



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181141

Seq: 1

Gender: F

Reported: 07/01/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 04/11/2002

DOB: 21/03/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Creatine Phosphokinase increased	Bromocriptine 5mg tds, benztropine 0.5mg tds, diazepam 2.5mg tds.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Catatonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 29/10/2002	Stopped: 05/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2003	Creatine				

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181141

Seq: 1

Gender: F

Reported: 07/01/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 04/11/2002

DOB: 21/03/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
Tablet	4.0 Milligram
	Daily
	Oral
Batch:	Started: 29/10/2002
	Stopped: 05/11/2002

Laboratory Investigations:

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181185

Seq: 1

Gender: F

Reported: 08/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Leucopenia	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application		Oral	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Neutrophils				

Additional Information:

The patient has developed leucopenia with other antipsychotic medication in the past.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181191 **Seq:** 1 **Gender:** M
Reported: 08/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 15
Onset Date: 17/08/2002 **DOB:** 13/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase incr Malaise Myalgia Neuroleptic malignant syndrome		Fever, Malaise, Ck was elevated on 27/08/2002 at 402 but unnoticed until his admission in 04/11/2002 when Ck was 1963. Neuroleptic Malignant Syndrome. Myalgia.	Date hospitalised 04/11/02.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/11/2002	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Creatine	CK range	27/08/2002	402	
08/01/2003	Creatine	CK range	04/11/2002	1963	
08/01/2003	Creatine	CK range	06/11/2002	3553	

Additional Information:

The dose start and stop date for the drug Olanzapine - 01/02 and 10/02. Dose start date for Risperidone - 01/01 and dose start date for Sertraline - 01/02. Despite 10 days of treatment, patient remains psychotic.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181196

Seq: 1

Gender: M

Reported: 08/01/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Neutrophils				

Additional Information:

Patient has been suffering from mild Agranulocytosis and Neutropenia wihtin the last year.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181460

Seq: 1

Gender: F

Reported: 13/01/2003

Weight: 0.00

Hospitalisation:

Age: 95

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mobility decreased	Severe	Reduced mobility, slow responses/reflexes, shuffling gait to almost inertia , flat affect and drowsiness.	
Confusional state	Severe		
Flat affect	Severe		
Gait disturbance	Severe		
Somnolence	Severe		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's history - Chair bound and lives in a nursing home.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181462

Seq: 1

Gender: M

Reported: 13/01/2003

Weight: 0.00

Hospitalisation:

Age: 85

Onset Date:

DOB: 23/02/1917

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mobility decreased Confusional state Flat affect Gait disturbance Somnolence		Gradual progression of reduced mobility, slowed responses/reflexes, flat affect and shuffling gait to almost inertia.	

Medicine Details:

RISPERDAL (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	1.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset - Oct 2002. Other drugs - Celebrex, Imdur, Renitec and Mogadon. Dementia with aggressive behaviour and delusions prior to use of Risperidone.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181568

Seq: 1

Gender: M

Reported: 14/01/2003

Weight: 0.00

Hospitalisation:

Age: 12Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephrolithiasis		Developed kidney stone and experienced dysuria.	
Dysuria			

Medicine Details:

METHYLPHENIDATE HYDROCHLORIDE (Other drug)		Reason:
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason: Behavior disorders of childhood
Tablet		Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181775

Seq: 1

Gender: M

Reported: 17/01/2003

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 17/12/2002

DOB: 22/05/1983

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Akathisia Oculogyration Opisthotonus Throat tightness		Restless legs, oculogyric crisis, opisthotonus and sensation of throat closing.	Two doses of benztropine mesilate 1gm. Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 16/12/2002	Stopped:	17/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Illicit drug abuse. Had previously been on Risperidone in the past for 12 months (dates unspecified), but ceased it due to drowsiness.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181831
Reported: 20/01/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 16/07/2002

Age: 49Y

Outcome: Recovered

16/07/2002

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Supraventricular tachycardia		Developed rapid irrregular pulse and drop in bp.	Adrenosine iv.
Hypotension			

Medicine Details:

TEMAZE (Other drug)		Reason: Specific disorders of sleep
	10.0 Milligram	As necessary Oral
Batch:	Started: 10/07/2002	Stopped:
LARGACTIL (Other drug)		Reason: Otr spec symp psychopathol nec
Tablet	50.0 Milligram	As necessary Oral
Batch:	Started: 13/07/2002	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified psychosis
Tablet	1.0 Milligram	Daily Oral
Batch:	Started: 11/07/2002	Stopped: 15/07/2002
RISPERDAL (Suspected)		Reason: Unspecified psychosis
Tablet	4.0 Milligram	Daily Oral
Batch:	Started: 15/07/2002	Stopped: 17/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 181843 **Seq:** 1 **Gender:** M
Reported: 21/01/2003 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 82Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Required Visit to Doctor	Cogwheel rigidity, short shuffling gait, expressionless face.	Risperidone ceased.
Gait disturbance	Required Visit to Doctor		
Hypertonia	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/02/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Furosemide, Metoprolol, Aspirin, Zocor, Cipramil, Imdur, Perindopril, Slow K, Digoxin, Amlodipine, Pethexiline and Coloxyl with Senna.
Date of onset August 2001.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182082
Reported: 28/01/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 09/12/2002

Age: 25

DOB: 08/09/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Spontaneous abortion, approximately 12 weeks after her last menstrual period.	

Medicine Details:

FOLIC ACID (Suspected)	Reason: Anxiety neurosis
Oral application	Oral
Batch:	Started: 23/10/2002 Stopped: contin
RISPERDAL (Suspected)	Reason: Anxiety neurosis
Tablet 3.0 Milligram Daily	Oral
Batch:	Started: Stopped: contin
ZOLOFT (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily	Oral
Batch:	Started: Stopped: contin
ALPRAZOLAM (Suspected)	Reason: Anxiety neurosis
Tablet 6.0 Milligram Daily	Oral
Batch:	Started: Stopped: 27/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/01/2003	Radiology				

Additional Information:

Risk factors - smoking, pregnant, maternal aunt had miscarriage. Patient's history - includes genital warts prior to pregnancy.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182082

Seq: 1

Gender: F

Reported: 28/01/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 09/12/2002

DOB: 08/09/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Suspected)

Reason: Migraine

Oral application

40.0 Milligram

Daily

Oral

Batch:

Started:

Stopped: 24/10/2002

Laboratory Investigations:

Additional Information:

Risk factors - smoking, pregnant, maternal aunt had miscarriage. Patient's history - includes genital warts prior to pregnancy.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182101
Reported: 28/01/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 30
DOB: 05/07/1972
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity Rash Swollen tongue		An a allergic reaction with a rash on the front of chest and back, "right of arm" and swelling of tongue.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Dose Unspecified 2 times	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182563 **Seq:** 1 **Gender:** M
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 26
Onset Date: 14/08/2002 **DOB:** 25/11/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Cardiomyopathy-life threatening and influenza symptoms a few days before presentation.	Given ventilated inotrope support.
Hypoventilation	Life threatening	Cardiomyopathy-life threatening and influenza symptoms a few days before presentation.	Given ventilated inotrope support.
Influenza like illness	Life threatening	Cardiomyopathy-life threatening and influenza symptoms a few days before presentation.	Ventilated inotrope support.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
FLUPENTHIXOL DECANOATE (Suspected)		Reason: Unspecified schizophrenia	
Injection	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182574

Seq: 1

Gender: F

Reported: 10/02/2003

Weight: 0.00

Hospitalisation:

Age: 78

Onset Date:

DOB: 13/04/1924

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity		Stiff, protruding neck dystonia and drowsiness, cogwheeling, felt hot to touch but no fever, difficulty eating and drinking.	Risperidone ceased. Treated with diazepam, benzotropine mesylate, haloperido;
Dysphagia		Stiff, protruding neck dystonia and drowsiness, cogwheeling, felt hot to touch but no fever, difficulty eating and drinking.	Risperidone ceased. Treated with diazepam, benzotropine mesylate, haloperido;
Dystonia		Stiff, protruding neck dystonia and drowsiness, cogwheeling, felt hot to touch but no fever, difficulty eating and drinking.	Risperidone ceased. Treated with diazepam, benzotropine mesylate, haloperido;

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Risperidone started in May 2002 for mental and behavioral problems. Patient also taking donepezil, hydrochloride, quinidine sulfate, nitrofurantoin, aricept, kinidin, macrodantin, noroxin, amoxycillin trihydrate/potassium clavulanate. Her chin and chest is very severe and therefore has difficulty eating and drinking. The patient must be pushed to drink, as it is very difficult given to her body posture.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182574

Seq: 1

Gender: F

Reported: 10/02/2003

Weight: 0.00

Hospitalisation:

Age: 78

Onset Date:

DOB: 13/04/1924

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing		Stiff, protruding neck dystonia and drowsiness, cogwheeling, felt hot to touch but no fever, difficulty eating and drinking.	Risperidone ceased. Treated with diazepam, benzotropine mesylate, haloperido;
Somnolence		Stiff, protruding neck dystonia and drowsiness, cogwheeling, felt hot to touch but no fever, difficulty eating and drinking.	Risperidone ceased. Treated with diazepam, benzotropine mesylate, haloperido;

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Risperidone started in May 2002 for mental and behavioral problems. Patient also taking donepezil, hydrochloride, quinidine sulfate, nitrofurantoin, aricept, kinidin, macrodantin, noroxin, amoxycillin trihydrate/potassium clavulanate. Her chin and chest is very severe and therefore has difficulty eating and drinking. The patient must be pushed to drink, as it is very difficult given to her body posture.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 182799 **Seq:** 1 **Gender:** F
Reported: 12/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 18/01/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperthermia malignant		Hyperthermia malignant, headache, infection, stiff back and neck	
Headache			
Infection			
Meningism			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2003	C-Reactive Protein		24/01/2003	250	
12/02/2003	Erythrocyte		24/01/2003	33	
12/02/2003	White blood cells				

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 183962

Seq: 1

Gender: F

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 73

Onset Date: 15/09/2002

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash developed one day post commencing risperidone. Rash on face, periorbital, flexus elbow, groin area and wrist.	Given Phenergan

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	0.5 Milligram	Oral	
Batch:	Started: 13/09/2002	Stopped:	16/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking Ranitidine, Panadeine Forte, Ferrograd, and Neocytamen. 182370 is a duplicate.



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 184530 **Seq:** 1 **Gender:** F
Reported: 31/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 10/03/2003 **DOB:** 03/03/1939
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Myocardial infarction.	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 06/03/2003 Stopped: 09/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/03/2003	Electrocardiograph				

Additional Information:

Patient history: Metabolic disorders, diabetes and multiple medical conditions (unspecified).



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 184928

Seq: 1

Gender: M

Reported: 11/04/2003

Weight: 0.00

Hospitalisation:

Onset Date: 22/02/2003

Age: 67

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Tremor, Rash like a lumpy mass, can not lift his head up (head is permantly drooped forward so that hisi head is resting on his chest)	
Asthenia			
Rash			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1500.0 Milligram	Total	
Batch:	Started:	Stopped:	
IRBESARTAN (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of dermentia, ventricular tachycardia (1999) and atrial fibrillation (Nov-02 and Dec-02).



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Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 185588

Seq: 1

Gender: F

Reported: 31/03/2003

Weight: 0.00

Hospitalisation:

Age: 64

Onset Date: 10/03/2003

DOB: 03/03/1939

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Ataxia	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 06/03/2003 Stopped: 09/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Metabolic disorders. Diabetes and multiple medical conditions (unspecified).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 185692

Seq: 1

Gender: F

Reported: 09/05/2003

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 24/03/2003

DOB: 13/07/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea	Required Visit to Doctor	Amenorrhoea, galactorrhoea	
Galactorrhoea	Required Visit to Doctor	Amenorrhoea, galactorrhoea	

Medicine Details:

RISPERDAL (Suspected)		Reason: Hallucinations	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 21/02/2003	Stopped: 06/05/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Aropax, Tegretol, Voltaren.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 185695 **Seq:** 1 **Gender:** F
Reported: 07/05/2003 **Weight:** 72.00
Hospitalisation: Required a visit to the doctor **Age:** 99U
Onset Date: 22/03/2003 **DOB:**
Outcome: Not yet recovered 22/03/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drooling		Drooling from the mouth, speech impairment	
Rash		Rash, anxiety	
Anxiety			
Speech disorder			

Medicine Details:

RISPERDAL (Suspected)	Reason:		
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 22/02/2003	Stopped: 01/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 185794

Seq: 1

Gender: F

Reported: 12/05/2003

Weight: 0.00

Hospitalisation:

Age: 16Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia	
Influenza like illness			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Family history of cardiac problems concurrent illnesses include: social isolation, behavioural changes, inappropriate quilt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 186090

Seq: 1

Gender: F

Reported: 20/05/2003

Weight: 0.00

Hospitalisation:

Age: 88

Onset Date: 27/04/2003

DOB: 12/11/1914

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Hallucinations, uncommunicative, out of touch with reality and extremely psychotic. Fell out of bed.	Stopped Risperdal for 2 days then recommenced Serenace 0.5mg nocte.
Psychotic disorder	Required Visit to Doctor	Hallucinations, uncommunicative, out of touch with reality and extremely psychotic. Fell out of bed.	

Medicine Details:

RISPERDAL (Suspected)	Reason:
2.0 Milligram	Daily
Oral	
Batch:	Started: 26/04/2003
	Stopped: 07/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 186198

Seq: 1

Gender: F

Reported: 26/05/2003

Weight: 0.00

Hospitalisation:

Age: 78

Onset Date:

DOB: 10/05/1925

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal disorder		Gastro-intestinal disorder nos	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 04/03/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Sodium Valproate, Psyllium Hydrophilic, Mucilloid. metamucil, Alendronate, premia, Poly-tears, Phenytoin, paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 186621

Seq: 1

Gender: M

Reported: 05/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 17/03/2003

Age: 52Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Akathisia Parkinsonism Tardive dyskinesia		Dystonia, parkinsonism. Tardive dyskinesia and ongoing akathisia.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Oral	
Batch:	Started:	Stopped:	Contin
CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2001 L TERM	Stopped: 17/03/2003	
AMISULPRIDE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/03/2003	Stopped: 29/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Akathisia - patient on 4mg Risperidone, resolved after cessation of Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 186710

Seq: 1

Gender: M

Reported: 06/06/2003

Weight: 75.00

Hospitalisation:

Age: 35

Onset Date: 24/05/2003

DOB: 03/01/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism	Caused or prolonged inpatient hospitalisation	Priapism for four days requiring surgical decompression secondary to Risperidone.	Ceased Risperidone.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 26/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 187022

Seq: 1

Gender: F

Reported: 18/06/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 13/05/2003

DOB: 10/12/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash papular		4cm erythema patch with scattered papules over the abdomen, chest and breast - itchy.	Celestone and Sorbolene cream and was then switched to Amisulpride.

Medicine Details:

RISPERDAL (Suspected)	Reason:
1.0 Milligram	Daily
Oral	
Batch:	Started: 06/05/2003
	Stopped: 12/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Ciprmil, Benztropine and Thyroxine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 187661

Seq: 1

Gender: F

Reported: 23/06/2003

Weight: 80.00

Hospitalisation:

Age: 39

Onset Date: 14/06/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Galactorrhoea	Commenced on Chlorpromazine 100mg/daily.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 30/05/2003	Stopped: 20/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 187913

Seq: 1

Gender: M

Reported: 27/06/2003

Weight: 70.00

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Tremors	Cogentin

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
3.0 Milligram	Daily
Batch:	Started: 14/06/2003 Stopped: 25/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking Zyprexa



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188176

Seq: 1

Gender: M

Reported: 27/06/2003

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 09/06/2003

DOB: 09/01/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Metabolic acidosis	Caused or prolonged inpatient hospitalisation	Metabolic acidosis, lithium toxicity, diabetes.	Haloperidol, Chlorvescent, Magmin, Sosium Bicarbonate,
Diabetes insipidus	Caused or prolonged inpatient hospitalisation		
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
	1500.0 Milligram	Daily	
Batch:	Started: 09/06/2003	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 09/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2003	Carbon dioxide content blood		06/10/2003	26	
27/06/2003	Chloride		09/06/2003	111	
27/06/2003	Chloride		06/10/2003	97	
27/06/2003	Creatinine		09/06/2003	178	
27/06/2003	Creatinine		09/06/2003	178	
27/06/2003	Creatinine		06/10/2003	140	
27/06/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188176

Seq: 1

Gender: M

Reported: 27/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 09/06/2003

Age: 35

Outcome: Not yet recovered

DOB: 09/01/1968

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
	1500.0 Milligram	Daily	
Batch:	Started: 09/06/2003	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 09/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2003	Other data				
27/06/2003	Pharmacokinetics				
27/06/2003	Potassium		09/06/2003	4.2	
27/06/2003	Potassium		06/10/2003	4.0	
27/06/2003	Serum glucose		10/06/2003	37.0	
27/06/2003	Serum glucose		06/10/2003	13.0	
27/06/2003	Sodium		09/06/2003	142	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188176

Seq: 1

Gender: M

Reported: 27/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 09/06/2003

Age: 35

DOB: 09/01/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
	1500.0 Milligram	Daily	
Batch:	Started: 09/06/2003	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 09/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2003	Sodium		23/06/2003	141	
27/06/2003	Urea		09/06/2003	16.0	
27/06/2003	Urea		10/06/2003	7.0	
27/06/2003	pH		09/06/2003	7.11	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188553
Reported: 17/07/2003

Seq: 1

Gender: M
Weight: 68.00

Hospitalisation:

Onset Date: 04/11/2002

Age: 15

DOB: 13/03/1987

Outcome: Recovered

18/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation	malaise, fevers, delerium, muscles aches, creatine kinase increased.	Ceased Risperidone and Olanzapine.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/07/2003	Creatine				

Additional Information:

History of intellectual and global speeches delay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188553

Seq: 1

Gender: M

Reported: 17/07/2003

Weight: 68.00

Hospitalisation:

Age: 15

Onset Date: 04/11/2002

DOB: 13/03/1987

Outcome: Recovered

18/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Additional Information:

History of intellectual and global speeches delay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 188612

