (Suspected)	Reason :	Oral
Batch :	Started :	Stopped :

# Public Case Detail

Cases Count: 104

**Case Number : 237175**

**Data Entry Date :** 22/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 13Y

**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>
Weight increased		weight gain of 10kg within 8 weeks of starting risperidone	

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

# Public Case Detail

Cases Count: 104

**Case Number : 237199**

**Data Entry Date :** 22/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 93

**Onset Date :** 26/05/2006

**Age :**

**DOB :** 06/07/1963

**Outcome :** 02/01/2008

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Nightmare	Incapacity/disability	nightmares and other unpleasant dreams with associated daytime tiredness	
Fatigue	Incapacity/disability		

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Injection	37.5 Milligram	Alternate weeks	Intramuscular
<b>Batch :</b> various	<b>Started :</b> 17/05/2006	<b>Stopped :</b> 05/12/2007	

# Public Case Detail

Cases Count: 104

**Case Number : 237277**

**Data Entry Date :** 24/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Iron deficiency anaemia			

<b>Medicine details :</b>			
RISPERDAL (Suspected)		Reason :	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 104

**Case Number : 237463**

**Data Entry Date :** 31/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 42Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased		weight increased, hepatic infection, kidney infection, syncope and dizziness	
Dizziness			
Haematuria			
Hepatic infection			
Kidney infection			
Syncope			

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

**Case Number : 237534**

**Data Entry Date :** 04/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 14Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** Patient has possible Autism

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Weight increased		increased weight and multiple adverse events	
Abdominal distension			
Anxiety			
Dizziness			
Face oedema			
Fatigue			
Haematochezia			
Musculoskeletal stiffness			
Nausea			
Restless legs syndrome			
Skin striae			
Vision blurred			

## Medicine details :

**Risperdal Consta (Suspected)**

**Reason :** Unspecified schizophrenia

Injection

Intramuscular

**Batch :**

**Started :** 01/11/2007

**Stopped :** 15/01/2008

0

# Public Case Detail

Cases Count: 104

**Case Number : 237574**

**Data Entry Date :** 05/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 18/01/2008

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		bilateral ankle oedema	
Hepatic function abnormal			

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection	50 Milligram	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0



# Public Case Detail

Cases Count: 104

**Case Number : 237857**

**Data Entry Date :** 13/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 26Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hyperprolactinaemia		elevated prolactin	
Tachycardia		tachycardia	

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

# Public Case Detail

Cases Count: 104

**Case Number : 237885**

**Data Entry Date :** 14/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		lip smacking	

**Medicine details :**

RISPERDAL (Suspected)

**Reason :**

Milligram      Daily      Oral

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 104

**Case Number : 238157**

**Data Entry Date :** 21/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 46Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Sperm count abnormal		low sperm count	
Infertility		patient taking risperidone for 8-9 months experienced subfertility and low sperm count	
Infertility		subfertility , low sperm count. The fact that the patient cannot have any children has affected the patients life to the extent that he has become suicidal.	

<b>Medicine details :</b>			
RISPERIDONE (Suspected)	Reason :		
		Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				semen anaylsis one month after discontinuation of drug revealed sperm was 14 mil/mL " subfertile"

# Public Case Detail

Cases Count: 104

**Case Number : 238290**

**Data Entry Date :** 26/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 30/01/2008

**Age :**

**DOB :** 29/09/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Salivary gland enlargement		Patient experienced salivary gland swelling.	Antibiotics and Ibruprofen.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	625 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/03/2006	<b>Stopped :</b>	
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 238293**

**Data Entry Date :** 26/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 11/02/2008

**Age :**

**DOB :** 01/07/1918

**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>
Electrocardiogram QT prolonged		Patient experienced prolonged QT interval, sinus rhythm 50 bpm,	
Bradycardia			
Electrocardiogram T wave inversion			
Electrocardiogram abnormal			

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Otr spec symp psychopathol nec	
Tablet	250 Microgram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/01/2008		<b>Stopped :</b> 11/02/2008
<b>ALENDRONATE SODIUM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>ALLOPURINOL (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>ASPIRIN (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>LACTULOSE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>PARACETAMOL (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>THYROXINE SODIUM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 238305**