Seq: 1

Gender: M

Reported: 18/07/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 13/06/2003

DOB: 09/09/1952

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema		Angioneuretic oedema.	
Lip oedema		Swelling around lips.	
Periorbital oedema		Swelling under eyes.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)		Reason:	
Injection		Dose Unspecified	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Schizophrenia	
Injection	37.5 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was previously on oral Risperidone with no history of allergy to drug. The next dose of IM Risperidone has been delayed, but will continue.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189091

Seq: 1

Gender: F

Reported: 30/07/2003

Weight: 70.00

Hospitalisation:

Onset Date: 10/07/2003

Age: 54

DOB: 20/05/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Required Visit to Doctor	Blurred vision, dry mouth.	
Dry mouth	Required Visit to Doctor		

Medicine Details:

SEROQUEL (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2003	Stopped:	
RISPERDAL (Interaction)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 02/09/2002	Stopped:	03/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189091

Seq: 1

Gender: F

Reported: 30/07/2003

Weight: 70.00

Hospitalisation:

Age: 54

Onset Date: 10/07/2003

DOB: 20/05/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Interaction)

Reason:

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 02/09/2002

Stopped: 03/06/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189156
Reported: 04/08/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 04/02/2001

Age: 65

DOB: 11/12/1935

Outcome: Recovered

13/02/2001

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase incr		Elevated temperature, increased CK.	Ceased Risperidone

Medicine Details:

CARBAMAZEPINE (Other drug)		Reason: Otr spec symp psychopathol nec	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	1.5 Milligram	Daily	
Batch:	Started: 30/01/2001	Stopped: 05/02/2001	
GEMFIBROZIL (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189159

Seq: 1

Gender: M

Reported: 04/08/2003

Weight: 0.00

Hospitalisation:

Onset Date: 23/07/2003

Age: 26

DOB: 23/12/1976

Outcome: Recovered

23/07/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Life threatening	Dystonic reaction, opisthotonus.	Cogentin
Opisthotonus	Life threatening		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Augmentin Duo Forte, Methadone, Rulide, Nicotine, Ventolin, Valacyclovir, Nevirapine, Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189643

Seq: 1

Gender: M

Reported: 18/08/2003

Weight: 0.00

Hospitalisation:

Age: 67

Onset Date:

DOB: 16/04/1936

Outcome: Recovered

16/07/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia		Muscular aches in arms	

Medicine Details:

CIPRAMIL (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2003	Stopped: 09/07/2003	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	1.5 Milligram	Daily	Oral
Batch:	Started: 09/04/2003	Stopped: 09/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset May 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189749 **Seq:** 1 **Gender:** M
Reported: 21/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20Y
Onset Date: 08/08/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphadenopathy		Cervical lymphadenopathy	
Conjunctivitis		Conjunctivitis	
Pyrexia		Fibrile - 41c	
Influenza like illness		Flu - like symptoms	
Haematemesis		Haematemesis - bright red blood	
Mucosal inflammation		Mucositis	
Myalgia		Myalgia	
Pharyngitis		Pharyngitis	
Rash macular		Red - rash macular desquamating on lips, peri-orbital and trunk, broken areas and blistered.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 10/08/2003	
CARBAMAZEPINE (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 29/07/2003	Stopped: 10/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies to Penicillin and Aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189749 **Seq:** 1 **Gender:** M
Reported: 21/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20Y
Onset Date: 08/08/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills		Rigors	
Pharyngolaryngeal pain		Sore throat	
Vomiting		Vomiting - bright red blood	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 10/08/2003	
CARBAMAZEPINE (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 29/07/2003	Stopped: 10/08/2003	

Laboratory Investigations:

Additional Information:

Allergies to Penicillin and Aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189826

Seq: 1

Gender: F

Reported: 25/08/2003

Weight: 0.00

Hospitalisation:

Onset Date: 21/03/2003

Age: 37

DOB: 16/03/1966

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dry mouth		Swollen toungue, dry mouth.	
Swollen tongue		Swollen toungue, dry mouth.	

Medicine Details:

Reasons Details:		
RISPERDAL (Suspected)	Reason:	Schizophrenia
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Zyprexa, Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 189919

Seq: 1

Gender: M

Reported: 28/08/2003

Weight: 0.00

Hospitalisation:

Age: 62

Onset Date: 03/03/2003

DOB: 01/11/1940

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Maculopapular rash over most of trunk, no anaphylactic features.	

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified psychosis		
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 03/03/2003	Stopped: 04/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 190355

Seq: 1

Gender: M

Reported: 10/09/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety Agitation		Anxiety, agitation.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other medication taken: 2 or 3 NR6 Herbalife tablets. Whether treatment or concurrent medication is not known.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 190514

Seq: 1

Gender: M

Reported: 15/09/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose Suicide attempt		Overdose	

Medicine Details:

RISPERDAL (Suspected)	Reason:
	10.0 Milligram Daily
Batch:	Started: 26/06/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Overdose of 60 x 3 mg tablets



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 190834

Seq: 1

Gender: M

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Caused or prolonged inpatient hospitalisation	Hepatitis nos	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 190838

Seq: 1

Gender: M

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 27/08/2003

DOB: 25/10/1973

Outcome: Recovered

03/09/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Pulmonary embolism	Risperidone ceased

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	1.0 Milligram Daily Oral
Batch:	Started: 11/08/2003 Stopped: 19/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Epilim ceased 3 weeks prior to the commencement of risperidone. Valproate 1/2 life 8 - 12 hours.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191277

Seq: 1

Gender: M

Reported: 14/10/2003

Weight: 90.00

Hospitalisation:

Age: 29

Onset Date: 25/09/2003

DOB: 17/03/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema	Required Visit to Doctor	Angioedema:- periorbital oedema, facial swelling, tongue swelling.	Ceased Risperidone.
Skin disorder	Required Visit to Doctor	Dry cracking skin on face and hands.	
Erythema	Required Visit to Doctor	Red hands	
Periorbital oedema	Required Visit to Doctor		
Swelling face	Required Visit to Doctor		
Tongue oedema	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 25/09/2003	Stopped: 25/09/2003	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2003	Stopped: 01/10/2003	
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 24/09/2003	Stopped: 24/09/2003	
Zolpidem Sandoz (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191277

Seq: 1

Gender: M

Reported: 14/10/2003

Weight: 90.00

Hospitalisation:

Age: 29

Onset Date: 25/09/2003

DOB: 17/03/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ATENOLOL (Suspected)

Reason:

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 23/09/2003

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191442 **Seq:** 1 **Gender:** F
Reported: 20/10/2003 **Weight:** 61.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea	Caused or prolonged inpatient hospitalisation	Patient "felt weird", then became increasingly agitated.	
Galactorrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Other drug)		Reason: Unspecified schizophrenia
	100.0 Milligram	Daily
Batch:	Started: 25/09/2003	Stopped:
RISPERIDONE (Suspected)		Reason: Schizophrenia
	3.0 Milligram	Daily
Batch:	Started: 01/07/2003	Stopped: 28/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Hepc + pain IVI drugs. Is said then became aggressive when treated with interferon and rebetol. Stopped in July 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191747
Reported: 30/10/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 52
DOB: 01/03/1951
Causality: Causality possible

Hospitalisation:

Onset Date: 17/10/2003
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/09/2003	Stopped: 17/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191758

Seq: 1

Gender: F

Reported: 30/10/2003

Weight: 75.00

Hospitalisation:

Age: 20

Onset Date: 06/08/2003

DOB: 05/04/1983

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Neutropenia x 6 daily treatment.	
Weight increased	Required Visit to Doctor	Weight gain - 65kg at commencement - 75kg at cessation.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
		Dose Unspecified Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
		Dose Unspecified Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191823

Seq: 1

Gender: F

Reported: 03/11/2003

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date:

DOB: 02/07/1938

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Electrocardiograph		15/10/2003	Normal with a	
03/11/2003	Electroencephalog		22/10/2003	Normal sinus	

Additional Information:

The reporter states that the patient was switched from fluphenazine decanoate to risperidone two years ago secondary to tardive dyskinesia concerns.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191884

Seq: 1

Gender: M

Reported: 05/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 03/10/2003

Age: 44

DOB: 03/01/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation		loss of epidermis to bilateral palms and lower lip.	Risperidone ceased - symptoms resolved.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
PANADEINE (Other drug)		Reason: Pain	
	8.0 Dose Unspecified	Daily	Oral
Batch:	Started: 03/10/2003	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 03/10/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose start date: for Paroxetine - 09/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191979

Seq: 1

Gender: M

Reported: 07/11/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		Priapism	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Erection for 3 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 191987

Seq: 1

Gender: F

Reported: 10/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 15/06/2003

Age: 50Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Abnormal involuntary movements of the tongue, mouth and limbs	Risperidone has been stopped permanently.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
	2.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped: 31/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192334

Seq: 1

Gender: F

Reported: 19/11/2003

Weight: 0.00

Hospitalisation:

Age: 91Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tradive dyskinesia	Risperidone reduced from 2mg to 1mg.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose of risperidone was reduced from 2mg to 1mg and the symptoms improved.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192361

Seq: 1

Gender: U

Reported: 21/11/2003

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 06/11/2003

DOB: 03/06/1944

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Clonic convulsion.	Risperdal Consta ceased.

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

2 days after the dose increase, the patient experienced myoclonic jerks (outcome unknown). The patient had previously been on Clozapine and had a similar reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192394

Seq: 1

Gender: F

Reported: 21/11/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Confusion, slurred speech, daze.	
Dysarthria	Required Visit to Doctor		
Feeling abnormal	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 21/10/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms after increasing dose of Risperdal from half morning and night to one morning and night.
Other drugs taken: Feldene, Aropax, Lipitor, Aricept, Paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192793

Seq: 1

Gender: F

Reported: 03/12/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 27/10/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neonatal		Drug withdrawal syndrome. Neonatal disorder NOS - abnormality.	
Neonatal disorder			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Intrauterine
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	
MOCLOBEMIDE (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Marcain and Fentanyl.
Baby was exposed from 20+ weeks. The baby experienced withdrawl symptoms (from risperidone) for 2 days, on days 3 and 4, however, did not require medication to control it.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192835

Seq: 1

Gender: F

Reported: 04/12/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 10/11/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe	Severe dystonic reaction, tardive dyskinesia.	Risperdal stopped.
Tardive dyskinesia			

Medicine Details:

CLOPIXOL-ACUPHASE (Other drug)		Reason:	
		3.0 Dose Unspecified Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified neurosis	
Tablet		1.0 Dose Unspecified Daily Oral	
Batch:	Started: 27/10/2003	Stopped: 10/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concomitant medication commenced approximately 4 weeks ago. Patient was on Risperidone for 1-2 weeks. 2 weeks following cessation of Risperidone, there has been no improvement in Tardive Dyskinesia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192916 **Seq:** 1 **Gender:** M
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 14/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation	Fell on floor, high fever (39.2degrees Celcius, HR 104), increased tone all limbs, flushed face. Observations/signs/symptoms seem consistent with Neuroleptic Malignant Syndrome.	IV Fluids (hydration). Given benzos if agitated and paracetamol. Risperidone ceased.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 14/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2003	Creatine phosphokinase		15/10/2003	18960	
05/12/2003	White blood cells				

Additional Information:

Patient also administered: FGF, Mogadon, Simvastatin, Omeprazole, Panadeine Forte.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192916 **Seq:** 1 **Gender:** M
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 14/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason: Schizophrenia
Tablet	4.0 Milligram Daily Oral
Batch:	Started: Stopped: 14/10/2003

Laboratory Investigations:

Additional Information:

Patient also administered: FGF, Mogadon, Simvastatin, Omeprazole, Panadeine Forte.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192916 **Seq:** 1 **Gender:** M
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 14/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason: Schizophrenia
Tablet	4.0 Milligram Daily Oral
Batch:	Started: Stopped: 14/10/2003

Laboratory Investigations:

Additional Information:

Patient also administered: FGF, Mogadon, Simvastatin, Omeprazole, Panadeine Forte.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 192916 **Seq:** 1 **Gender:** M
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 14/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 14/10/2003	

Laboratory Investigations:

Additional Information:

Patient also administered: FGF, Mogadon, Simvastatin, Omeprazole, Panadeine Forte.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 193736

Seq: 1

Gender: F

Reported: 09/01/2004

Weight: 82.00

Hospitalisation:

Age: 57

Onset Date: 09/12/2003

DOB: 21/10/1946

Outcome: Recovered

16/01/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Extreme anxiety, agitation, headache, polydipsia.	
Medication error	Required Visit to Doctor	Prescribe dose 4mg/daily, increased by GP in apparent crisis situation to level above recommended dose.	
Agitation	Required Visit to Doctor		
Headache	Required Visit to Doctor		
Polydipsia	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started: 25/11/2003	Stopped: 24/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Very severe paradoxical reaction due to excessive dose. Other drugs: Diazepam, Medroxyprogesterone and Paracet/Cod.DHCS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 193799

Seq: 1

Gender: F

Reported: 12/01/2004

Weight: 90.00

Hospitalisation:

Age: 99U

Onset Date: 05/01/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Life threatening	Bilateral Ca breast almost mirror image.	In progress.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194030
Reported: 22/01/2004
Hospitalisation:
Onset Date: 14/01/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 61Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions Nos	

Medicine Details:

Risperdal Consta (Interaction)		Reason: Schizophrenia	
Inhalation	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	
CARBAMAZEPINE (Interaction)		Reason: Epilepsy	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Interaction)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/01/2004	
FOLIC ACID (Other drug)		Reason:	
	Dose Unspecified		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Epilepsy Nos - ongoing.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194032

Seq: 1

Gender: M

Reported: 22/01/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anger		Difficult to control temper and outburst of anger	
Elevated mood		Mood has "escalated",	Change in medications from Risperdal 1.5mg/nocte, Zoloft 100mg/mane and Zoloft 50mg/mid-day. Prescribed with 5mg Diazepam tablets since the adverse event.
Violent ideation		Violent thoughts of "wanted to kill my parents"	
Aggression		Which lead to being placed under arrest by police	

Medicine Details:

EFEXOR (Suspected)		Reason:		
	150.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		
RISPERDAL (Suspected)		Reason:		
	3.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Seeing a psychiatrist for 5 years. Diagnosed with schizophrenia. Advised that he did not have a history of violence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194071
Reported: 23/01/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 18Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Social avoidant behaviour		Social avoidant behaviour, vomiting, faecal incontinence, salivary hypersecretion, hallucination, obsessional state.	
Tourette's disorder		Tourette's syndrome symptoms experienced head and tongue movements and "bizarre" body movements. Seemed more withdrawn "like his mind is blocked", giggling.	
Tic		Tourette's syndrome	
Tremor		Tremor one leg	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified neurosis
Tablet	2.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Seroquel, Lithium, Efexor.
These symptoms also occurred when he was on quetiapine fumarate, which is why he was changed to risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194071

Seq: 1

Gender: M

Reported: 23/01/2004

Weight: 0.00

Hospitalisation:

Age: 18Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence Hallucination Obsessive-compulsive disorder Salivary hypersecretion Vomiting			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified neurosis
Tablet	2.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Patient was also taking Seroquel, Lithium, Efexor.
These symptoms also occurred when he was on quetiapine fumarate, which is why he was changed to risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194201

Seq: 1

Gender: M

Reported: 02/02/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Antiphospholipid antibodies positiv		Antiphospholipid antibodies positive and hypoproteinaemia	
Hypoproteinaemia			

Medicine Details:

MIRTAZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194217

Seq: 1

Gender: F

Reported: 03/02/2004

Weight: 63.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 27/06/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Sedation		Weight gain, sedation.	Changed medication.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 15/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Diazepam, Aripiprazole, Sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194351

Seq: 1

Gender: U

Reported: 04/02/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation	Hepatic function abnormal.	Hospitalised for a week.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Hepatitic picture.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194393

Seq: 1

Gender: F

Reported: 06/02/2004

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 24/01/2004

DOB: 22/05/1960

Outcome: Recovered

02/02/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast tenderness	Required Visit to Doctor	Breast tenderness, breast enlarged female, blood prolactin increased.	Risperdal ceased.
Blood prolactin increased	Required Visit to Doctor		
Breast enlargement	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/02/2004	Prolactin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194704

Seq: 1

Gender: M

Reported: 18/02/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus - non insulin dependent.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194777
Reported: 20/02/2004

Seq: 1

Gender: F
Weight: 65.00

Hospitalisation:

Onset Date: 04/02/2004
Outcome: Unknown

Age: 53

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mutism	Caused or prolonged inpatient hospitalisation	Mutism, depressive symptom, tardive dyskinesia, treatment non compliance, ALT increased.	Commenced on mirtazapine, haloperidol was ceased.
Alanine aminotransferase increase	Caused or prolonged inpatient hospitalisation		
Depressive symptom	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	Stopped:	
HALDOL DECANOATE (Suspected)		Reason: Unspecified schizophrenia	
Injection			
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection		25.0 Milligram	Fortnightly Intramuscular
Batch:	Started: 02/02/2004	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient 's problem is considered to be behavioural.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194777
Reported: 20/02/2004

Seq: 1

Gender: F
Weight: 65.00

Hospitalisation:

Onset Date: 04/02/2004
Outcome: Unknown

Age: 53
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	Stopped:	
HALDOL DECANOATE (Suspected)		Reason: Unspecified schizophrenia	
Injection			
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection		25.0 Milligram	Fortnightly Intramuscular
Batch:	Started: 02/02/2004	Stopped:	contin

Laboratory Investigations:

Additional Information:

The patient 's problem is considered to be behavioural.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194779

Seq: 1

Gender: M

Reported: 20/02/2004

Weight: 0.00

Hospitalisation:

Age: 73

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis		February 2004 Deep vein thrombosis.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started: 27/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/02/2004	D-Dimer				

Additional Information:

Patient also administered: Aspirin, Sinemet, Aropax, Florinef, cardiprin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194795

Seq: 1

Gender: M

Reported: 20/02/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Muscle rigidity Speech disorder Trismus		Dystonia, rigidity, jaw spasm, speech impaired.	

Medicine Details:

MIDAZOLAM (Suspected)		Reason:	
Injection	7.0 Milligram	Intravenous	
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
Injection	10.0 Milligram	Intravenous	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194840

Seq: 1

Gender: M

Reported: 23/02/2004

Weight: 0.00

Hospitalisation:

Age: 75Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Caused or prolonged inpatient hospitalisation	Deep vein thrombosis, swelling of legs (right thigh).	Hospitalisation & TED stockings. No change in doses or meds ATOR.
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason: Hallucinations
Tablet	0.5 Milligram Daily
Batch:	Started: 15/07/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/02/2004	D-Dimer				
23/02/2004	Other data				

Additional Information:

Patient also administered: Kinson, Aropax, Florinef.
Patient maintained with TED stockings at this stage.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194945

Seq: 1

Gender: F

Reported: 26/02/2004

Weight: 0.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gallbladder disorder		Gallbladder disorder, raised liver function tests, blood lactate dehydrogenase increased.	Gallbladder removed
Blood lactate dehydrogenase incre			
Liver function test abnormal			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2004	Hepatitis C				

Additional Information:

All LFT's returned to normal except LDH which remains elevated (250).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 194975

Seq: 1

Gender: M

Reported: 27/02/2004

Weight: 0.00

Hospitalisation:

Age: 64Y

Onset Date: 22/12/2003

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure decreased		Blood pressure decrease.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 21/12/2003	Stopped: 24/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2004	Other data				

Additional Information:

Patient also administered: Coversyl plus, Atenolol, Norvasc, Gliclazide, Metformin.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195057
Reported: 01/03/2004

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 10/02/2004

Age: 93

DOB: 29/03/1910

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bile duct obstruction	Required Visit to Doctor	Drug induced hepatitis, bile duct obstruction, lymphopenia.	Risperdal ceased.
Hepatitis	Caused or prolonged inpatient hospitalisation	Severe drug induced hepatitis.	
Lymphopenia	Required Visit to Doctor		

Medicine Details:

LOSEC (Suspected)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
		1.5 Milligram	Daily Oral
Batch:	Started: 05/05/2003	Stopped: 10/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/03/2004	Biochemistry				
01/03/2004	Other data				

Additional Information:

Other therapy taken nitrolingual spray, ikorel, didrocal, plavix, GTN patch, betaloc, losec, multivitamin, viscotears, lanoxin



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195075

Seq: 1

Gender: F

Reported: 03/03/2004

Weight: 0.00

Hospitalisation:

Age: 75Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle disorder		Muscle disorder (muscle breakdown),	
Swelling face		Swelling face (unilateral)	

Medicine Details:

NORVASC (Other drug)		Reason:	
Tablet	10.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Other drug)		Reason:	
Tablet	10.0 Milligram	Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195376
Reported: 11/03/2004

Seq: 1

Gender: M
Weight: 70.00
Age: 15
DOB: 20/04/1988
Causality: Causality certain

Hospitalisation:

Onset Date: 09/11/2003
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness Agitation Confusional state Faecal incontinence Muscle rigidity Neuroleptic malignant syndrome Tachycardia Tremor		Increasing restlessness, agitation, faecal incontinence, tremor, muscle rigidity, tachycardia, neuroleptic malignant syndrome, confusion.	Cogentin 1mg then 1mg orally bd.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
Tablet	1.5 Milligram
	Daily
	Oral
Batch:	Started: 01/11/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar episode 3 years ago--> psychosis.
Also suffered Extra Pyramidal syndrome.
Readmitted 28/11/03 for hypertension.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195542 **Seq:** 1 **Gender:** F
Reported: 17/03/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74
Onset Date: 15/02/2004 **DOB:** 17/12/1929
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Caused or prolonged inpatient hospitalisation	Cerebrovascular accident.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concurrent illness of Alzheimer's disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195800

Seq: 1

Gender: F

Reported: 22/03/2004

Weight: 0.00

Hospitalisation:

Age: 71

Onset Date: 04/02/2004

DOB: 28/01/1933

Outcome: Recovered

09/02/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Supraventricular tachycardia	Caused or prolonged inpatient hospitalisation	Patient admitted with symptomatic paroxysmal SVT and orthostatic hypotension.	Risperidone ceased.
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
3.0 Milligram	Daily
Batch:	Started: 22/09/2003 Stopped: 05/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 195877

Seq: 1

Gender: F

Reported: 23/03/2004

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date:

DOB: 12/04/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		Menorrhagia, with the use of risperidone. (Was being cross tapered with Stelazine being phased out.)	
Loss of libido		Loss of libido	
		Menorrhagia, with the use of risperidone. (Was being cross tapered with Stelazine being phased out.) Loss of libido	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	22/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 196164

Seq: 1

Gender: M

Reported: 02/04/2004

Weight: 0.00

Hospitalisation:

Age: 10

Onset Date: 18/03/2004

DOB: 31/08/1993

Outcome: Death

18/03/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Patient suddenly collapsed, failed to respond to cardiopulmonary resuscitation and died.	Cardiopulmonary resuscitation.
Circulatory collapse			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified neurosis
Tablet	0.5 Milligram
	Daily
	Oral
Batch:	Started: 18/12/2003
	Stopped: 18/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2004	Electrocardiograph				The ECG done about 1 month prior, was normal.

Additional Information:

The physician thinks the patient's death is related to perhaps "congenital heart problem", or family history of "coronary artery disease" and does not think the Risperdal was related to the death".



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 196470

Seq: 1

Gender: M

Reported: 15/04/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		Loss of consciousness.	Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Olanzapine and Diazepam.
The patient was previously on oral risperidone although was not compliant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 196949

Seq: 1

Gender: F

Reported: 13/04/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 18/10/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Continued persecutory delusions, auditory hallucinations and suicidal ideation, including planned overdoses.	Risperidone ceased.
Drug ineffective			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 196954

Seq: 1

Gender: M

Reported: 03/05/2004

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increased.	Risperdal ceased and given Olanzapine.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On an unspecified date the patient gained 15kg. He was taken off Risperdal and dropped 10kg quickly. He was then put on Olanzapine due to need for an antipsychotic and gained 23kg in 5 weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197178
Reported: 10/05/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 87Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotension, BP 65/25.	Ceased Risperidone, lasix, magmin, Allopurinol, Thiamine.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started: 22/12/2003	Stopped: 27/12/2003	
ALLOPURINOL (Suspected)		Reason:	
Tablet	100.0 Milligram Daily	Oral	
Batch:	Started:	Stopped: 27/12/2003	
MAGMIN (Suspected)		Reason:	
Tablet	1.0 Gram Daily	Oral	
Batch:	Started:	Stopped: 27/12/2003	
LASIX (Suspected)		Reason:	
Tablet	40.0 Milligram Daily	Oral	
Batch:	Started:	Stopped: 27/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Amoxycillin-Clavulanic Acid, Hexamine hippurate, Docusate-Senna, Mirtazapine, Digoxin. paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197178

Seq: 1

Gender: M

Reported: 10/05/2004

Weight: 0.00

Hospitalisation:

Age: 87Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

THIAMINE (Suspected)

Reason:

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started:

Stopped: 27/12/2003

Laboratory Investigations:

Additional Information:

Patient was also taking Amoxycillin-Clavulanic Acid, Hexamine hippurate, Docusate-Senna, Mirtazapine, Digoxin. paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197311
Reported: 13/05/2004

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 05/05/2004

Age: 14

DOB: 15/02/1990

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Required Specialist Consultation	galactorrhoea developed 2 weeks after commencing 0.5 mg daily of Risperidone.	cessation of medication

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	0.5 Milligram	1 time	Oral
Batch:	Started: 23/04/2004	Stopped: 06/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Prolactin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197321 **Seq:** 1 **Gender:** F
Reported: 13/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 15/02/2004 **DOB:** 05/03/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intracranial pressure increased	Caused or prolonged inpatient hospitalisation	Intracranial pressure increased, retinal haemorrhage, hypomania, severe headache, ataxia, papilloedema. cerebrospinal fluid pressure was 29	
Headache	Caused or prolonged inpatient hospitalisation		
Hypomania	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 30/07/2001	Stopped:	0
LITHIUM CARBONATE (Suspected)		Reason: Manic depressive psycho, depre	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 10/02/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

medical history includes diabetes, hypothyroidism and bipolar disorder.further information stated that lithium was ceased. the patient's mood was not maintained on lamotrigine, nortriptyline and olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197321 **Seq:** 1 **Gender:** F
Reported: 13/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 15/02/2004 **DOB:** 05/03/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Papilloedema	Caused or prolonged inpatient hospitalisation		
Retinal haemorrhage	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 30/07/2001	Stopped:	0
LITHIUM CARBONATE (Suspected)		Reason: Manic depressive psycho, depre	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 10/02/2004	Stopped:	0

Laboratory Investigations:

Additional Information:

medical history includes diabetes, hypothyroidism and bipolar disorder.further information stated that lithium was ceased. the patient's mood was not maintained on lamotrigine, nortriptyline and olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197789

Seq: 1

Gender: M

Reported: 01/06/2004

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 10/03/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Required Visit to Doctor	Suspected tardive dyskinesia. Increased frequency of sudden jerking of head over past 18/12 especially when stressed. Reported agitation on Risperdal 7mg. Initial evident 10 years ago (? pre-dating Risperdal but following initial psychosis and exposure to anti-psychotics.	
Agitation	Required Visit to Doctor		
Akathisia	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
7.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Been on risperidone for 10 years. TD symptoms have been on and off for years.
Medical history includes: autoimmune disorder, no active symptoms for 7 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 197892

Seq: 1

Gender: F

Reported: 04/06/2004

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 20/06/2002

DOB: 13/05/1957

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Hyperprolactinaemia.	Risperidone ceased changed to Quetiapine.
Amenorrhoea			

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 20/06/2002	Stopped: 23/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/06/2004	Prolactin		20/06/2002	7870	
04/06/2004	Prolactin		31/12/2003	1010	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198000

Seq: 1

Gender: M

Reported: 09/06/2004

Weight: 115.00

Hospitalisation:

Age: 14

Onset Date: 01/06/2002

DOB: 17/07/1987

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glucose tolerance impaired	Required Specialist Consultation	weight increase, impaired glucose metabolism	Monitoring of blood glucose
Weight increased	Required Specialist Consultation	weight increase, impaired glucose metabolism	Monitoring of blood glucose

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason: Depression
Tablet	Dose Unspecified	Oral
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason: Neuroses
	Dose Unspecified	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198280

Seq: 1

Gender: M

Reported: 18/06/2004

Weight: 0.00

Hospitalisation:

Onset Date: 20/01/2004

Age: 32

DOB: 02/03/1971

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Drug level in blood increased.	

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected)		Reason: Unspecified psychosis	
Injection	1.0 Dose Unspecified 1 time	Intramuscular	
Batch:	Started:	Stopped:	
CLONAZEPAM (Suspected)		Reason:	
Injection	6.0 Milligram Total	Intramuscular	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram Daily		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/06/2004	Other data				

Additional Information:

Patient was also taking Clonazepam, Risperidone.
Probable cause of death by reporter, respiratory arrest.
Patient died 20/01/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198466
Reported: 24/06/2004

Seq: 1

Gender: M
Weight: 33.00

Hospitalisation:

Onset Date: 27/10/2003

Age: 10

DOB: 27/05/1993

Outcome: Recovered

28/10/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swelling face	Caused or prolonged inpatient hospitalisation	Patient experienced facial swelling, difficulty breathing, painful throat and a stiff jaw.	Risperidone ceased.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Joint stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason: Unspecified psychosis	
Capsule	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LITHICARB (Other drug)		Reason: Unspecified psychosis	
Tablet	625.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	7mths ago
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 22/10/2003	Stopped: 27/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Allergic reaction with Tachycardia Catapress - n + v, hayfever and asthma.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198466
Reported: 24/06/2004

Seq: 1

Gender: M
Weight: 33.00

Hospitalisation:

Onset Date: 27/10/2003

Age: 10

DOB: 27/05/1993

Outcome: Recovered

28/10/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngolaryngeal pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason: Unspecified psychosis	
Capsule	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LITHICARB (Other drug)		Reason: Unspecified psychosis	
Tablet	625.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	7mths ago
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 22/10/2003	Stopped: 27/10/2003	

Laboratory Investigations:

Additional Information:

Patient history: Allergic reaction with Tachycardia Catapress - n + v, hayfever and asthma.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198580

Seq: 1

Gender: F

Reported: 29/06/2004

Weight: 86.00

Hospitalisation:

Age: 58

Onset Date:

DOB: 02/09/1945

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Inflammatory, sarcoid-like condition with associated raised ACE levels, eosinophilia and inflaming skin rash.	Ceased Risperidone
Dyspnoea			
Rash			

Medicine Details:

PROVERA (Other drug)		Reason: Menopausal symptoms	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Contin
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 01/02/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 198722

Seq: 1

Gender: F

Reported: 05/07/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/04/2003

Age: 24Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Loss of efficacy of Risperidone.	

Medicine Details:

TEGRETOL (Interaction)		Reason: Other&unspecified epilepsy	
	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Continuing
RISPERDAL (Interaction)		Reason: Other&unspecified epilepsy	
	1.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped: Continuing
ZOLOFT (Other drug)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tegretol was increased to 1gram daily when depressed. Risperidone not working since dosage of Tegretol was increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199157

Seq: 1

Gender: F

Reported: 19/07/2004

Weight: 0.00

Hospitalisation:

Age: 52Y

Onset Date: 15/06/2004

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue spasm		Tongue spasming on sides and inside of mouth, unusual upper legs twitching and spasming.	Ceased Risperdal, given Cogentin.
Muscle spasms			
Muscle twitching			

Medicine Details:

RISPERDAL (Suspected)		Reason: Disturbance of sleep	
Tablet	0.5 Milligram	As necessary	Oral
Batch:	Started: 15/06/2004	Stopped:	15/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199277

Seq: 1

Gender: M

Reported: 21/07/2004

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 07/05/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Raised blood Creatine Phosphokinase levels.	

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2004	Creatine				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199439

Seq: 1

Gender: F

Reported: 27/07/2004

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety		Extrapyramidal symptoms including anxiety, trembling, rigidity, loss of balance and no facial movement.	
Balance disorder			
Muscle rigidity			
Tremor			

Medicine Details:

CLOPIXOL DEPOT (Other drug)		Reason:	
Injection		Dose Unspecified	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199558

Seq: 1

Gender: M

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 46Y

Onset Date: 15/05/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin hypopigmentation		Hypopigmentation - mottley appearance under both arms which spread down arms.	
Livedo reticularis			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified neurosis	
	2.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199702 **Seq:** 1 **Gender:** M
Reported: 05/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 19/07/2004 **DOB:** 09/06/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Patient took an overdose of Risperidone and experienced chest pain, palpitations and minor extrapyramidal side effects.	Benzotropine 2mg and several small doses of Diazepam.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason:
130.0 Milligram	1 time
Batch:	Started: 19/07/2004 Stopped: 19/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199829

Seq: 1

Gender: M

Reported: 10/08/2004

Weight: 101.00

Hospitalisation:

Onset Date: 05/07/2004

Age: 60

DOB: 29/12/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Commenced Risperidone 4mg daily on 29th June 2004, 1 week later developed widespread rash, shortness of breath, blurred vision, dry mouth, "heavy muscles".	Slowly weaning off.
Dry mouth	Required Visit to Doctor		
Dyspnoea	Required Visit to Doctor		
Feeling abnormal	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 29/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199829

Seq: 1

Gender: M

Reported: 10/08/2004

Weight: 101.00

Hospitalisation:

Age: 60

Onset Date: 05/07/2004

DOB: 29/12/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 29/06/2004	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 199937

Seq: 1

Gender: M

Reported: 12/08/2004

Weight: 0.00

Hospitalisation:

Age: 10

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphasia		Dysphasia.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200210 **Seq:** 1 **Gender:** F
Reported: 20/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39Y
Onset Date: 15/04/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Drug failed to have an appropriate effect. Patient found drug 'useless'.	

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified psychosis
Injection	1.0 Dose Unspecified Alternate weeks Intramuscular
Batch:	Started: 09/03/2004 Stopped: 30/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200545

Seq: 1

Gender: M

Reported: 03/09/2004

Weight: 65.00

Hospitalisation:

Age: 56

Onset Date: 15/03/2004

DOB:

Outcome: Recovered

08/12/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient experienced tardive dyskinesia.	Risperdal dosage decreased. Treated with benztropine and benzodiazepine.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose of risperidone was decreased from 4mg to 3mg and finally to 1mg daily PH: depressive symptoms, intermittent claudication and heavy smoking



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200573

Seq: 1

Gender: M

Reported: 06/09/2004

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachypnoea		Patient experienced tachypnoea and pericarditis.	Clozapine discontinued.
Pericarditis			

Medicine Details:

OLANZAPINE (Other drug)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Other drug)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has prior history of pericardial effusion.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200579

Seq: 1

Gender: M

Reported: 06/09/2004

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 19/10/1964

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion		Delusional beliefs.	
Priapism		Patient experienced mild priapism (fullness of the penis)	

Medicine Details:

EFEXOR (Other drug)		Reason:	
Batch:	Started:	Stopped: Oral	
INDERAL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	1 time	Oral
Batch:	Started: L TERM	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The physician reports that it appears that the ' symptoms' is linked to the patient's delusional beliefs stating that 'others are aware of it', and even 'photographed it'. History: Patient suffers from a schizophrenic disorder with comorbid depressive features from time to time. Also has an "underlying sensitivity of personality".