**Data Entry Date :** 26/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 28Y

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Rash generalised	Caused or prolonged inpatient hospitalisation	generalised itchy, blotchy rash and muscle spasms.	treated with steroid injection
Muscle spasms	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>		
Injection	25 Milligram	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 238376**

**Data Entry Date :** 28/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 13/02/2008

**Age :** 22Y

**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>
Hyperglycaemia	Life threatening	hyperglycemia	

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
Tablet	2 Milligram	1 time	Oral
<b>Batch :</b>	<b>Started :</b> 10/01/2008	<b>Stopped :</b>	
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	25 Milligram		Intramuscular
<b>Batch :</b>	<b>Started :</b> 31/01/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 238503**

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

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** Patient was noted to be overeating.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Weight increased		weight increased of 20 kilos in 3 months.	

## Medicine details :

<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	50 Milligram	Fortnightly	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 104

**Case Number : 238504**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 40Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased		weight gain and sexual dysfunction	
Sexual dysfunction			

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection		25 Milligram	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Case Number : 238795**

**Data Entry Date :** 11/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 30/01/2008

**Age :**

**DOB :** 04/11/1972

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Mild neutropenia and anaemia.	
Anaemia			

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Injection	75 Milligram	Fortnightly	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	19/02/2008 0
<b>Risperdal Quicklet (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/01/2008	<b>Stopped :</b>	15/02/2008
<b>ANTENEX (Other drug)</b>		<b>Reason :</b> Otr spec symp psychopathol nec	
	5 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 30/01/2008	<b>Stopped :</b>	
<b>ZYPREXA (Other drug)</b>		<b>Reason :</b> Otr spec symp psychopathol nec	
Tablet	5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/01/2008	<b>Stopped :</b>	15/02/2008

# Public Case Detail

Cases Count: 104

**Case Number : 238932**

**Data Entry Date :** 13/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** The patient believed that his HIV was cured and has refused to take his (unspecified) HIV medications.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		The patient's medical history and concurrent conditions included; advanced human immunodeficiency virus (HIV) disease and manic depressive schizophrenia. The patient was treated with risperidone (unspecified, oral) 4mg a day, initiated on an unknown date for manic depressive schizophrenia. On an unknown date, the patient experienced advanced human immunodeficiency virus (HIV) disease ("HIV disease not suppressed") and increased prolactin levels.	

## Medicine details :

<b>RISPERDAL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
<b>Batch :</b>	4 Milligram      Daily      Oral
<b>Started :</b>	<b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Prolactin				>500
Other data				Viral load is 119,000 and T-cells 3.2

# Public Case Detail

Cases Count: 104

**Case Number : 239020**

**Data Entry Date :** 17/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 91Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Patient experienced a stroke, Risperidone was ceased, she recovered, a few months after the stroke risperidone was restarted, the patient was reported not responding as well this time, was still aggressive, doing such things as throwing food and pushing the nurses.	Risperdal reduced.
Aggression			
Therapeutic response decreased			

**Medicine details :**

<b>RISPERDAL (Suspected)</b>	<b>Reason :</b> Unspecified psychosis
	1 Dose Unspec Daily
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>

# Public Case Detail

Cases Count: 104

## Case Number : 239103

Data Entry Date : 18/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 46

Onset Date : 11/02/2008

Age :

DOB : 18/07/1979

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Patient developed a rash and itchy skin, muscle stiffness and difficulty breathing.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Pruritus	Caused or prolonged inpatient hospitalisation		

Medicine details :			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Unspecified psychosis		
Injection	25 Milligram	1 time	Intramuscular
<b>Batch :</b>	<b>Started :</b> 11/02/2008	<b>Stopped :</b>	

**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

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

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

<b>Laboratory Investigations :</b>				
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: 104

**Case Number : 239227**

**Data Entry Date :** 26/03/2008

**Gender :** M

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

**Weight (kg) :** 110

**Onset Date :**

**Age :**

**DOB :** 28/10/1973

**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>
Anorgasmia		Anorgasmia	Ceased risperidone.

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/12/2007	<b>Stopped :</b> 04/03/2008	
<b>GEMFIBROZIL (Other drug)</b>		<b>Reason :</b> Othr&unspec metabolic diseases	
	1200 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 104

**Case Number : 239387**

**Data Entry Date :** 31/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 23/02/2008

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hyperprolactinaemia		Blood prolactin increased.	