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200691 **Seq:** 1 **Gender:** F
Reported: 09/09/2004 **Weight:** 69.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 20/07/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Patient was admitted to hospital with increasing confusion, tremor, rigidity, bradykinesia and dysphagia.	All antipsychotics ceased, patient rehydrated. Augmentin Duo Forte for aspiration pneumonia.
Pneumonia aspiration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason:	
Injection	10.0 Milligram	3 times	Intramuscular
Batch:	Started: 12/05/2004	Stopped: 10/06/2004	
OXAZEPAM (Other drug)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SINEMET (Other drug)		Reason: Paralysis agitans	
Tablet	3.0 Dose Unspecified	Daily	Oral
Batch:	Started: L TERM	Stopped:	
CITALOPRAM HYDROBROMIDE (Other drug)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200691

Seq: 1

Gender: F

Reported: 09/09/2004

Weight: 69.00

Hospitalisation: Admitted to hospital

Age: 99U

Onset Date: 20/07/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PANAMAX (Other drug)		Reason:	
Oral Liquid	10.0 Millilitre	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped: 11/07/2000	
TEMAZEPAM (Other drug)		Reason:	
	40.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2004	Stopped:	
FRUSEMIDE (Other drug)		Reason:	
	40.0 Milligram	Alternate days	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200691	Seq: 1	Gender: F
Reported: 09/09/2004		Weight: 69.00
Hospitalisation: Admitted to hospital		Age: 99U
Onset Date: 20/07/2004		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Batch:	Started:	S TERM	Stopped:
PERICYAZINE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200743

Seq: 1

Gender: F

Reported: 10/09/2004

Weight: 0.00

Hospitalisation:

Age: 12Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		Obsessive compulsive symptoms, increased anxiety, confrontational and compulsive.	
Aggression			
Anxiety			

Medicine Details:

RISPERDAL (Suspected)		Reason: Behavior disorders of childhood	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Treating doctor intends to provide further information.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200768

Seq: 1

Gender: M

Reported: 13/09/2004

Weight: 0.00

Hospitalisation:

Age: 17

Onset Date: 12/12/2003

DOB: 11/10/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Elevated prolactin levels.	Risperidone weaned and ceased. Changed to Quetiapine.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Tablet	3.0 Milligram Daily Oral
Batch:	Started: 15/10/2003 Stopped: 19/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/09/2004	Prolactin	(105-485 mul/L			prolactin levels 1462

Additional Information:

Patient already in hospital.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200937
Reported: 17/09/2004
Hospitalisation:
Onset Date:
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 44
DOB: 14/11/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor	After increasing the drug dosage from .5mg to 1mg daily the patient developed discharge from her breast. She reported that the Risperidone made her feel very depressed and suicidal and caused sleeplessness and a weight gain of 4 kg.	
Breast discharge	Required Visit to Doctor		
Insomnia	Required Visit to Doctor		
Suicidal ideation	Required Visit to Doctor		

Medicine Details:

Lexapro (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Neuroses	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 200937

Seq: 1

Gender: F

Reported: 17/09/2004

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date:

DOB: 14/11/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor		

Medicine Details:

Lexapro (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Neuroses	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/09/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201079

Seq: 1

Gender: F

Reported: 23/09/2004

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 24/04/2004

DOB: 22/06/1953

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis Drug toxicity		Fatty liver and drug toxicity	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Injection		Intramuscular	
Batch:	Started: 24/02/2004	S TERM	Stopped: 16/04/2004 0
MIRTAZAPINE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
Zolpidem Sandoz (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 18/03/2004	Stopped:	02/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2004	Autopsy report				Severe fatty change in liver and chronic liver disease. Severe diffuse microvesicular fatty changes throughout the liver. Lungs, heart, kidney and brain.

Additional Information:

Chronic liver disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201081

Seq: 1

Gender: M

Reported: 23/09/2004

Weight: 80.00

Hospitalisation:

Age: 46

Onset Date: 01/09/2004

DOB: 18/08/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction	Required Visit to Doctor	Erectile dysfunction.	

Medicine Details:

SOLIAN (Other drug)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
EPILIM (Other drug)		Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 05/08/2004	Stopped: 17/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201303 **Seq:** 1 **Gender:** M
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 27Y
Onset Date: 10/09/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	Patient became aggressive.	Study medication was increased as a result of this event and then stopped.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started: 26/05/2004	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 03/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was supplemented with oral Risperidone 2mg until the next scheduled dose on 28/09/2004 which was increased to 37.5mg IM.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201369
Reported: 30/09/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2004

Age: 43

DOB: 25/05/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lip neoplasm		The patient developed a cancerous lesion on his lower lip which initially started as a cold sore that never healed.	The lesion is scheduled to be removed and ceasing Risperidone therapy is being considered.
Medication error			
Squamous cell carcinoma			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	100.0 Milligram	Weekly	Intramuscular
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
LAMOTRIGINE (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201608
Reported: 11/10/2004
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: M
Weight: 30.00
Age: 10
DOB: 26/11/1993
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Loss of control of impulsive behaviour when changed from Risperidone 1mg daily tabs to Risperidone 1mg daily elixir control restored on return to Risperidone 1mg tablets.	Restarted tablets and ceased elixir.
Drug ineffective			

Medicine Details:

Ritalin LA (Other drug)	Reason: Behavior disorders of childhood
Capsule	40.0 Milligram Daily Oral
Batch:	Started: Stopped:
CLONIDINE HYDROCHLORIDE (Other drug)	Reason: Behavior disorders of childhood
	50.0 Microgram Daily
Batch:	Started: Stopped:
ZOLOFT (Other drug)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified psychosis
Oral Liquid	1.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201895
Reported: 21/10/2004

Seq: 1

Gender: M
Weight: 72.00

Hospitalisation:

Onset Date: 27/09/2004

Age: 75

DOB: 19/02/1929

Outcome: Recovered

06/10/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	The patient developed confusion, agitation, incontinence, muscle rigidity, hyperreflexia, hyperthermia at 38.5 degrees Celsius and elevated CPK at 515. The diagnosis of neuroleptic malignant syndrome was made.	Amisulpride ceased.
Agitation	Life threatening		
Confusional state	Life threatening		
Hyperreflexia	Life threatening		

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified psychosis	
	200.0 Milligram	Daily	Oral
Batch:	Started: 22/09/2004	Stopped: 24/09/2004	0
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 24/09/2004	Stopped: 26/09/2004	0
SOLIAN (Suspected)		Reason: Unspecified psychosis	
	400.0 Milligram	Daily	Oral
Batch:	Started: 24/09/2004	Stopped: 26/09/2004	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2004	Stopped: 23/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 201895

Seq: 1

Gender: M

Reported: 21/10/2004

Weight: 72.00

Hospitalisation:

Age: 75

Onset Date: 27/09/2004

DOB: 19/02/1929

Outcome: Recovered

06/10/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Incontinence	Life threatening		
Muscle rigidity	Life threatening		
Pyrexia	Life threatening		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	3.0 Milligram	Daily	Oral
Batch:	Started: 22/09/2004	Stopped: 22/09/2004	
SERENACE (Suspected)		Reason: Unspecified psychosis	
	500.0 Microgram	Daily	
Batch:	Started: 26/08/2004	Stopped: 26/08/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202673

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
QUETIAPINE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
AVANZA (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202676

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient was violent.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202696

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient had fast thoughts and akathisia.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202698 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: **DOB:** 23/12/1983
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation	Caused or prolonged inpatient hospitalisation	Attempted homicide with a bread knife.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)	Reason:
Injection	
Batch:	Started: Stopped:
ALCOHOL (Suspected)	Reason:
Oral Liquid	Oral
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
4.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202717

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202727

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal.	Needed ECT.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202770

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Patient experienced overdose and suicide attempt.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202772

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient was violent.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202777
Reported: 18/11/2004

Seq: 1

Gender: U

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation and suicide attempt.	
Suicide attempt			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)	Reason:
Capsule	Oral
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202778

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression		Suicidal ideation and violence.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202786

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202794

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation		Patient became homicidal and developed akathisia.	
Akathisia			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202814

Seq: 1

Gender: M

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide		Completed suicide.	

Medicine Details:

EFEXOR (Suspected)		Reason:	
Batch:		Stopped: Oral	
Started:			
RISPERIDONE (Suspected)		Reason:	
Batch:		Stopped:	
Started:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202835

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 202841

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia		Homicidal ideation and akathisia.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203047
Reported: 25/11/2004

Seq: 1

Gender: F
Weight: 70.00
Age: 80
DOB: 18/11/1924
Causality: Causality possible

Hospitalisation:

Onset Date: 25/11/2004
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Supraventricular tachycardia		Patient experienced supraventricular tachycardia and hypotension.	Verapamil 180mg given.
Hypotension			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 19/11/2004	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2004	Blood pressure				Blood pressure 100/60, heart rate of 150 beats per minute.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203113
Reported: 29/11/2004

Seq: 1

Gender: U
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abnormal behaviour Dysarthria Hypoaesthesia Salivary hypersecretion Tardive dyskinesia		The patient experienced dribble, tongue in and out, speech mangled and incoherent, unable to watch TV or listen to the radio, no feeling around mouth, disabled socially and unwilling to venture out.	

Medicine Details:

MODECATE (Suspected) Injection Batch:	Reason: Started:	Stopped:
CLOZAPINE (Suspected) Tablet Batch:	Reason: Started:	Oral Stopped:
RISPERDAL (Suspected) Batch:	Reason: Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203230

Seq: 1

Gender: U

Reported: 02/12/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Patient had previously received oral Risperidone and was reportedly "doing well", however was switched to Risperidone Microspheres due to compliance reasons. The patient "suddenly dropped dead".	
Sudden death			

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Intramuscular
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203296 **Seq:** 1 **Gender:** M
Reported: 06/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 09/06/2004 **DOB:**
Outcome: Recovered 09/06/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Patient was admitted after a suicide attempt. Risperdal stopped.	Patient remained hospitalised through 02/07/04.

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
Tablet	15.0 Milligram	Oral	
Batch:	Started: 09/03/2004	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 27/05/2004	Stopped: 08/06/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203792

Seq: 1

Gender: U

Reported: 23/12/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia.	Risperdal stopped.

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has history of neutropenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203815

Seq: 1

Gender: M

Reported: 23/12/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion.	

Medicine Details:

ATENOLOL (Other drug)	Reason:
25.0 Milligram	
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason:
100.0 Milligram	
Batch:	Started: Stopped:
CALTRATE (Other drug)	Reason:
600.0 Milligram	
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

PMHx: Hypertension, obesity, osteoarthritis and schizoaffective disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 203815

Seq: 1

Gender: M

Reported: 23/12/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
	1.0 Milligram		
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 01/11/2004	Stopped: 0	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

PMHx: Hypertension, obesity, osteoarthritis and schizoaffective disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204233
Reported: 14/01/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 30/11/2004

Age: 27

DOB: 08/08/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Neutropenia.	Olanzapine discontinued.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
300.0 Milligram	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
5.0 Milligram	Daily Oral
Batch:	Started: 30/09/2004 Stopped:
OLANZAPINE (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily
Batch:	Started: 16/11/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Neutrophils				1.67 and 1.45

Additional Information:

further information received and stated that the patient's condition has stabilized
Report 218010 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204398 **Seq:** 1 **Gender:** F
Reported: 21/01/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 06/11/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Patient experienced suicidal ideation, aggression, injury and ankle fracture.	Risperdal Consta was increased.
Aggression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection, powder for	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 21/10/2004	Stopped: 16/11/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204405

Seq: 1

Gender: M

Reported: 21/01/2005

Weight: 0.00

Hospitalisation:

Age: 81

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient's white blood cell count decreased again.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204556 **Seq:** 1 **Gender:** M
Reported: 24/01/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 33
Onset Date: 31/12/2004 **DOB:** 30/04/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dermatitis	Required Visit to Doctor	Desquamating dermatitis both hands and arms.	Steroids.
Skin exfoliation	Required Visit to Doctor		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection, powder for	25.0 Milligram Alternate weeks Intramuscular
Batch:	Started: Stopped: 15/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204626

Seq: 1

Gender: M

Reported: 25/01/2005

Weight: 74.50

Hospitalisation:

Age: 18

Onset Date: 01/12/2004

DOB: 05/01/1986

Outcome: Recovered

20/12/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		The patient developed thrombocytopenia.	Valproate ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started: 27/09/2004	S TERM	Stopped: 06/01/2005
SODIUM VALPROATE (Suspected)		Reason:	
	1.0 Gram	Daily Oral	
Batch:	Started: 15/11/2004	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2005	Platelets		01/12/2004	163	
25/01/2005	Platelets		13/12/2004	133 x 10 ⁹	
25/01/2005	Platelets		20/12/2004	150	
25/01/2005	Platelets		03/01/2005	195	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204970
Reported: 05/02/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 11/03/2004

Age: 41

Outcome: Recovered

11/03/2004

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Treated in outpatient department only	Collapse and syncope, extrapyramidal syndrome, medication error.	Reduce dose back to 4mg.
Extrapyramidal disorder	Treated in outpatient department only		
Medication error	Treated in outpatient department only		

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Tablet	6.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Was meant to decreased dose of Risperidone but increased dose in error.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 204970

Seq: 1

Gender: M

Reported: 05/02/2005

Weight: 0.00

Hospitalisation:

Onset Date: 11/03/2004

Age: 41

DOB:

Outcome: Recovered

11/03/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Treated in outpatient department only		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Was meant to decreased dose of Risperidone but increased dose in error.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205183 **Seq:** 1 **Gender:** F
Reported: 11/02/2005 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 36
Onset Date: 03/02/2005 **DOB:** 20/02/1968
Outcome: Recovered without treatment **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Caused or prolonged inpatient hospitalisation	Elevated prolactin levels (resting) : 5300mU/L (normal range: < 420)	Risperdal was ceased gradually. A new antipsychotic was introduced.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	1 time	Oral
Batch:	Started: 19/01/2005	Stopped:	08/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205458

Seq: 1

Gender: M

Reported: 22/02/2005

Weight: 0.00

Hospitalisation:

Age: 50Y

Onset Date: 03/12/2004

DOB:

Outcome: Death, maybe drug

03/12/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide		The patient committed suicide by hanging.	

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 21/04/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205541 **Seq:** 1 **Gender:** F
Reported: 25/02/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 78
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism.	Warfarin.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
3.0 Milligram	Daily
Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205664
Reported: 01/03/2005

Seq: 1

Gender: F
Weight: 76.00

Hospitalisation:

Onset Date: 12/01/2005

Age: 45

DOB: 27/09/1959

Outcome: Recovered

17/02/2005

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Patient was agitated, anxious, aggressive and constipated. Patient also suffered insomnia.	Ceased Risperdal.
Aggression	Required Visit to Doctor		
Anxiety	Required Visit to Doctor		
Insomnia	Required Visit to Doctor		

Medicine Details:

Reasons Details:			
SERENACE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OXAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Mirtazon (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to drug-hypersalvation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205664

Seq: 1

Gender: F

Reported: 01/03/2005

Weight: 76.00

Hospitalisation:

Age: 45

Onset Date: 12/01/2005

DOB: 27/09/1959

Outcome: Recovered

17/02/2005

Causality: Causality probable

Reaction Details:

Medicine Details:

ACIMAX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PREMIA CONTINUOUS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 14/12/2004	Stopped: 15/02/2005	

Laboratory Investigations:

Additional Information:

Previous exposure to drug-hypersalvation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205690

Seq: 1

Gender: F

Reported: 02/03/2005

Weight: 0.00

Hospitalisation:

Onset Date: 01/01/2005

Age: 87

Outcome: Recovered

16/02/2005

DOB:

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia/rigidity neck + head, increased over 1 month.	Risperdal ceased.
Nuchal rigidity			

Medicine Details:

ATENOLOL (Other drug)	Reason:
Batch:	Started: Stopped:
BRICANYL (Other drug)	Reason:
Batch:	Started: Stopped:
CAPTOPRIL (Other drug)	Reason:
Batch:	Started: Stopped:
DILTIAZEM HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205690

Seq: 1

Gender: F

Reported: 02/03/2005

Weight: 0.00

Hospitalisation:

Onset Date: 01/01/2005

Age: 87

Outcome: Recovered

16/02/2005

DOB:

Causality: Causality probable

Reaction Details:

Medicine Details:

FRUSEMIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
MIANSERIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OXAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 05/04/2004	Stopped: 10/02/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205816

Seq: 1

Gender: F

Reported: 07/03/2005

Weight: 0.00

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Recovered

01/02/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Blood creatine phosphokinase incr Delirium Neuroleptic malignant syndrome Pyrexia Torticollis		The patient developed dystonia and increased CK, delirium/psychosis likely due to withdrawal of Aripiprazole in present of Risperidone depot.	Aripiprazole withdrawn. Treated with Anticholinergic, Clonazepam, oral hydration, supportive.

Medicine Details:

Aripiprazole (Interaction)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: Stopped: 0
RISPERIDONE (Interaction)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Currently undergoing treatment for psychosis secondary to schizophrenia. Aripiprazole is drug interaction not suspected.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205976
Reported: 11/03/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 11/02/2005

Age: 30

DOB: 22/10/1974

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration Akathisia Movement disorder Parkinsonism Tremor		For approximately six months, the patient has been experiencing akathisia and a parkinsonian tremor. On 11/02/05, the patient experienced oculogyric crisis which was controlled with an extra dose of Benztropine. Patient also experienced an unusual movement disorder of the head and neck, lasting for about 20 minutes each time.	Oral Risperidone discontinued. Treated with Benztropine 2mg/daily, which was increased to 2mg/twice daily.

Medicine Details:

Risperdal Consta (Suspected)		Reason:		
Injection	50.0 Milligram	Fortnightly	Intramuscular	
Batch:	Started: 15/08/2004	Stopped:	07/02/2005	0
RISPERDAL (Suspected)		Reason:		
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

discontinued antipsychotic resulted in resolution of movement disorder. Olanzapine was reintroduced and no recurrent of the movement was noted.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 205995

Seq: 1

Gender: F

Reported: 14/03/2005

Weight: 70.00

Hospitalisation:

Age: 24

Onset Date: 21/02/2005

DOB: 05/06/1980

Outcome: Recovered

28/02/2005

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		The patient experienced lactation whilst on Risperidone.	Risperidone ceased, changed to Amisulpride.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 08/02/2005	Stopped: 25/02/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 206074

Seq: 1

Gender: F

Reported: 16/03/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation	Caused or prolonged inpatient hospitalisation	Patient experienced constipation.	

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 206425 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 72Y
Onset Date: 04/05/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia	Caused or prolonged inpatient hospitalisation	Hypokalaemia, hyponatraemia and confusion.	Potassium and Sodium Chloride supplementation.
Confusional state	Caused or prolonged inpatient hospitalisation		
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:	
INDAPAMIDE HEMIHYDRATE (Suspected)		Reason: Essential benign hypertension	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/05/2004	
PERINDOPRIL (Suspected)		Reason: Essential benign hypertension	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/03/2005	Potassium	3.5-5mmol/L	04/05/2004	2.1	
31/03/2005	Sodium	135-145mmol/L	04/05/2004	109	

Additional Information:

Non-compliant with Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 206467 **Seq:** 1 **Gender:** F
Reported: 01/04/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	The patient experienced extra-pyramidal symptoms.	Risperdal Consta ceased.

Medicine Details:

MODECATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Othr&unspec metabolic diseases	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207451 **Seq:** 1 **Gender:** F
Reported: 27/04/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79Y
Onset Date: 05/05/2004 **DOB:**
Outcome: Recovered 12/05/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia	Caused or prolonged inpatient hospitalisation	Patient experienced generalised weakness and mobility decreased.	Risperidone stopped. Treated with Cogentin.
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FELODIPINE (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
METOPROLOL TARTRATE (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
IRBESARTAN (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
CELEBREX (Other drug)	Reason: Osteoarthritis
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207451 **Seq:** 1 **Gender:** F
Reported: 27/04/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79Y
Onset Date: 05/05/2004 **DOB:**
Outcome: Recovered 12/05/2004 **Causality:** Causality possible

Reaction Details:

Medicine Details:

SIMVASTATIN (Other drug)	Reason: Chron isch heart dis no hyper
Batch:	Started: Stopped:
FERRO-GRADUMET (Other drug)	Reason: Unspecified anemia
Batch:	Started: Stopped:
GLYCERYL TRINITRATE (Other drug)	Reason: Chron isch heart dis no hyper
Batch:	Started: Stopped:
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207451

Seq: 1

Gender: F

Reported: 27/04/2005

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 79Y

Onset Date: 05/05/2004

DOB:

Outcome: Recovered

12/05/2004

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecified schizophrenia

2.0 Milligram

Daily

Oral

Batch:

Started: 21/04/2004

Stopped: 05/05/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207528
Reported: 02/05/2005

Seq: 1

Gender: M
Weight: 0.00
Age: 84
DOB: 29/01/1921
Causality: Causality possible

Hospitalisation:

Onset Date: 29/03/2005
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Just over a month after increasing dose of Aricept the patient developed a bowel obstruction.	Aricept ceased.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	Mar 8 2005, Aricept was increased to 10mg from 5mg	
Lethargy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ADVANTAN (Other drug)		Reason:	
Cream		Topical	
Batch:	Started:	Stopped:	0
FERROUS SULPHATE (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
NEO-CYTAMEN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ELOCON (Other drug)		Reason:	
Cream		Topical	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/05/2005	Abdomen X-ray				30/03/2005dilated small bowel with fluid levels

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207528

Seq: 1

Gender: M

Reported: 02/05/2005

Weight: 0.00

Hospitalisation:

Age: 84

Onset Date: 29/03/2005

DOB: 29/01/1921

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALLOPURINOL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
AVAPRO HCT NOS (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
LOMOTIL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
PANAMAX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207528

Seq: 1

Gender: M

Reported: 02/05/2005

Weight: 0.00

Hospitalisation:

Age: 84

Onset Date: 29/03/2005

DOB: 29/01/1921

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PLAVIX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
RISPERDAL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
TEMAZE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
ARICEPT (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 08/01/2005	S TERM	Stopped: 29/03/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207606 **Seq:** 1 **Gender:** M
Reported: 05/05/2005 **Weight:** 48.00
Hospitalisation: Required a visit to the doctor **Age:** 13
Onset Date: 15/02/2005 **DOB:** 29/10/1991
Outcome: Recovered 15/04/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphemia		Patient developed stuttering (speech dysphemia).	Nil

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started: 15/07/2004	Stopped: 15/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: AD/HD, ODD, global learning disorder, developmental speech and language disorder, school refusal, social disorder, separation anxiety.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207714
Reported: 10/05/2005

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 28/02/2005

Age: 38

DOB: 26/01/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		On 17 January 2005 it was confirmed that the patient, who was taking Risperdal Consta, was pregnant. She experienced a spontaneous abortion.	
Drug exposure during pregnancy			

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	50.0 Milligram
	Alternate weeks Intramuscular
Batch:	Started: 23/04/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On 17 Jan 2005 a pregnancy was confirmed. The start date of the subject's last menses prior to the pregnancy was Dec 2004.
additional information received: concomitant medications include aripiprazole, quetiapine, chlorpromazine, diazepam, benzhexol, multivitamin and folic acid.
history of smoking and alcohol use with no recreational drug use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207812
Reported: 13/05/2005
Hospitalisation:
Onset Date: 29/09/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 27Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia and anxiety.	Risperidone ceased.
Anxiety			
Therapy regimen changed			

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	500.0 Microgram	Daily	Oral
Batch:	Started: 04/09/1998	Stopped: 06/10/1998	
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	0
PROCYCLIDINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE1: RODOS
Report 207816 is the second sequence to this report.
Patient on variable dose of Risperdal from 0.5 mg to 6 mg



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207816
Reported: 13/05/2005

Seq: 1

Gender: M
Weight: 0.00
Age: 25Y

Hospitalisation:

Onset Date: 23/11/1996
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	The patient experienced side stiffness.	Given Cogentin 4mg daily.

Medicine Details:

DIAZEPAM (Other drug)	Reason:
15.0 Milligram	
Batch:	Started: 23/11/1996 Stopped:
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped: Contin
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: RODOS
Report 207812 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207819
Reported: 13/05/2005

Seq: 1

Gender: M
Weight: 0.00
Age: 47Y

Hospitalisation:

Onset Date: 19/02/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	On 19 February 1999 the patient experienced akathisia (stiffness in legs). He experienced akathisia again on 23 February 1999.	Zuclopenthixol ceased. Benztropine given.
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Oral	
Batch:	Started: 19/02/1999	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 19/02/1999	Stopped: 19/02/1999	0
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Daily	Intravenous
Batch:	Started:	Stopped: 23/02/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207820

Seq: 1

Gender: F

Reported: 13/05/2005

Weight: 62.00

Hospitalisation:

Age: 51Y

Onset Date: 16/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia Salivary hypersecretion Therapy regimen changed		The patient experienced hypersalivation and akathisia.	Benztropine given.

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
0.5 Milligram	
Batch:	Started: 10/03/1999 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
4.0 Milligram	Daily Oral
Batch:	Started: 11/03/1999 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: Rodos



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207821
Reported: 13/05/2005

Seq: 1

Gender: M
Weight: 82.00

Hospitalisation:

Onset Date: 07/12/1998
Outcome: Unknown

Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient experienced akathisia.	Risperdal ceased.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LORAZEPAM (Other drug)		Reason:	
	2.0 Milligram		
Batch:	Started: 18/11/1998	Stopped: 05/12/1998	
BENZTROPINE MESYLATE (Other drug)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started: 26/11/1998	Stopped:	
CLONAZEPAM (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 29/11/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 18/11/1998	Stopped: 08/12/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207821

Seq: 1

Gender: M

Reported: 13/05/2005

Weight: 82.00

Hospitalisation:

Age: 99u

Onset Date: 07/12/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)

Reason:

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started: 06/12/1998

Stopped: 08/12/1998

Laboratory Investigations:

Additional Information:

Clinical Trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207822

Seq: 1

Gender: F

Reported: 13/05/2005

Weight: 55.00

Hospitalisation:

Age: 20Y

Onset Date: 20/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness		The patient experienced extrapyramidal syndrome - stiffness.	Given Bzotropine.
Extrapyramidal disorder			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 18/03/1999	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 16/03/1999	Stopped: 20/03/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207824
Reported: 13/05/2005

Seq: 1

Gender: M
Weight: 105.00
Age: 25Y

Hospitalisation:

Onset Date: 23/10/1998
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Joint stiffness	Incapacity/disability	The patient experienced mild stiffness in the knee joints.	

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	15.0 Milligram		
Batch:	Started: 23/10/1998	Stopped:	
BENZTROPINE MESYLATE (Other drug)		Reason:	
		Oral	
Batch:	Started: 21/10/1998	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Oral	
Batch:	Started: 20/10/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 21/10/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I:RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207829
Reported: 13/05/2005
Hospitalisation:
Onset Date: 20/07/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 98.00
Age: 49Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	The patient experienced cogwheeling, stiffness and extrapyramidal syndrome.	Given Bzotropine.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	8.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 23/07/1998	
OLANZAPINE (Suspected)		Reason:	
	8.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/07/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I:RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207831
Reported: 16/05/2005
Hospitalisation:
Onset Date: 18/03/1999
Outcome: Unknown

Seq: 1

Gender: F
Weight: 46.00
Age: 29Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	The patient experienced generalised mild stiffness.	Benzotropine given.
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

UNISOM SLEEPGELS (Other drug)		Reason:	
	1.0 Dose Unspecified	Oral	
Batch:	Started: 11/03/1999	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram Daily	Oral	
Batch:	Started: 01/03/1999	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
	6.0 Milligram Daily		
Batch:	Started: 18/03/1999	Stopped: Continuing	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I:RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207839
Reported: 16/05/2005
Hospitalisation:
Onset Date: 26/11/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 106.00
Age: 51Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	The patient experienced cogwheel rigidity of arms, stiffness, tremor of hands, agitation and dystonic reaction.	Given Cogentin.
Agitation	Caused or prolonged inpatient hospitalisation		
Dystonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUPHENAZINE DECANOATE (Other drug)	Reason:
100.0 Milligram	
Batch:	Started: Stopped:
STELAZINE (Other drug)	Reason:
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207839
Reported: 16/05/2005

Seq: 1

Gender: M
Weight: 106.00

Hospitalisation:

Onset Date: 26/11/1998
Outcome: Unknown

Age: 51Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
	4.0 Milligram Daily Oral
Batch:	Started: 17/11/1998 Stopped: 26/11/1998

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207843

Seq: 1

Gender: M

Reported: 16/05/2005

Weight: 0.00

Hospitalisation:

Onset Date: 24/12/1998

Age: 35Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	The patient experienced a slightly stiff neck.	Cogentin given.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	
	200.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1998	Stopped:	
DIAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	20.0 Milligram	Daily	Oral
Batch:	Started: 22/12/1998	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Acuphase.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207844

Seq: 1

Gender: F

Reported: 16/05/2005

Weight: 65.00

Hospitalisation:

Age: 40Y

Onset Date: 26/11/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Amenorrhoea Muscle rigidity Salivary hypersecretion		The patient experienced jaw dystonia, rigidity, hypersalivation and amenorrhoea.	Benzotropine given.

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Other drug)	Reason:
Batch:	Started: Stopped:
THIORIDAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
CARBAMAZEPINE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207844

Seq: 1

Gender: F

Reported: 16/05/2005

Weight: 65.00

Hospitalisation:

Age: 40Y

Onset Date: 26/11/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

LACTULOSE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 16/11/1998	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207850

Seq: 1

Gender: F

Reported: 16/05/2005

Weight: 62.00

Hospitalisation:

Age: 27Y

Onset Date: 15/04/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity		The patient experienced muscle rigidity and tremor.	Benzotropine given.
Therapy regimen changed			
Tremor			

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
ZOPICLONE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramidal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207850
Reported: 16/05/2005

Seq: 1

Gender: F
Weight: 62.00
Age: 27Y

Hospitalisation:

Onset Date: 15/04/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

METAMUCIL (Other drug)			Reason:
Batch:	Started:	Stopped:	
PARACETAMOL (Other drug)			Reason:
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)			Reason:
Batch:	Started:	Stopped:	
TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)			Reason: Unspecified schizophrenia
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramidal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207850

Seq: 1

Gender: F

Reported: 16/05/2005

Weight: 62.00

Hospitalisation:

Age: 27Y

Onset Date: 15/04/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	5.0 Milligram	Daily	Oral
Batch:	Started: 04/02/1999	Stopped:	
LORAZEPAM (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 19/01/1999	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramidal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207860

Seq: 1

Gender: M

Reported: 16/05/2005

Weight: 0.00

Hospitalisation:

Onset Date: 07/04/2005

Age: 21Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria	Caused or prolonged inpatient hospitalisation	The patient experienced widespread urticarial rash, wheeze, shortness of breath and chest tightness.	Hydrocortisone, Promethazine, nebulised Adrenaline, Prednisolone and Ventolin prn.
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Other drug)		Reason:	
400.0 Milligram		Oral	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection, modified release		1 time Intramuscular	
Batch:	Started: 06/04/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously had 2 x depots 3/12 with no reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207860

Seq: 1

Gender: M

Reported: 16/05/2005

Weight: 0.00

Hospitalisation:

Age: 21Y

Onset Date: 07/04/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus	Caused or prolonged inpatient hospitalisation		
Wheezing	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Other drug)		Reason:	
	400.0 Milligram		Oral
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	
	Injection, modified release	1 time	Intramuscular
Batch:	Started: 06/04/2005	Stopped:	

Laboratory Investigations:

Additional Information:

Patient had previously had 2 x depots 3/12 with no reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207900

Seq: 1

Gender: M

Reported: 17/05/2005

Weight: 0.00

Hospitalisation:

Age: 30Y

Onset Date: 03/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient experienced akathisia.	Given Benztropine.

Medicine Details:

SALBUTAMOL (Other drug)		Reason:
Batch:	Started:	Stopped:
PARACETAMOL (Other drug)		Reason:
Batch:	Started:	Stopped:
MYLANTA (Other drug)		Reason:
Batch:	Started:	Stopped:
RANITIDINE (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207900

Seq: 1

Gender: M

Reported: 17/05/2005

Weight: 0.00

Hospitalisation:

Age: 30Y

Onset Date: 03/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PROMETHAZINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	Oral
Batch:	Started: 24/12/1998	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207976

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 107.00

Hospitalisation:

Age: 37Y

Onset Date: 23/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation	The patient experienced postural hypotension.	

Medicine Details:

LORAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
CLONAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
PARACETAMOL (Other drug)		Reason:
Batch:	Started:	Stopped:
ZOPICLONE (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207976

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 107.00

Hospitalisation:

Age: 37Y

Onset Date: 23/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified schizophrenia

2.0 Milligram

Daily

Oral

Batch:

Started: 22/01/1999

Stopped:

0

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207978
Reported: 19/05/2005

Seq: 1

Gender: M
Weight: 60.00
Age: 32Y

Hospitalisation:

Onset Date: 11/03/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	The patient's drug dose gradually increased from 1mg to 6mg. On 11 March 1999 he experienced cogwheel rigidity, muscle rigidity, difficulty swallowing and restlessness, on 15 March he developed a strange grimace, on 18 March 1999 he developed a stooped posture, on 13 April 1999 he experienced Parkinsonism.	Benztropine given.
Dysphagia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
MULTIVITAMINS (Other drug)	Reason:
Batch:	Started: Stopped:
FOLIC ACID (Other drug)	Reason:
Batch:	Started: Stopped:
LORAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207978
Reported: 19/05/2005

Seq: 1

Gender: M
Weight: 60.00
Age: 32Y

Hospitalisation:

Onset Date: 11/03/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation		
Parkinsonism	Caused or prolonged inpatient hospitalisation		
Posture abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IMOVANE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
MYCOSTATIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
METAMUCIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	5.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1999	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207978

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 60.00

Hospitalisation:

Age: 32Y

Onset Date: 11/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason:
Batch:	Started:	Stopped:
MULTIVITAMINS (Other drug)		Reason:
Batch:	Started:	Stopped:
FOLIC ACID (Other drug)		Reason:
Batch:	Started:	Stopped:
LORAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207978

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 60.00

Hospitalisation:

Age: 32Y

Onset Date: 11/03/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

IMOVANE (Other drug)			Reason:		
Batch:		Started:		Stopped:	
MYCOSTATIN (Other drug)			Reason:		
Batch:		Started:		Stopped:	
METAMUCIL (Other drug)			Reason:		
Batch:		Started:		Stopped:	
RISPERDAL (Suspected)			Reason: Unspecified schizophrenia		
5.0 Milligram			Daily Oral		
Batch:		Started: 01/03/1999		Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207979

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 86.00

Hospitalisation:

Age: 48Y

Onset Date: 25/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		The patient experienced extrapyramidal symptoms.	Given Cogentin.