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
		4 Milligram	Daily
<b>Batch :</b>	<b>Started :</b> 19/02/2008	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Prolactin		23/02/2008	1400	

# Public Case Detail

Cases Count: 104

**Case Number : 239745**

**Data Entry Date :** 09/04/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**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>
Neutropenia		neutropenia	

<b>Medicine details :</b>			
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>	
		2 Milligram	
<b>Batch :</b>	<b>Started :</b> 15/03/2008	<b>Stopped :</b>	
<hr/>			
<b>OLANZAPINE (Other drug)</b>		<b>Reason :</b>	
		5 Milligram	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 240529**

**Data Entry Date :** 01/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 42Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality probable

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy, exercise tolerance decreased, liver function test abnormal and paraesthesia.	
Exercise tolerance decreased			
Liver function test abnormal			
Paraesthesia			

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b>	
Injection		Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 18 months.

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Liver function tests				Liver function tests abnormal.

# Public Case Detail

Cases Count: 104

**Case Number : 240795**

**Data Entry Date :** 12/05/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 80

**Onset Date :**

**Age :** 79Y

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality possible

**Information:** Further information - Patient's medical history include gastritis, high cholesterol, hypothyroidism, delusional behaviour, diabetes, leg oedema and IHD. The PI for risperdal consta includes heart blocks as an ADR.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block	Caused or prolonged inpatient hospitalisation	experienced heart block and hospitalised. Ceased risperidone and when restarted again, the patient's symptoms were only controlled for eight days and then she became delusional again. Thought someone was gassing the ward.	
Delusion	Caused or prolonged inpatient hospitalisation		
Therapeutic response decreased	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Otr spec symp psychopathol nec
25 Milligram	
<b>Batch :</b>	<b>Started :</b> 24/05/2006 <b>Stopped :</b> 0
<b>COLOXYL WITH SENNA (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>IRBESARTAN (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>IRBESARTAN (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>METOPROLOL TARTRATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Medicine details :

SIMVASTATIN (Other drug)

Reason :

Batch :

Started :

Stopped :

---

THYROXINE SODIUM (Other drug)

Reason :

Batch :

Started :

Stopped :

---

# Public Case Detail

Cases Count: 104

**Case Number : 241544**

**Data Entry Date :** 04/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/01/2008

**Age :**

**DOB :** 19/11/1989

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** Medical History and concurrent conditions included: anxiety, depression, obsessive-compulsive disorder, panic disorder, and Tourette's disorder.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Ectopic pregnancy	Congenital anomaly / birth defect	ectopic pregnancy	

## Medicine details :

<b>Manerix (Suspected)</b>	<b>Reason :</b> Depression
600 Milligram	
<b>Batch :</b>	<b>Started :</b> 01/01/2002
	<b>Stopped :</b> 0
<b>RISPERDAL (Suspected)</b>	<b>Reason :</b>
2 Milligram	Daily
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> Contin

## Case Number : 241547

**Data Entry Date :** 04/06/2008

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Age :** 99u

**Onset Date :**

**DOB :**

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** History of dementia.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation	Diarrhoea, dysphagia and dementia.	
Dementia	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	1 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>BACLOFEN (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 242077**

**Data Entry Date :** 19/06/2008

**Gender :** F

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

**Weight (kg) :** 66

**Onset Date :** 26/05/2008

**Age :**

**DOB :** 29/06/1982

**Outcome :** 26/05/2008

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Oculogyric crisis		EPSE - oculogyric crisis	IM Benztropine 2 mg

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	5 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 07/05/2008		<b>Stopped :</b>
<b>DIAZEPAM (Other drug)</b>		<b>Reason :</b>	
	20 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>



# Public Case Detail

Cases Count: 104

**Case Number : 242086**

**Data Entry Date :** 19/06/2008

**Gender :** F

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

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 19/05/1921

**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>
Rash maculo-papular		Macullopapular rash on back, abdominal wall and upper limbs.	