Medicine Details:

DROPERIDOL (Other drug)			Reason:		
Batch:		Started:		Stopped:	
LITHIUM CARBONATE (Other drug)			Reason:		
Batch:		Started:		Stopped:	
DIAZEPAM (Other drug)			Reason:		
Batch:		Started:		Stopped:	
MIDAZOLAM (Other drug)			Reason:		
Batch:		Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207979

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 86.00

Hospitalisation:

Age: 48Y

Onset Date: 25/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

NITRAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
CLONAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
EPILIM (Other drug)		Reason:
Batch:	Started:	Stopped:
HALOPERIDOL (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207979

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 86.00

Hospitalisation:

Age: 48Y

Onset Date: 25/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified schizophrenia

1.0 Milligram

Daily

Oral

Batch:

Started: 22/01/1999

Stopped:

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207981
Reported: 19/05/2005

Seq: 1

Gender: F
Weight: 61.00

Hospitalisation:

Onset Date: 08/11/1998
Outcome: Unknown

Age: 63Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	On 8 November 1998 the patient experienced extrapyramidal symptoms. On 21 November 1998 she experienced a dystonic reaction.	Benzotropine given.
Dystonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
VITAMIN B COMPLEX (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
LORAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207981

Seq: 1

Gender: F

Reported: 19/05/2005

Weight: 61.00

Hospitalisation:

Age: 63Y

Onset Date: 08/11/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecifid affective psychosis	
	2.0 Milligram	Daily	Oral
Batch:	Started: 07/11/1998	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 207983
Reported: 19/05/2005
Hospitalisation:
Onset Date: 29/10/1998
Outcome: Unknown

Seq: 1

Gender: F
Weight: 55.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	The patient experienced extrapyramidal symptoms after her dosage was decreased from 6mg daily to 4mg daily.	Benzotropine given.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.5 Gram	Oral	
Batch:	Started: 19/10/1998	Stopped:	0
LORAZEPAM (Other drug)		Reason:	
Tablet	2.0 Milligram	Oral	
Batch:	Started: 18/10/1998	Stopped:	0
PROPRANOLOL HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	Oral
Batch:	Started: 18/10/1998	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208007
Reported: 19/05/2005
Hospitalisation:
Onset Date: 17/11/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 79.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Caused or prolonged inpatient hospitalisation	On 17 November 1998 the patient experienced blurred vision and slurred speech. On 6 December 1998 the patient experienced dizziness. On 14 December 1998 the patient experienced akathisia. On 15 December 1998 the patient experienced extrapyramidal symptoms and on 16 December 1998 the patient experienced restlessness.	Risperdal ceased. Benzotropine given.
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)		Reason:	
50.0 Milligram		Oral	
Batch:	Started: 13/11/1998	Stopped: 16/11/1998	
AMOXICILLIN TRIHYDRATE (Other drug)		Reason:	
1.5 Gram			
Batch:	Started: 30/10/1998	Stopped:	
NAPROXEN (Other drug)		Reason:	
750.0 Milligram		Oral	
Batch:	Started: 30/10/1998	Stopped: 20/11/1998	
TEMAZEPAM (Other drug)		Reason:	
20.0 Milligram		Oral	
Batch:	Started: 02/11/1998	Stopped: 05/11/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208007
Reported: 19/05/2005

Seq: 1

Gender: M
Weight: 79.00
Age: 71Y

Hospitalisation:

Onset Date: 17/11/1998
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation		
Dysarthria	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
	2.0 Gram		Oral
Batch:	Started:	Stopped:	
PARACETAMOL (Other drug)		Reason:	
	1.0 Gram		Oral
Batch:	Started: 05/11/1998	Stopped: 19/11/1998	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily	Oral
Batch:	Started: 29/10/1998	Stopped: 11/12/1998	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208007

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 79.00

Hospitalisation:

Age: 71Y

Onset Date: 17/11/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)		Reason:	
	50.0 Milligram		Oral
Batch:	Started: 13/11/1998	Stopped: 16/11/1998	
AMOXICILLIN TRIHYDRATE (Other drug)		Reason:	
	1.5 Gram		
Batch:	Started: 30/10/1998	Stopped:	
NAPROXEN (Other drug)		Reason:	
	750.0 Milligram		Oral
Batch:	Started: 30/10/1998	Stopped: 20/11/1998	
TEMAZEPAM (Other drug)		Reason:	
	20.0 Milligram		Oral
Batch:	Started: 02/11/1998	Stopped: 05/11/1998	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208007

Seq: 1

Gender: M

Reported: 19/05/2005

Weight: 79.00

Hospitalisation:

Age: 71Y

Onset Date: 17/11/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
	2.0 Gram		Oral
Batch:	Started:	Stopped:	
PARACETAMOL (Other drug)		Reason:	
	1.0 Gram		Oral
Batch:	Started: 05/11/1998	Stopped: 19/11/1998	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily	Oral
Batch:	Started: 29/10/1998	Stopped: 11/12/1998	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I; RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208008
Reported: 19/05/2005
Hospitalisation:
Onset Date: 09/10/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 37.00
Age: 39Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Insomnia Muscle rigidity Restlessness Tachycardia Tremor		The patient experienced excess salivation, Parkinsonian effects, dysphagia, rigidity, tachycardia, difficulty swallowing, posturing, restlessness and insomnia.	Given Bzotropine and Amantadine.

Medicine Details:

LORAZEPAM (Other drug)	Reason:
2.0 Milligram	
Batch:	Started: 09/10/1998 Stopped:
TEMAZEPAM (Other drug)	Reason:
10.0 Milligram	
Batch:	Started: 09/10/1998 Stopped: 10/10/1998
CLONAZEPAM (Other drug)	Reason:
2.0 Milligram	
Batch:	Started: 18/09/1998 Stopped: 09/10/1998
RISPERDAL (Suspected)	Reason:
2.0 Milligram Daily Oral	
Batch:	Started: 18/09/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208045 **Seq:** 1 **Gender:** F
Reported: 20/05/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 81
Onset Date: 28/04/2005 **DOB:** 04/03/1924
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		The patient experienced a photosensitivity skin reaction to the face and neck only. She developed erythema and mild desquamation of the skin.	Aropax ceased.
Erythema			
Skin exfoliation			

Medicine Details:

AROPAX (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 05/05/2005	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	500.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208162 **Seq:** 1 **Gender:** M
Reported: 25/05/2005 **Weight:** 64.00
Hospitalisation: Required a visit to the doctor **Age:** 36
Onset Date: **DOB:** 16/07/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin hyperpigmentation		Patient experienced facial hyperpigmentation.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	
COMBIVIR (Suspected)		Reason: Hiv infection	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	Continuing.
LUVOX (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
NEVIRAPINE (Suspected)		Reason: Hiv infection	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208162

Seq: 1

Gender: M

Reported: 25/05/2005

Weight: 64.00

Hospitalisation: Required a visit to the doctor

Age: 36

Onset Date:

DOB: 16/07/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VALACICLOVIR HYDROCHLORIDE (Suspected)

Reason:

1.0 Gram

Daily

Batch:

Started:

Stopped:

0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208232 **Seq:** 1 **Gender:** M
Reported: 27/05/2005 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 23/04/2005 **DOB:** 08/05/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Patient experienced a rash.	Phenergan 25mg, Risperdal was ceased and Olanzapine was prescribed.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 22/04/2005	Stopped: 23/04/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208235

Seq: 1

Gender: F

Reported: 27/05/2005

Weight: 0.00

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Patient experienced increased prolactin levels and amenorrhea.	Risperidone oral was ceased and started on Risperidone microspheres.
Amenorrhoea			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208236 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208236

Seq: 1

Gender: F

Reported: 27/05/2005

Weight: 0.00

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Recovered

02/04/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed a fever and rigors.	
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208235 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208237 **Seq:** 1 **Gender:** M
Reported: 27/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: 23/09/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	The patient experienced restlessness and agitation. The following day he experienced akathisia.	
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	Oral
Batch:	Started: 03/09/1998	Stopped:	
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 22/09/1998	Stopped:	
PROPRANOLOL HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 23/09/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208238

Seq: 1

Gender: M

Reported: 30/05/2005

Weight: 63.00

Hospitalisation:

Age: 47Y

Onset Date: 14/06/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		The patient experienced dystonic movements.	Benztropine given.

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Other drug)		Reason:
Batch:	Started:	Stopped:
CLONAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
SODIUM VALPROATE (Other drug)		Reason:
Batch:	Started:	Stopped:
CHLORAMPHENICOL (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WVAE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208238

Seq: 1

Gender: M

Reported: 30/05/2005

Weight: 63.00

Hospitalisation:

Age: 47Y

Onset Date: 14/06/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

LORAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	Oral
Batch:	Started: 14/06/1998	Stopped: 14/06/1998	0

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WVAE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208239

Seq: 1

Gender: F

Reported: 30/05/2005

Weight: 52.00

Hospitalisation:

Age: 36Y

Onset Date: 29/12/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity Hypertonia		The patient experienced stiffness.	

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason:
Batch:	Started:	Stopped:
TEMAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
PARACETAMOL (Other drug)		Reason:
Batch:	Started:	Stopped:
HALOPERIDOL (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208239

Seq: 1

Gender: F

Reported: 30/05/2005

Weight: 52.00

Hospitalisation:

Age: 36Y

Onset Date: 29/12/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)			Reason:
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)			Reason:
Batch:	Started:	Stopped:	
BENZTROPINE MESYLATE (Other drug)			Reason:
Batch:	Started:	Stopped:	
MYLANTA (Other drug)			Reason:
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208239

Seq: 1

Gender: F

Reported: 30/05/2005

Weight: 52.00

Hospitalisation:

Age: 36Y

Onset Date: 29/12/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	1.5 Milligram	Daily	Oral
Batch:	Started: 21/10/1998	Stopped: 21/10/1998	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208255

Seq: 1

Gender: U

Reported: 30/05/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		The patient experienced suspected neutropenia.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208280

Seq: 1

Gender: F

Reported: 30/05/2005

Weight: 103.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Incapacity/disability	The patient experienced stiffness of the neck.	

Medicine Details:

FLUPHENAZINE DECANOATE (Other drug)	Reason:
Batch:	Started: Stopped:
CARBAMAZEPINE (Other drug)	Reason:
Batch:	Started: Stopped:
TERBUTALINE SULPHATE (Other drug)	Reason:
Batch:	Started: Stopped:
TRANDOLAPRIL (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208280

Seq: 1

Gender: F

Reported: 30/05/2005

Weight: 103.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

SENEGA AND AMMONIA (Other drug)		Reason:	
Batch:	Started:	Stopped:	
BENZTROPINE MESYLATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1998	Stopped: 29/12/1998	0

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208333

Seq: 1

Gender: M

Reported: 31/05/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		The patient experienced priapism.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208436 **Seq:** 1 **Gender:** F
Reported: 02/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73Y
Onset Date: 03/02/2005 **DOB:**
Outcome: Death 06/02/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Patient experienced chronic respiratory failure and cardiac failure congestive and died.	
Cardiac failure congestive			
Respiratory failure			

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	25.0 Milligram 2 times Intramuscular
Batch:	Started: 12/01/2004 Stopped: 27/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/06/2005	Other data				Death certificate reports cause of death as end stage respiratory failure due to severe emphysema, chronic schizophrenia, right pleural effusion, and congestive cardiac failure.

Additional Information:

Clinical trial RIS-AUS-MA1: e-STAR.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208469

Seq: 1

Gender: U

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 13/05/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania		The patient developed acute homicidal mania and later burnt a ward after a quarrel.	
Homicidal ideation			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208516 **Seq:** 1 **Gender:** F
Reported: 06/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 81
Onset Date: **DOB:** 26/05/1924
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Caused or prolonged inpatient hospitalisation	Patient experienced ischaemic left cerebral ventricular accident.	

Medicine Details:

NORVASC (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
PREDNISOLONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecifid affective psychosis	
Batch:	Started:	Stopped:	
TEVETEN (Suspected)		Reason: Essential benign hypertension	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient participated in a post-marketing observational study (Solvay AUS-02).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208541 **Seq:** 1 **Gender:** M
Reported: 07/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44Y
Onset Date: 07/12/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Patient experienced a decrease in his mental state complicated by "alcohol binging" and needed to be hospitalised due to "suicidal" ideation.	
Alcoholism	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	Intramuscular
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RIS-AUS-MA1:e-STAR.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208591
Reported: 09/06/2005
Hospitalisation:
Onset Date: 16/11/1998
Outcome: Unknown

Seq: 1

Gender: F
Weight: 103.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient experienced akathisia and postural hypotension.	Given Benztropine.
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)		Reason:	
5.0 Milligram		Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
6.0 Milligram		Daily Oral	
Batch:	Started: 19/10/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208755
Reported: 20/06/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 08/01/1999
Outcome: Unknown

Age: 44Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	The patient experienced extrapyramidal symptoms, stiffness of joints and stiffness of the jaw.	
Joint stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PARACETAMOL (Other drug)		Reason:
Batch:	Started:	Stopped:
TEMAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
	2.0 Milligram	Daily
Batch:	Started: 04/01/1999	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208755

Seq: 1

Gender: F

Reported: 20/06/2005

Weight: 0.00

Hospitalisation:

Age: 44Y

Onset Date: 08/01/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)		Reason:	
Injection	40.0 Milligram	Daily	
Batch:	Started: 06/01/1999	Stopped:	
ARTANE (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 08/01/1999	Stopped:	

Laboratory Investigations:

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208758
Reported: 20/06/2005

Seq: 1

Gender: F
Weight: 0.00
Age: 27Y

Hospitalisation:

Onset Date: 02/12/1998
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Catatonia	Caused or prolonged inpatient hospitalisation	The patient experienced catatonia.	Benztropine given.

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
	4.0 Milligram Daily Oral
Batch:	Started: 27/11/1998 Stopped: 27/11/1998 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208760
Reported: 20/06/2005
Hospitalisation:
Onset Date: 24/12/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	The patient experienced a stiff neck and hypersalivation.	
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
	20.0 Milligram		Oral
Batch:	Started: 22/12/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
	200.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1998	Stopped:	
DIAZEPAM (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208905
Reported: 22/06/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 19/05/2005
Outcome: Recovered

21/05/2005

Age: 36
DOB: 04/07/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		The patient experienced agitation, mainly in the legs, whilst taking Risperdal Consta.	Took 59 Biperiden tablets over 1.5 days.

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	2.0 Milligram	Oral	
Batch:	Started: 14/01/2005	Stopped:	
LANSOPRAZOLE (Other drug)		Reason:	
Capsule	50.0 Milligram	Oral	
Batch:	Started: 14/03/2005	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Weekly	Intramuscular
Batch:	Started: 21/03/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RIS-AUS-MA1: e-STAR electronic schizophrenia treatment adherence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208989
Reported: 23/06/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 24/03/2005

Age: 65

DOB: 18/12/1939

Outcome: Recovered

24/03/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced a seizure which lasted for 25 minutes. There was no history of epilepsy.	IV Diazepam.

Medicine Details:

HYDROCHLOROTHIAZIDE (Other drug)		Reason:		Osteoarthritis
Batch:	Started:	Stopped:		
CANDESARTAN CILEXETIL (Other drug)		Reason:		Essential benign hypertension
Batch:	Started:	Stopped:		
RISPERDAL CONSTA (Suspected)		Reason:		Unspecified psychosis
Injection	1.0	Dose Unspecified	1 time	Intramuscular
Batch:	Started: 10/03/2005		Stopped: 10/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: thiazide - hyponatraemia



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208989

Seq: 1

Gender: F

Reported: 23/06/2005

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 24/03/2005

DOB: 18/12/1939

Outcome: Recovered

24/03/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	Oral
Batch:	Started: 17/03/2005	Stopped: 24/03/2005	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 18/02/2005	Stopped: 17/03/2005	

Laboratory Investigations:

Additional Information:

Patient history: thiazide - hyponatraemia



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 208998

Seq: 1

Gender: F

Reported: 23/06/2005

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 15/04/2005

DOB: 28/08/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Life threatening	Patient experienced breast cancer with lung metastases.	
Metastases to lung	Life threatening		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 15/04/1998	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209126
Reported: 27/06/2005

Seq: 1

Gender: M
Weight: 95.00
Age: 30Y

Hospitalisation:

Onset Date: 06/06/2005
Outcome: Recovered

DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		The patient experienced a grand mal seizure.	

Medicine Details:

ZOLOFT (Other drug)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Oral
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason: Other&unspecified epilepsy
	5.0 Dose Unspecified
Batch:	Started: Stopped:
VALIUM (Other drug)	Reason:
	5.0 Milligram Alternate days
Batch:	Started: Stopped: 0
Risperdal Consta (Suspected)	Reason:
Injection	50.0 Milligram Alternate weeks
Batch:	Started: 16/02/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209132

Seq: 1

Gender: M

Reported: 27/06/2005

Weight: 0.00

Hospitalisation:

Age: 53Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infarction		The patient experienced infarction.	

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	16.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133

Seq: 1

Gender: M

Reported: 27/06/2005

Weight: 61.00

Hospitalisation:

Age: 21

Onset Date: 08/04/2005

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity	Caused or prolonged inpatient hospitalisation	The patient experienced hypersensitivity, described as urticaria, wheals and wheeze. There was an interruption in therapy from Oct 2004, The patient received his next injection on 05/04/2005. On 08/04/2005 presented to hospital with shortness of breath, slight stridor, rash on his feet, hands arms, trunk and thigh. His heart rate was 90, oxygen saturation 93% and respiratory rate 18. 10/04/2005 He presented on his second admission, increased itching, increased shortness of breath, tightness of the chest and ongoing rash. Heart ...	

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Intramuscular	
Batch:	Started: 25/09/2004	Stopped: 05/04/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133
Reported: 27/06/2005

Seq: 1

Gender: M
Weight: 61.00

Hospitalisation:

Onset Date: 08/04/2005

Age: 21

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		... rate 110, oxygen saturation 90%.The patient had a drug screen test on 11/04/2005 whihc was positive for benzodiazepine, cannabinoids and a tryptase test performed on 15/04/2005, 8.3ng/ml (normal < 15.0ng/mL). The patient's third hopsital admission occurred on 21/04/05 third, patient presented with rash, difficulty swallowing, thightness in his throat, nocturnal wheeze, shortness of breath, genaralised rash. heart rate 96, blood pressure 120/80. the patient was admitted for the fourth time 22/04/2005 with increased umbilical ...	

Medicine Details:

Aripiprazole (Other drug)		Reason:
Batch:	Started:	Stopped:
Risperdal Consta (Suspected)	Reason:	Unspecified schizophrenia
Injection	25.0 Milligram	Intramuscular
Batch:	Started: 25/09/2004	Stopped: 05/04/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133

Seq: 1

Gender: M

Reported: 27/06/2005

Weight: 61.00

Hospitalisation:

Age: 21

Onset Date: 08/04/2005

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest discomfort	Caused or prolonged inpatient hospitalisation	... rash, lip and tongue oedema. The patient had a tryptase test performed on 27/04/2005, 15.4ng/ml	
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Intramuscular	
Batch:	Started: 25/09/2004	Stopped:	05/04/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133
Reported: 27/06/2005

Seq: 1

Gender: M
Weight: 61.00

Hospitalisation:

Onset Date: 08/04/2005

Age: 21

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heart rate abnormal	Caused or prolonged inpatient hospitalisation		
Lip oedema	Caused or prolonged inpatient hospitalisation		
Pharyngeal oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Other drug)		Reason:
Batch:	Started:	Stopped:
Risperdal Consta (Suspected)	Reason:	Unspecified schizophrenia
Injection	25.0 Milligram	Intramuscular
Batch:	Started: 25/09/2004	Stopped: 05/04/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133
Reported: 27/06/2005

Seq: 1

Gender: M
Weight: 61.00

Hospitalisation:

Onset Date: 08/04/2005

Age: 21

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus	Caused or prolonged inpatient hospitalisation		
Rash	Caused or prolonged inpatient hospitalisation		
Stridor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Other drug)		Reason:
Batch:	Started:	Stopped:
Risperdal Consta (Suspected)	Reason:	Unspecified schizophrenia
Injection	25.0 Milligram	Intramuscular
Batch:	Started: 25/09/2004	Stopped: 05/04/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209133

Seq: 1

Gender: M

Reported: 27/06/2005

Weight: 61.00

Hospitalisation:

Age: 21

Onset Date: 08/04/2005

DOB: 22/12/1983

Outcome: Recovered

03/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Throat tightness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Intramuscular	
Batch:	Started: 25/09/2004	Stopped:	05/04/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209251 **Seq:** 1 **Gender:** F
Reported: 29/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 27/02/2005 **DOB:** 15/07/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy	Life threatening	Admitted to PA 10/02 for decreased behaviour (intellectual impairment) constant screaming. No treatable reason found, CT clear. Risperidone commenced 18/02 at 0.5mg. Patient more settle and discharged on same 22/02. OK for 1/52. 27/03 - listless and lethargic 28/03 - sudden collapse. Seizure suspected, whole back very hot and red with cold peripheries. Admitted to hospital - severe rhabdomyolysis and ARF, 2 days in ICU. Episode noted as possible neuroleptic malignant syndrome secondary Risperidone or Haloperidol.	