<b>Medicine details :</b>			
<b>AMPICILLIN (Suspected)</b>		<b>Reason :</b> Cellul&absc otr,mult&nos sites	
	4 Gram	Daily	
<b>Batch :</b>	<b>Started :</b> 27/05/2008	<b>Stopped :</b> 27/05/2008	
<b>CEPHAZOLIN SODIUM (Suspected)</b>		<b>Reason :</b> Cellul&absc otr,mult&nos sites	
	3 Gram	Daily	
<b>Batch :</b>	<b>Started :</b> 23/05/2008	<b>Stopped :</b> 27/05/2008	
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	1 Gram	Daily	
<b>Batch :</b>	<b>Started :</b> 24/05/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 242385**

**Data Entry Date :** 30/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 14/04/2008  
**Causality :** Causality probable

**Information:** This parent/child case is linked to 20071105528.  
 The patient's mother medical history and concurrent conditions included marijuana use (but ceased during pregnancy), psychosis, and tobacco use (5-6 cigarettes/day).

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neonatal		Gestational age 39 weeks. The patient's mother was treated with risperidone for psychosis. On an unknown date, the patient experienced possible neonatal withdrawal syndrome. The patient was described to be jittery.	Observation in hospital. Antibiotics as prophylaxis.
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>RISPERDAL (Suspected)</b>	<b>Reason :</b>
Tablet	2 Milligram Daily
<b>Batch :</b>	<b>Started :</b> 10/08/2007 <b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 242555**

**Data Entry Date :** 03/07/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 121

**Onset Date :** 12/07/2007

**Age :** 15Y

**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>
Weight increased		The patient initially had put on 9 kg to start with and later his weight increased by 22 kg.	changed to paliperidone.

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood		
Tablet	3 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/06/2006	<b>Stopped :</b>	0
<b>DEXAMPHEMINE SULPHATE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>FLUOXETINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 242911**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/06/2008

**Age :** 39Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Syncope		Re syncope	

**Medicine details :**

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

# Public Case Detail

Cases Count: 104

**Case Number : 242969**

**Data Entry Date :** 16/07/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cerebral palsy		Baby was born with cerebral palsy.	
Drug exposure during pregnancy			

<b>Medicine details :</b>			
<b>EFEXOR (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SYNTOCINON (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 243280**

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

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/06/2008

**Age :** 63Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:** Mechanism of Action: Cipramil weak inhibition of CIP2D6 - hepatic enzyme. increase of Risperidone.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient was treated with Risperidone long acting injection (microspheres, intra-muscular) 50 mg initiated on an unknown date for an unknown indication and Risperidone (tablets, oral) 2 mg twice a day, indication unknown on an unknown date for an unknown indication. It was reported that patient started taking Risperidone (tablets, oral) about 6 weeks prior to the suspected onset of neuroleptic malignant syndrome. On 17/06/08, the patient developed suspected neuroleptic malignant syndrome and on an unknown date, the patient showed signs of extrapyramidal syndrome like side effects; he experienced increase in blood pressure, increase in creatine kinase and suffered from rigidity.	Risperidone LAI and Risperidone tablets withdrawn.
Blood creatine phosphokinase increased			
Blood pressure increased			
Extrapyramidal disorder			
Muscle rigidity			

## Medicine details :

**CIPRAMIL (Suspected)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

**Medicine details :**

Risperdal Consta (Suspected) Reason :

Injection 50 Milligram Daily Intramuscular

Batch : Started : Stopped :

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Blood pressure				Blood pressure increased
Creatine kinase MB				Creatine kinase increased

## Case Number : 243524

**Data Entry Date :** 05/08/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 06/05/2008  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 13/02/1921  
**Causality :** Causality possible