Medicine Details:

BISACODYL (Other drug)	Reason: Constipation
20.0 Milligram	
Batch:	Started: Stopped:
FOLIC ACID (Other drug)	Reason:
5.0 Milligram	
Batch:	Started: Stopped:
PANTOPRAZOLE (Other drug)	Reason:
40.0 Milligram	
Batch:	Started: Stopped:
HALOPERIDOL (Suspected)	Reason: Otr spec symp psychopathol nec As necessary
Batch:	Started: 15/12/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209251 **Seq:** 1 **Gender:** F
Reported: 29/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 27/02/2005 **DOB:** 15/07/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Renal failure acute	Life threatening		
Rhabdomyolysis	Life threatening		

Medicine Details:

RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
0.5 Milligram	Daily
Batch:	Started: 18/02/2005 Stopped: 27/02/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209280

Seq: 1

Gender: M

Reported: 29/06/2005

Weight: 0.00

Hospitalisation:

Age: 19Y

Onset Date: 03/02/2005

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		hyperprolactinaemia 03/02/2005 prolactin 1143miu/L ref range (45-375)	risperidone tablets and consta ceased. Olanzapine commenced

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
	2.0 Milligram		
Batch:	Started: 02/02/2005	Stopped: 09/02/2005	
Risperdal Consta (Suspected)		Reason:	
	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 19/01/2005	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	Oral
Batch:	Started: 28/01/2005	Stopped: 09/02/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209381

Seq: 1

Gender: M

Reported: 01/07/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient experienced tardive dyskinesia.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209425

Seq: 1

Gender: U

Reported: 04/07/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	The patient committed suicide while being treated with Risperidone.	

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Intramuscular
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209481
Reported: 05/07/2005
Hospitalisation:
Onset Date: 19/05/2005
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 32
DOB: 23/04/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	The patient was found confused and agitated at home by a family member and had not been compliant with his antipsychotic medications for a few days. The GCS score was 14; he had a blunt affect and slow speech on admission. Suspected neuroleptic malignant syndrome and weight increased.	Treated with IV Saline, Sodium Bicarbonate and Valium. All Antipsychotic medications discontinued.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOCOR (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: 07/05/2003 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	4.0 Milligram Daily Oral
Batch:	Started: 15/05/2001 Stopped: 19/05/2005
SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 15/05/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2005	Creatine		20/05/2005	1430	
05/07/2005	Creatine		23/05/2005	2250	
05/07/2005	Creatine		25/05/2005	467	
05/07/2005	Creatinine		20/05/2005	101	
05/07/2005	Creatinine		25/05/2005	76	
05/07/2005	Other data		20/05/2005	291	Lactic Dehydrogenase.
05/07/2005	Urea		25/05/2005	2.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209481
Reported: 05/07/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 19/05/2005

Age: 32

DOB: 23/04/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOCOR (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: 07/05/2003 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	4.0 Milligram Daily Oral
Batch:	Started: 15/05/2001 Stopped: 19/05/2005
SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 15/05/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2005	White blood cells		20/05/2005	11.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209554
Reported: 06/07/2005
Hospitalisation:
Onset Date: 15/12/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 33
DOB: 29/08/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nipple exudate bloody		In 12/04 patient experienced a bloody discharge from his left nipple (accompanied by gynecomastia) which subsided spontaneously then recurred in 04/05.	On 16/05/05 patient underwent a left sided subcutaneous mastectomy. Risperidone therapy discontinued.
Breast cancer male Gynaecomastia		breast cancer in situ	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
1.5 Milligram	Daily
Batch:	Started: 15/01/2004 Stopped: 15/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/07/2005	Histology				Histology of the tissue revealed low graded ductal carcinoma.
06/07/2005	Other data				A mammogram and score showed no active disease, a biopsy showed ductal carcinoma in situ.
06/07/2005	Prolactin				Preoperative serum prolactin levels were within normal range.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209855
Reported: 15/07/2005

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 15/05/2005

Age: 10

DOB: 13/12/1994

Outcome: Recovered

05/05/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Deterioration in control of seizures. The patient experienced a deterioration in seizure control, from one fit to five fits daily. These were partial seizures abd also possibly absence seizures.	Dose of Atomoxetine reduced to 25mg.

Medicine Details:

Strattera (Interaction)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started: 15/05/2005	S TERM	Stopped: 0
SODIUM VALPROATE (Interaction)		Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 15/02/2005	S TERM	Stopped:
CARBAMAZEPINE (Interaction)		Reason:	
Tablet	840.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Interaction)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 14/04/2004	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209855

Seq: 1

Gender: F

Reported: 15/07/2005

Weight: 0.00

Hospitalisation:

Age: 10

Onset Date: 15/05/2005

DOB: 13/12/1994

Outcome: Recovered

05/05/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)					Reason:	
	20.0	Milligram	Daily		Oral	
Batch:	Started: 15/03/2005	S TERM		Stopped:		
MELATONIN (Other drug)					Reason:	
	3.0	Milligram	Daily		Oral	
Batch:	Started: 15/01/2005	S TERM		Stopped:		

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 209978 **Seq:** 1 **Gender:** M
Reported: 19/07/2005 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 12
Onset Date: 30/06/2005 **DOB:** 08/08/1992
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Patient experienced a severe dystonic reaction.	

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210181
Reported: 27/07/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 19/07/2005

Age: 17

DOB: 24/09/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	Elevated Creatine Kinase - 4790U/L. Tachycardia - 126bpm	Risperdal ceased. Another antipsychotic commenced.; CK and pulse regularly monitored. CK on 21/07/2005 was 652U/L
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason:		
Tablet	1.0 Milligram	1 time	Oral	
Batch:	Started: 11/07/2005	Stopped:	19/07/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210218 **Seq:** 1 **Gender:** M
Reported: 28/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 27/06/2005 **DOB:** 12/04/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	The patient experienced suspected myocarditis and raised CK levels after commencing Clozaril. The patient also experienced fever dyspnoea, and events were complicated by suspected neuroleptic malignant syndrome	Clozaril , Risperidone ceased. Olanzapine initiated
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Life threatening		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 05/07/1999	Stopped:	12/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Historical condition: Childhood asthma and Seizures during clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210218 **Seq:** 1 **Gender:** M
Reported: 28/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 27/06/2005 **DOB:** 12/04/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Life threatening		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 05/07/1999	Stopped:	12/07/2005 0

Laboratory Investigations:

Additional Information:

Historical condition: Childhood asthma and Seizures during clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210221

Seq: 1

Gender: F

Reported: 28/07/2005

Weight: 100.00

Hospitalisation:

Age: 49

Onset Date: 22/07/2005

DOB: 30/07/1955

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Life threatening	Symptoms: abdominal pain and nausea, polyuria, polydypsia, hypotension (systolic 60 mmHg), hyperglycaemia (BSL 44), hypernatremia 166 mmol/l. Admitted to ICU with DKA	Insulin infusion, hydration
Diabetic ketoacidosis	Life threatening		
Hyperglycaemia	Life threatening		
Hypernatraemia	Life threatening		

Medicine Details:

Symbicort Turbuhaler 200/6 (Suspected)		Reason:	
Inhalation	1.0 Unit	2 times	Inhalation
Batch:	Started: 01/01/2004	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 01/02/2005	Stopped: 27/06/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2005	Biochemistry				Baseline blood glucose in Jan 2005, before commencing Risperdal;6.2 mmol/L.On admission 22/07: BSL 44mmol/L (3.6-7.7); Lactate 6.1 mmol/L (0.5 to 2.2), arterial gases pH 7.17 (7.35-7.45, BE -17.4 (-3 to +3). Abnormal LFTs, elevated amylase, lipase

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210221

Seq: 1

Gender: F

Reported: 28/07/2005

Weight: 100.00

Hospitalisation:

Age: 49

Onset Date: 22/07/2005

DOB: 30/07/1955

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Life threatening		
Liver function test abnormal	Life threatening		
Nausea	Life threatening		
Pancreatitis	Life threatening		
Polyuria	Life threatening		

Medicine Details:

Symbicort Turbuhaler 200/6 (Suspected)		Reason:	
Inhalation	1.0 Unit	2 times	Inhalation
Batch:	Started: 01/01/2004	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 01/02/2005	Stopped: 27/06/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210289

Seq: 1

Gender: F

Reported: 01/08/2005

Weight: 0.00

Hospitalisation:

Onset Date: 29/06/2005

Age: 80Y

DOB:

Outcome: Death, maybe drug

29/06/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Patient became agitate and experienced cerebrovascular accident.	
Agitation	Death		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis
Tablet		Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210290

Seq: 1

Gender: F

Reported: 01/08/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 15/01/2005

DOB:

Outcome: Death, maybe drug

01/05/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Patient experienced cerebrovascular accident.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210324 **Seq:** 1 **Gender:** M
Reported: 02/08/2005 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 12
Onset Date: 28/06/2005 **DOB:** 08/08/1992
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Acute dystonic reaction.	Treated with Bentropine.

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug) 300.0 Microgram Batch: Started: Stopped:	Reason: Manic-depression psycho,manic
METHYLPHENIDATE HYDROCHLORIDE (Other drug) 36.0 Milligram Batch: Started: Stopped:	Reason: Behavior disorders of childhood
NITRAZEPAM (Other drug) 5.0 Milligram Batch: Started: Stopped:	Reason: Manic-depression psycho,manic
SODIUM VALPROATE (Suspected) Tablet 1.0 Gram Daily Oral Batch: Started: Stopped: 28/06/2005	Reason: Manic-depression psycho,manic

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210324

Seq: 1

Gender: M

Reported: 02/08/2005

Weight: 45.00

Hospitalisation: Admitted to hospital

Age: 12

Onset Date: 28/06/2005

DOB: 08/08/1992

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Manic-depression psycho,manic

3.0 Milligram

Daily

Oral

Batch:

Started:

Stopped: 28/06/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210342

Seq: 1

Gender: F

Reported: 03/08/2005

Weight: 55.00

Hospitalisation:

Age: 75

Onset Date:

DOB: 17/07/1930

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Sudden onset of shakiness, more agitation and severe dystonia in upper limbs, having been on Risperidone up to 2mg which has been reduced to 1mg nocte. Had previously had a course of Risperidone 2mg without any signs of dystonia.	Benzotropine for dystonia.
Agitation			
Tremor			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec
	1.0 Milligram	Daily
Batch:	Started: 04/07/2005	Stopped: 12/07/2005
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason: Depression
	225.0 Milligram	Daily
Batch:	Started: 05/07/2005	Stopped: 07/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 210347 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210347

Seq: 1

Gender: F

Reported: 03/08/2005

Weight: 55.00

Hospitalisation:

Age: 74

Onset Date: 06/07/2005

DOB: 17/07/1930

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia on and off during 2005. Noted again on 06/07/05 after Venlafaxine restarted (making slow recovery since).	Cease Venlafaxine added salt tablets and restrict fluids.

Medicine Details:

RISPERIDONE (Interaction)		Reason: Otr spec symp psychopathol nec
	1.0 Milligram	Daily
Batch:	Started: 04/07/2005	Stopped: 12/07/2005
VENLAFAXINE HYDROCHLORIDE (Interaction)		Reason: Depression
	225.0 Milligram	Daily
Batch:	Started: 05/07/2005	Stopped: 07/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 210342 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210436 **Seq:** 1 **Gender:** M
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 80
Onset Date: 24/06/2005 **DOB:** 25/03/1925
Outcome: Recovered 26/06/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Patient developed hypotension (BP 75/45 mmHg) , slurred speech, shaky, unsteady gait.	Ceased Risperdal and decreased Ramipril dose to 2.5 mg mane.
Dysarthria	Caused or prolonged inpatient hospitalisation		
Gait disturbance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASASANTIN SR (Other drug)		Reason:	Acute,ill-def cerebrovascular disease w/o hyperte
Batch:	Started:	Stopped:	
LUVOX (Other drug)		Reason:	Depression
Batch:	Started:	Stopped:	
COLOXYL WITH SENNA (Other drug)		Reason:	Conjunctivitis and ophthalmia
Batch:	Started:	Stopped:	
ZOCOR (Other drug)		Reason:	Othr&unspec metabolic diseases
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210436 **Seq:** 1 **Gender:** M
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 80
Onset Date: 24/06/2005 **DOB:** 25/03/1925
Outcome: Recovered 26/06/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Explosive personality disorder
Batch:	Started: 23/06/2005	Stopped: 25/06/2005 0
TRITACE (Suspected)		Reason: Essential benign hypertension
	5.0 Milligram Daily	
Batch:	Started: 27/04/2005	Stopped: 27/06/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210523

Seq: 1

Gender: M

Reported: 09/08/2005

Weight: 0.00

Hospitalisation:

Onset Date: 18/07/2005

Age: 44Y

DOB:

Outcome: Death, maybe drug

19/07/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly	Death	Patient died due to cardiomegaly.	

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 21/04/2005	Stopped: 04/07/2005	
RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On 18 Jul 05, the patient died; conroner's cuase was reported as cardiomegaly.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210561

Seq: 1

Gender: F

Reported: 10/08/2005

Weight: 0.00

Hospitalisation: Required a specialist consultation

Age: 17Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinopathy		Patient developed symptoms of blurred vision and a diagnosis of retinopathy.	
Vision blurred			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Erythema multiforme
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210745

Seq: 1

Gender: F

Reported: 16/08/2005

Weight: 0.00

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Life threatening	Patient developed breast cancer.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Residual schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 15/12/2002 L TERM	Stopped: 26/07/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2005	Prolactin				01/08/2005-6mcg/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210746

Seq: 1

Gender: F

Reported: 16/08/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deafness congenital	Congenital anomaly / birth defect	Baby experienced loss of hearing in right ear.	

Medicine Details:

RISPERDAL (Suspected)	Reason:
Batch:	Started: 09/09/2004 Stopped:
EPILIM (Suspected)	Reason:
Batch:	Started: 09/09/2004 Stopped:
ERYTHROMYCIN (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210800

Seq: 1

Gender: M

Reported: 16/08/2005

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 09/03/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		After risperidone was discontinued, the patient developed stiff leg, hip pain, and muscle pain on left side.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Intellectually disabled, petit mal seizure as a child, and no grand mal seizure prior to Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210800

Seq: 1

Gender: M

Reported: 16/08/2005

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 09/03/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		After starting Risperidone the patient experienced a number of symptoms gradually: he constantly had the urge to move and would not sit still, had become incontinent, had one grand mal and one petit mal seizure, his left arm was rigid, his thumb tucked under and his elbow held tightly, lost the ability to hold a cup and feed himself, and was 'very staggering' to the extent that his mother now felt the need to take him out in a wheelchair.	Treated with a trial of Sodium Valproate. Gradually ceased risperdal
Gait disturbance			
Muscle contracture			

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Medical history: Intellectually disabled, petit mal seizure as a child, and no grand mal seizure prior to Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210800

Seq: 1

Gender: M

Reported: 16/08/2005

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 09/03/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness			
Urinary incontinence			

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Medical history: Intellectually disabled, petit mal seizure as a child, and no grand mal seizure prior to Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210852 **Seq:** 1 **Gender:** F
Reported: 17/08/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 67
Onset Date: 24/07/2005 **DOB:** 02/06/1938
Outcome: Recovered 28/07/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		The patient developed an urticarial rash, raised, red and itchy patches of varying sizes involving trunk and limbs. Worse on the hands, which are red uniformly and puffy. Flexor aspect of knees and elbows involved.	Treated with Promethazine 10mg prn (1 dose).
Pruritus			

Medicine Details:

RANITIDINE (Other drug)	Reason: Other diseases of esophagus
Batch:	Started: Stopped:
VENTOLIN (Other drug)	Reason: Otr respiratory systm diseases
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
CENTRUM TABLETS (Other drug)	Reason: Unspec vitamin deficien states
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies: Sudafed - rash, Augmentin - rash, Keflex, Aspirin, trout, tomato sauce and citrus fruits.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 210852 **Seq:** 1 **Gender:** F
Reported: 17/08/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 67
Onset Date: 24/07/2005 **DOB:** 02/06/1938
Outcome: Recovered 28/07/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	
Batch:	Started: 20/07/2005	Stopped: 20/07/2005	
Risperdal Quicklet (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 23/07/2005	

Laboratory Investigations:

Additional Information:

Allergies: Sudafed - rash, Augmentin - rash, Keflex, Aspirin, trout, tomato sauce and citrus fruits.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211008

Seq: 1

Gender: F

Reported: 22/08/2005

Weight: 0.00

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		The patient experienced thinning of her hair and her prolactin level was found to be over 2000.	Prescribed Cabergoline.
Alopecia			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/08/2005	Prolactin				Prolactin over 2000.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211088

Seq: 1

Gender: M

Reported: 25/08/2005

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 12/05/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness		Within two days of receiving his first Risperidone injection the patient became aggressive, was pacing, 'animal-like' and 'out of control'. Two weeks ago a second injection of Risperidone was given and he experienced the same reaction again. This time, he 'went insane' and escaped from the institution.	
Aggression			

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Intramuscular
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of head injury and acutaly sensitive to medications