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Caused or prolonged inpatient hospitalisation	Possible stroke (CVA) due to Risperidone. Hypertension, dementia, hallucination, pain.	Added aspirin
Confusional state	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b> Unspecified psychosis
Wafer	1 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>CEFTRIAXONE (Other drug)</b>	<b>Reason :</b> Otr&nos infec&parasit diseases
Injection	1 Gram Daily
<b>Batch :</b>	<b>Started :</b> 06/05/2008 <b>Stopped :</b>
<b>FOLIC ACID (Other drug)</b>	<b>Reason :</b>
	5 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>HALOPERIDOL (Other drug)</b>	<b>Reason :</b> Otr spec symp psychopathol nec
Tablet	3 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 06/05/2008 <b>Stopped :</b>
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b> Otr spec symp psychopathol nec
Tablet	5 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 06/05/2008 <b>Stopped :</b>
<b>PARACETAMOL (Other drug)</b>	<b>Reason :</b> Osteoarthritis
Tablet	4000 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>TELMISARTAN (Other drug)</b>	<b>Reason :</b> Essential benign hypertension
Tablet	1 Dose Unspec Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>



# Public Case Detail

Cases Count: 104

**Case Number : 243663**

**Data Entry Date :** 11/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 28Y

**Outcome :**

**DOB :**

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		Rasied prolactin levels	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection			Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Prolactin	2.8 - 29.2			Prolactin 43 mcg/L

# Public Case Detail

Cases Count: 104

**Case Number : 243667**

**Data Entry Date :** 11/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 06/07/2008

**Age :** 52Y

**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>
Neuroleptic malignant syndrome		Patient experienced suspected neuroleptic malignant syndrome.	Risperidone withdrawn.

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
Tablet	5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SERTRALINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
Tablet			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

## Case Number : 243813

**Data Entry Date :** 13/08/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/03/2008  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :** 71Y  
**DOB :**  
**Causality :** Causality possible

**Information:** Possible interaction between fluoxetine and risperidone, increase the risperidone!?  
 Interaction description in MIMS

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	Patient was hospitalised in mid-June 2008 for management of "convulsions". Jerky, involuntary movements, including arms flung in the air, grunts. She was hospitalised for two weeks where they reduced the Epilim to zero and ceased the fluoxetine and jerky movements gradually faded away. They gradually reintroduced the Epilim and the jerky movements did not return.	

### Medicine details :

<b>LOVAN (Interaction)</b>	<b>Reason :</b>
40 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b> 15/06/2008
<b>RISPERDAL (Interaction)</b>	<b>Reason :</b>
2.5 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>ALPHA-TOCOPHEROL (Other drug)</b>	<b>Reason :</b>
1 Gram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>ARICEPT (Other drug)</b>	<b>Reason :</b>
10 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>EPILIM (Other drug)</b>	<b>Reason :</b>
200 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>
<b>LIPITOR (Other drug)</b>	<b>Reason :</b>
40 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>

## Medicine details :

NEXIUM (Other drug)

Reason :

40 Milligram Daily

Batch :

Started :

Stopped :



# Public Case Detail

Cases Count: 104

**Case Number : 244016**

**Data Entry Date :** 21/08/2008

**Hospitalisation :**

**Onset Date :** 01/06/2008

**Outcome :**

Not yet recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 04/01/1935

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extra-pyramidal side effects, shuffling gait and parkinsonism	
Gait disturbance			
Parkinsonism			

**Medicine details :**

**RISPERIDONE (Suspected)**

**Reason :** Unspecified schizophrenia

2 Milligram Daily

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 104

**Case Number : 244174**

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

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 35Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** Medical history: Schizoaffective disorder - ongoing.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient experienced muscle stiffness and sedation occurring from the time of injection for 2 to 3 days. Patient was unable to attend work as he could not get out of bed during this period.	
Muscle rigidity			

## Medicine details :

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Injection	25 Milligram	Daily	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>BENZTROPINE MESYLATE (Other drug)</b>		<b>Reason :</b>	
	4 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 104

**Case Number : 244231**

**Data Entry Date :** 28/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 11/08/2008

**Age :**

**DOB :** 22/02/1970

**Outcome :** 11/08/2008

**Causality :** Causality possible

Death

**Information:** Further information received - Medical history: Pt had h/o COPD and polycythaemia. The cause of death was related to underlying disease.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient experienced a myocardial infarction and died whilst being treated with Clopine.	

## Medicine details :

### CLOPINE (Suspected)

#### Reason :

Tablet 600 Milligram Daily Oral  
**Batch :** **Started :** 29/05/2006 **Stopped :** 11/08/2008

### CLOZAPINE (Suspected)

#### Reason :

Tablet 600 Milligram Daily Oral  
**Batch :** **Started :** 19/10/1994 **Stopped :** 29/05/2006

### RISPERIDONE (Suspected)

#### Reason : Unspecified schizophrenia

1 Milligram Daily  
**Batch :** **Started :** **Stopped :** 09/08/2008 0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient's white cell count and neutrophil counts were generally within the normal ranges throughout.

# Public Case Detail

Cases Count: 104

**Case Number : 244251**

**Data Entry Date :** 29/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 27

**Onset Date :** 01/06/2008

**Age :**

**DOB :** 21/10/1999

**Outcome :**

**Causality :** Causality certain

Recovered

**Information:** Cert: rechall

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Dystonia	Incapacity/disability	Dystonic reaction with Risperidone: occurred on each of the first 3 doses: tongue stuck out, distressed, unable to swallow saliva	Ceased medication

## Medicine details :

RISPERDAL (Suspected)		Reason :	
Oral Liquid, syrup	0.5 Millilitre	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/06/2008	<b>Stopped :</b> 03/06/2008	0



# Public Case Detail

Cases Count: 104

**Case Number : 244388**

**Data Entry Date :** 04/09/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Neutrophil count decreased.	

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

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Neutrophils		21/07/2008	1.4 x 10 to 9	

# Public Case Detail

Cases Count: 104

**Case Number : 244679**

**Data Entry Date :** 17/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 35Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Weight increased		Immediately after commencing the treatment, the patient started gaining weight. In six months the patient had a weight gain of 20 kilograms. Since then (for the last year and a half) the patient's weight had remained unchanged. The patient was administered the drug through a wrong route (subcutaneous).	
Incorrect route of drug administration			

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Injection	Subcutaneous
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 245027**

**Data Entry Date :** 01/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 58

**Onset Date :** 20/08/2008

**Age :** 67Y

**Outcome :** 24/08/2008

**DOB :**

Recovered

**Causality :** Causality probable

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	<p>Suspected atypical neuroleptic syndrome. Patient was an inpatient in psychiatric unit since 30/04/2008 with long term risperidone 0.5mg/bd. During admission gradually increased to 1.5mg/tds. Risperidone dose had been gradually reduced since 17/08/2008 due to increased tremor, sedation and rigidity despite tolerating risperidone well previously. On the 20/08/2008 increasing drowsiness, tremor and increased tone, temperature of 38 degrees with fluctuation blood pressure and heart rate. On the 21/08/2008 patient became hypotonic, and fell into unconscious coma.</p>	Risperidone ceased. Other medications restarted without incident with resolving bloods.

**Medicine details :**

<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	2 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 21/08/2008	
<b>EPILIM (Other drug)</b>		<b>Reason :</b>	
Tablet	1.2 Gram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>OXAZEPAM (Other drug)</b>		<b>Reason :</b>	
Tablet	30 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		22/08/2008	6.5	Patient had an elevated white cell count of ( $12.4 \times 10^9/L$ ), serum creatinine of ( $105 \mu\text{mol/L}$ ) and CK of (453). CT scans all negative for CVA. White blood cell count $4.0-11.0 \times 10^9/L$
White blood cells		21/08/2008	12.4 (H)	
Creatine phosphokinase		22/08/2008	281	Patient had an elevated white cell count of ( $12.4 \times 10^9/L$ ), serum creatinine of ( $105 \mu\text{mol/L}$ ) and CK of (453). CT scans all negative for CVA. White blood cell count $4.0-11.0 \times 10^9/L$
Creatine phosphokinase		21/08/2008	453 (H)	
Creatinine		22/08/2008	62	Valproate drug level:
Creatinine		21/08/2008	105 (H)	
Serum drug level		21/08/2008	83mg/L	
Neutrophils		21/08/2008	8.8 (H)	



# Public Case Detail

Cases Count: 104

**Case Number : 245227**

**Data Entry Date :** 07/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/11/2007

**Age :**

**DOB :** 21/06/1924

**Outcome :**

**Causality :** Causality certain

Not yet recovered

**Information:** History of cellulitis.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Injection site mass	Death	The patient was treated with risperidone long acting injection (LAI) (microspheres, intra-muscular) 37.5 (unit unspecified) from 4 years for paranoid schizophrenia. Approximately 6 months ago (March 2008) the patient developed hard movable granulating lumps around injection site in both buttocks. Condition had worsened since the pain.	
Injection site pain	Death		

## Medicine details :

<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Unspecifid affective psychosis		
Injection	37.5 Milligram	Fortnightly	Intramuscular
<b>Batch :</b>	<b>Started :</b> 15/04/2006	<b>Stopped :</b>	0

## Case Number : 245355

Data Entry Date : 13/10/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 31.8

Onset Date : 29/07/2008

Age :

DOB : 13/10/1920

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Akathisia		Akathisia	

#### Medicine details :

##### RISPERIDONE (Suspected)

Reason : Abnormal involuntary movement

0.5 Milligram Daily

Batch :

Started : 28/07/2008

Stopped : 29/07/2008

##### ASPIRIN (Other drug)

Reason :

100 Milligram Daily

Batch :

Started :

Stopped :

##### DIGOXIN (Other drug)

Reason :

62.5 Microgram Daily

Batch :

Started :

Stopped :

##### FOLIC ACID (Other drug)

Reason :

5 Milligram Daily

Batch :

Started :

Stopped :

##### PERINDOPRIL (Other drug)

Reason :

2.5 Milligram Daily

Batch :

Started :

Stopped :

##### TRIMETHOPRIM (Other drug)

Reason :

300 Milligram Daily

Batch :

Started :

Stopped :

## Case Number : 245382

**Data Entry Date :** 13/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 03/07/2008  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 11/03/1933  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	Patient confused, unable to get out of bed with cogwheel rigidity and neuroleptic malignant syndrome.	Seroquel ceased.
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>RISPERIDONE (Suspected)</b>	<b>Reason :</b>
Tablet	0.5 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 02/05/2008 <b>Stopped :</b> 05/05/2008

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				CK 1200

# Public Case Detail

Cases Count: 104

**Case Number : 245433**

**Data Entry Date :** 14/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 45Y

**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>
Extrapyramidal disorder		Patient experienced extrapyramidal side effects.	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Injection	25 Milligram	Daily	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	





# Public Case Detail

Cases Count: 104

**Case Number : 245461**

**Data Entry Date :** 15/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/10/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Parkinsonism		Patient experienced swollen ankles and shakes.	
Joint swelling			
Tremor			

**Medicine details :**

<b>RISPERDAL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

## Case Number : 246209

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

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** The patient's medical history and concurrent conditions included: alcohol abuse (drinking 2 litres of alcohol per day), illicit drug abuse.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Priapism	Caused or prolonged inpatient hospitalisation	Physician reported that the patient had been receiving risperidone LAI for at least 18 months.	Risperidone permanently discontinued.
Blood prolactin	Caused or prolonged inpatient hospitalisation		

### Medicine details :

Risperdal Consta (Suspected)

**Reason :**

Injection

75 Milligram

Fortnightly

Intramuscular

**Batch :**

**Started :**

**Stopped :**

0

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Prolactin				Prolactin level 1494 miu/l

# Public Case Detail

Cases Count: 104

## Case Number : 246312

Data Entry Date : 17/11/2008

Hospitalisation :

Onset Date : 24/08/2008

Outcome :  
Recovered

Gender : F

Weight (kg) : 0

Age : 42Y

DOB :

Causality : Causality possible

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Trouble swallowing-choking noises in throat, muscle stiffness in back, stooped gait.	Benzotropine 2mg orally.
Choking	Caused or prolonged inpatient hospitalisation		
Gait disturbance	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine details :			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 21/08/2008	<b>Stopped :</b>	
<b>TEMAZEPAM (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
	20 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/07/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 246577**

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

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Age :** 99u

**Onset Date :**

**DOB :**

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** History of anxiety and dipression.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Caused or prolonged inpatient hospitalisation	Patient experienced (got loopy) feeling abnormal and collapsed.	Risperdal discontinued.
Syncope	Caused or prolonged inpatient hospitalisation		

## Medicine details :

**RISPERDAL (Suspected)**

**Reason :** Anxiety neurosis

Tablet

1 Milligram

Daily

Oral

**Batch :**

**Started :**

**Stopped :**

0

# Public Case Detail

Cases Count: 104

**Case Number : 246697**

**Data Entry Date :** 28/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** F  
**Weight (kg) :** 0  
**Age :** 63Y  
**DOB :**  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Haemoptysis	Caused or prolonged inpatient hospitalisation	On an unknown date, while the patient was on risperidone LAI the patient developed pulmonary embolism, non-st elevated myocardial infarction and haemoptysis which was diagnosed on hospital admission.	Risperidone LAI withdrawn, oral risperidone not changed.
Myocardial infarction	Caused or prolonged inpatient hospitalisation		
Pulmonary embolism	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>	
Injection	50 Milligram	Fortnightly	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>WARFARIN SODIUM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 246725**

**Data Entry Date :** 01/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 93

**Onset Date :**

**Age :**

**DOB :** 17/04/1988

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Suicidal ideation		I started thinking about suicide, and I went out and bought a razor blade.	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Injection	25 Milligram	Fortnightly	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 246939**

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

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cerebrovascular accident		cerebrovascular accident	

<b>Medicine details :</b>			
<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
	50 Milligram	Fortnightly	Intramuscular
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 247419**

**Data Entry Date :** 28/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 93

**Onset Date :**

**Age :**

**DOB :** 17/04/1988

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Visual impairment		After starting treatment with Risperdal Consta and additional 2mg of oral Risperidone I started seeing eyes in the pattern on the carpet, I felt depressed and tried allieving the depression by taking melatonin tablets to help me sleep and I became impotent, unable to ejaculate. My fasting blood glucose went from 4.8 mmol/L to 5.2 mmol/L. The texture of my skin became rancid.	
Depressed mood			
Ejaculation disorder			
Erectile dysfunction			
Skin odour abnormal			

**Medicine details :**

<b>Risperdal Consta (Suspected)</b>		<b>Reason :</b>		
Injection	25 Milligram	Fortnightly	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b>		
Tablet	2 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		



# Public Case Detail

Cases Count: 104

**Case Number : 247521**

**Data Entry Date :** 08/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 81Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cerebrovascular accident		Cerebrovascular accident within 24 hours of taking risperidone.	

<b>Medicine details :</b>			
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
Tablet	8 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 104

**Case Number : 247834**

**Data Entry Date :** 20/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Abdominal distension		Patient reported to the pharmacist that after one or two days of treatment with risperidone she experienced swelling of the abdomen giving the appearance of being several months pregnant.	

**Medicine details :**

<b>RISPERDAL (Suspected)</b>	<b>Reason :</b>	
Tablet		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>

# Public Case Detail

Cases Count: 104

**Case Number : 247850**

**Data Entry Date :** 21/01/2009

**Gender :** M

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

**Weight (kg) :** 39

**Onset Date :**

**Age :**

**DOB :** 24/05/2000

**Outcome :**

**Causality :** Causality certain

Recovered

**Information:** Cert(rechall)

Symptoms occurred when commenced on Risperdal, resolved when ceased and restarted when re-introduced. Slowly disappeared over 3 months.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Testicular pain		Testicular pain.	

## Medicine details :

RISPERDAL (Suspected)

**Reason :**

1 Milligram Daily

**Batch :**

**Started :**

**Stopped :**

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: RISPERDAL, RISPERIDONE, Risperdal Consta, Risperdal Quicklet