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211306

Seq: 1

Gender: F

Reported: 01/09/2005

Weight: 74.00

Hospitalisation:

Age: 73

Onset Date:

DOB: 05/07/1932

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epistaxis	Incapacity/disability	Epistaxis	nil

Medicine Details:

FLUANXOL (Other drug)		Reason:	
Injection	80.0 Milligram	Weekly	Intramuscular
Batch:	Started:	Stopped:	07/06/2005
Risperdal Consta (Suspected)		Reason:	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 15/03/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211544

Seq: 1

Gender: F

Reported: 09/09/2005

Weight: 0.00

Hospitalisation:

Onset Date: 01/10/2005

Age: 89Y

DOB:

Outcome: Death, maybe drug

01/09/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died while being treated with risperidone.	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211764

Seq: 1

Gender: M

Reported: 20/09/2005

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Patient experienced impotence after receiving Risperidone for a few months.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211788

Seq: 1

Gender: U

Reported: 21/09/2005

Weight: 0.00

Hospitalisation:

Onset Date: 22/08/2005

Age: 34

DOB: 14/02/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia		Patient developed bradycardia, whilst taking Risperdal treatment.	
Chest pain			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
AMOXICILLIN SODIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started: 27/07/2005	Stopped:	22/08/2005 0
RISPERDAL (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2005	Stopped:	24/08/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/09/2005	Electrocardiograph		22/08/2005	sinus	
21/09/2005	Electrocardiograph		25/08/2005	sinus rhythm	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211829 **Seq:** 1 **Gender:** F
Reported: 20/09/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 25
Onset Date: 06/09/2005 **DOB:** 07/08/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Patient developed galactorrhoea and elevated serum prolactin.	
Blood prolactin increased			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	1.3 Gram	Daily	
Batch:	Started:	L TERM	Stopped: Continuing.
OROXINE (Other drug)		Reason: Myxedema	
	50.0 Microgram	Daily	
Batch:	Started:	L TERM	Stopped: Continuing.
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211893 **Seq:** 1 **Gender:** M
Reported: 22/09/2005 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 17
Onset Date: 15/11/2004 **DOB:** 20/11/1986
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Pateint developed elevated LFT's.	Ceased Risperidone.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 15/03/2004
CARBAMAZEPINE (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	L TERM	Stopped: 15/02/2005
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211991 **Seq:** 1 **Gender:** F
Reported: 26/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74
Onset Date: 05/09/2005 **DOB:** 02/08/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	Pateint developed parkinsonian like appearance secondary to Risperidone.	Ceased Risperidone

Medicine Details:

ASPIRIN (Other drug)	Reason:
100.0 Gram	
Batch:	Started: Stopped:
COVERSYL (Other drug)	Reason:
4.0 Milligram	
Batch:	Started: Stopped:
LANOXIN (Other drug)	Reason:
1.0 Dose Unspecified	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
2.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 211991 **Seq:** 1

Reported: 26/09/2005

Hospitalisation: Admitted to hospital

Onset Date: 05/09/2005

Outcome: Not yet recovered

Gender: F

Weight: 0.00

Age: 74

DOB: 02/08/1931

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Suspected)

Reason:

500.0 Milligram

Daily

Batch:

Started:

Stopped: 06/09/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212012

Seq: 1

Gender: M

Reported: 27/09/2005

Weight: 90.00

Hospitalisation:

Age: 18

Onset Date:

DOB: 20/11/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspartate aminotransferase increa		Patient experienced elevate liver function tests with alanine aminotransferase and aspartate aminotransferase.	Risperidone discontinued.
Alanine aminotransferase increase			

Medicine Details:

RISPERDAL (Suspected)		Reason: Other atyp forms schizophrenia	
	4.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 15/03/2005
CARBAMAZEPINE (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/09/2005	ALT = SGPT				ALT - 160-250.
27/09/2005	AST = SGOT				AST - 70-90.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212062

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 70.00

Hospitalisation:

Onset Date: 01/09/2005

Age: 56

DOB: 29/01/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness Agitation Clonus Hyperhidrosis Hypertonia Serotonin syndrome		Patient experienced stiffness, agitation, sweating, clonus ++ increased tone, serotonin syndrome or NMS.	Ceased all medication, ICU.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Manic-depression psycho,manic	
Batch:	Started: 18/08/2005	Stopped: 08/09/2005	
DOXEPIN HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped: 08/09/2005	
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped: 08/09/2005	
MELLERIL (Suspected)		Reason:	
Batch:	Started:	Stopped: 08/09/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212062

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 70.00

Hospitalisation:

Age: 56

Onset Date: 01/09/2005

DOB: 29/01/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Batch:	Started: 28/08/2005	Stopped: 08/09/2005	
LITHIUM CARBONATE (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 18/08/2005	Stopped: 08/09/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212107 **Seq:** 1 **Gender:** F
Reported: 29/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 14Y
Onset Date: 15/06/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		The patient developed diabetes which required insulin.	Risperidone ceased.

Medicine Details:

CIPRAMIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
2.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212337
Reported: 10/10/2005
Hospitalisation:
Onset Date:
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 22
DOB: 26/02/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Incapacity/disability	The patient developed galactorrhoea and weight gain.	
Weight increased	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 15/03/2005	Stopped: 15/06/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212340
Reported: 10/10/2005

Seq: 1

Gender: F
Weight: 60.00

Hospitalisation:

Onset Date: 15/03/2005

Age: 30Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain, ammenorrhoea, hyperprolactinaemia, headache, hair loss.	Dose of Risperdal decreased to 2mg.
Alopecia	Caused or prolonged inpatient hospitalisation		
Amenorrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ERYTHROMYCIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Batch:	Started: 15/02/2004	Stopped: 0	
CIPRAMIL (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/10/2005	Prolactin				Prolactin - 130ng/mL and 200ng/mL.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212340

Seq: 1

Gender: F

Reported: 10/10/2005

Weight: 60.00

Hospitalisation:

Age: 30Y

Onset Date: 15/03/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation		
Hyperprolactinaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Other drug)				Reason:	
Batch:		Started:		Stopped:	
ERYTHROMYCIN (Other drug)				Reason:	
Batch:		Started:		Stopped:	
RISPERDAL (Suspected)				Reason: Unspecified psychosis	
Batch:		Started: 15/02/2004		Stopped: 0	
CIPRAMIL (Suspected)				Reason:	
Tablet		40.0 Milligram		Daily Oral	
Batch:		Started:		Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212445
Reported: 12/10/2005
Hospitalisation:
Onset Date: 15/09/2005
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 60Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient was receiving Risperidone Consta for about 6 months. Smaller doses of Risperidone Consta 12.5mg or 15mg were used. On the small dose, suicidal thoughts were controlled. About 2 months ago, the dose was increased to 25mg. Over the last 2 weeks, patient had gained 3.5 kg. Also had ankle edema, was feeling apathetic and lethargic, plus suicidal thoughts had returned.	
Apathy Insomnia Lethargy			Nitrazepam

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecifid affective psychosis
Injection	25.0 Milligram Daily Intramuscular
Batch:	Started: 15/03/2005 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212445

Seq: 1

Gender: F

Reported: 12/10/2005

Weight: 0.00

Hospitalisation:

Age: 60Y

Onset Date: 15/09/2005

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			
Therapy regimen changed			
Weight increased			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecifid affective psychosis	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started: 15/03/2005	Stopped:	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212711

Seq: 1

Gender: F

Reported: 19/10/2005

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 26/08/2005

DOB: 23/01/1940

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female		Patient was diagnosed with breast cancer. confirmed by mamogram. The cancer had spread to anxillary glands with an aggressive pathology	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	4.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 212929

Seq: 1

Gender: F

Reported: 27/10/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		The patient experienced "stroke-like symptoms" including tongue rolling and spasms, or oversedation with slurring and falling	
Sedation			
Tongue paralysis			
Tongue spasm			

Medicine Details:

RISPERDAL (Suspected)	Reason:
0.5 Milligram	Daily
Oral	
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213019

Seq: 1

Gender: F

Reported: 31/10/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient experienced suspected neuroleptic malignant syndrome.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213047 **Seq:** 1 **Gender:** M
Reported: 01/11/2005 **Weight:** 100.00
Hospitalisation: Required a visit to the doctor **Age:** 35
Onset Date: **DOB:** 20/01/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia Agitation Restlessness Therapy regimen changed		Severe akathisia 5 days after IMI Risperidone 12.5mg increased to 25mg. Lasted 3 days with severe restlessness, agitation and then slowly settled to less severe restlessness for the next 10 days.	Treated with Diazepam for 3 days.

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Unspecified schizophrenia	
	1.5 Gram	Daily	
Batch:	Started:	L TERM	Stopped:
OROXINE (Other drug)		Reason: Myxedema	
Tablet	200.0 Microgram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Monthly	Intramuscular
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had previously trialled oral Risperidone 1mg nocte for 2 weeks and 12.5mg dose Risperidone IMI one month before commencement of monthly injections of 25mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213206

Seq: 1

Gender: F

Reported: 08/11/2005

Weight: 0.00

Hospitalisation:

Age: 32Y

Onset Date: 15/09/2005

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female		The patient was diagnosed with breast cancer, experienced elevated prolactin level, irregular periods and drug exposure during pregnancy.	
Blood prolactin increased			
Drug exposure during pregnancy			
Menstruation irregular			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
2.0 Milligram	Daily
	Oral
Batch:	Started: L TERM
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213271

Seq: 1

Gender: F

Reported: 09/11/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		The patient was admitted to a nursing home due to a "heightening of hallucinations".	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is 100 years old.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213354

Seq: 1

Gender: M

Reported: 14/11/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient experienced tardive dyskinesia and weight gain.	
Weight increased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213363

Seq: 1

Gender: F

Reported: 14/11/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		The patient became pregnant while taking Aripiprazole and had a miscarriage.	

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213378

Seq: 1

Gender: M

Reported: 14/11/2005

Weight: 0.00

Hospitalisation:

Onset Date: 15/10/2005

Age: 35Y

DOB:

Outcome: Death, maybe drug

10/11/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Patient committed suicide.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection			Intramuscular
Batch:	Started:	S TERM	Stopped: 15/10/2005
SODIUM VALPROATE (Suspected)		Reason:	
Batch:	Started:		Stopped:
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213465

Seq: 1

Gender: F

Reported: 15/11/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gestational diabetes		Patient experienced a drug exposure during pregnancy, the patient had a glucose tolerance test and was found to have gestational diabetes.	
Drug exposure during pregnancy			

Medicine Details:

Risperdal Consta (Suspected)		Reason:
Injection	75.0 Milligram	
Batch:	Started: 15/06/2005	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213544 **Seq:** 1 **Gender:** M
Reported: 17/11/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 08/06/2005 **DOB:** 21/12/1976
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient experienced akathisia. He had restless legs and arms.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 24/05/2005	Stopped: 09/06/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213584

Seq: 1

Gender: F

Reported: 18/11/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperthyroidism		Patient experienced thyrotoxicosis while on risperidone.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had been on Risperidone (microspheres) 25mg for 7 months. She had been on oral Risperidone for about 1 year before, but was non-compliant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213894

Seq: 1

Gender: F

Reported: 29/11/2005

Weight: 32.00

Hospitalisation:

Age: 10Y

Onset Date: 23/09/2005

DOB:

Outcome: Recovered

13/11/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	Abnormal involuntary movements - eg lip smacking, drooling , moving toes on withdrawal of Respidone	Slow withdrawl of Respidone and Aropax and then ceased.; Abnormal Movements observed in hospital but not medically treated
Drooling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	0.3 Milligram	5 times	Oral
Batch:	Started: 01/05/2003	Stopped: 07/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213894

Seq: 1

Gender: F

Reported: 29/11/2005

Weight: 32.00

Hospitalisation:

Age: 10Y

Onset Date: 23/09/2005

DOB:

Outcome: Recovered

13/11/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	0.3 Milligram	5 times	Oral
Batch:	Started: 01/05/2003	Stopped: 07/11/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 213908

Seq: 1

Gender: F

Reported: 30/11/2005

Weight: 0.00

Hospitalisation:

Age: 93Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Two days after commencing Risperidone the patient suffered a myocardial infarction and died. An X-ray showed pulmonary oedema "which was equal".	
Pulmonary oedema	Death		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
500.0 Microgram		Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214237 **Seq:** 1 **Gender:** F
Reported: 12/12/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 79
Onset Date: 15/03/2005 **DOB:** 25/10/1925
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Itchy rash arising in patches over limbs, trunk and neck, red spots, then vessicles (tiny) then crusted over. None resolved while on the Risperidone Consta, worse after each injection, improved towards end of fortnight.	Rash much improved by 29/11/05

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection 37.5 Milligram Daily Intramuscular	
Batch:	Started: 09/02/2005 Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
1.0 Milligram Daily Oral	
Batch:	Started: 20/01/2005 Stopped: 13/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214331

Seq: 1

Gender: U

Reported: 15/12/2005

Weight: 90.00

Hospitalisation:

Age: 36

Onset Date: 01/12/2005

DOB: 11/04/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Caused or prolonged inpatient hospitalisation	The patient experienced a stroke.	Risperdal Consta ceased.

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 23/11/2005	Stopped: 23/11/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increased blood pressure and obese.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214361

Seq: 1

Gender: F

Reported: 16/12/2005

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 07/04/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Patient experienced amenorrhea and high blood prolactin level.	Risperdal reduced from 4mg to 3mg.
Amenorrhoea			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
4.0 Milligram	Daily
Batch:	Started: 15/05/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2005	Prolactin	0 - 500	23/11/2005	2124	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214408
Reported: 19/12/2005

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 29/11/2005

Age: 87

DOB: 12/11/1918

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkalaemia		The patient experienced hyperkalaemia.	Sodium Polystyrene Sulphonate.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
MAGNESIUM NOS (Other drug)	Reason:
Batch:	Started: Stopped:
WARFARIN SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
AMLODIPINE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2005	Potassium		29/11/2005	6.7	
19/12/2005	Potassium		30/11/2005	4.9	
19/12/2005	Potassium		01/12/2005	3.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214408

Seq: 1

Gender: F

Reported: 19/12/2005

Weight: 0.00

Hospitalisation:

Age: 87

Onset Date: 29/11/2005

DOB: 12/11/1918

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

COLOXYL (Other drug)	Reason:
Batch:	Started: Stopped:
TRANSIDERM-NITRO (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
CALTRATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214408

Seq: 1

Gender: F

Reported: 19/12/2005

Weight: 0.00

Hospitalisation:

Age: 87

Onset Date: 29/11/2005

DOB: 12/11/1918

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

KEFLEX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
VALIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PANTOPRAZOLE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214546

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date:

DOB: 16/05/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia with suicidal and homicidal overtones.	
Homicidal ideation			
Suicidal ideation			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
150.0 Milligram	Daily
Batch:	Started: Stopped:
VALIUM (Suspected)	Reason:
5.0 Milligram	Daily
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
5.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214544 is the first sequence to this report and report 214545 is the second sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214561

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia and delirium. He suffered depression and agitation and wakes after sleeping only three hours, sleeping no more after that.	
Delirium			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
MIRTAZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214595 **Seq:** 1 **Gender:** F
Reported: 05/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 08/12/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Small for dates baby	Caused or prolonged inpatient hospitalisation	The patient's baby was small for his gestational age and he experienced mild respiratory distress.	IV antibiotics.
Respiratory distress	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	0
HALOPERIDOL (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214704
Reported: 09/01/2006
Hospitalisation:
Onset Date: 06/12/2005
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 29Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Pateint experienced acute anxiety, abdominal pain, and social isolation, he also experienced weight loss over the last few months, the patient attempted suicide by cutting his wrists.	Risperdal Consta was ceased.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:
LOVAN (Suspected)	Reason:
Batch:	Started: Stopped: Oral
Risperdal Consta (Suspected)	Reason:
Injection	25.0 Milligram Fortnightly Intramuscular
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

DRUG ADDICT, ALCOHOL



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214704

Seq: 1

Gender: M

Reported: 09/01/2006

Weight: 0.00

Hospitalisation:

Age: 29Y

Onset Date: 06/12/2005

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:
LOVAN (Suspected)	Reason:
Batch:	Started: Stopped: Oral
Risperdal Consta (Suspected)	Reason:
Injection 25.0 Milligram Fortnightly Intramuscular	Started: Stopped:

Laboratory Investigations:

Additional Information:

DRUG ADDICT, ALCOHOL



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214855

Seq: 1

Gender: F

Reported: 11/01/2006

Weight: 70.00

Hospitalisation:

Onset Date: 02/12/2005

Age: 40Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Incapacity/disability	The patient experienced dyskinesia. The symptoms were described as bilateral upper extremity tremor with "pill rolling", rising to crescendo at two weeks post-cessation of Risperidone.	Benzotropine Mesylate.
Drug withdrawal syndrome	Incapacity/disability		
Tremor	Incapacity/disability		

Medicine Details:

CIPRAMIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Abilify (Other drug)		Reason:	
Batch:	Started: 15/08/2005	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)		Reason: Depression	
100.0 Milligram			
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 20/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214905
Reported: 12/01/2006

Seq: 1

Gender: F
Weight: 87.00

Hospitalisation:

Onset Date: 17/02/2005
Outcome: Recovered

Age: 55
DOB: 26/11/1949

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Blood creatine phosphokinase incr Cold sweat Dyspnoea Hyperhidrosis		The patient experienced flu-like symptoms of fever, clammy skin, shortness of breath, shivers, stiff neck and upper respiratory tract congestion. She had increased tone of upper limbs, cogwheel rigidity, decreased reflexes and diaphoresis. Her creatine kinase increased.	Amisulpride ceased. IV fluids given.

Medicine Details:

ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:
FLUVOXAMINE MALEATE (Other drug)	Reason: Depression
Batch:	Started: Stopped: 0
TRIMETHOPRIM (Other drug)	Reason: Othr diseases of urinary tract
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2006	Creatine				Creatine kinase - 1283.

Additional Information:

PMH: Schizophreniform disorder with somatic delusions, bipolar disorder, intellectual disability, anxiety/panic attacks & hypercholesterolaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214905
Reported: 12/01/2006

Seq: 1

Gender: F
Weight: 87.00

Hospitalisation:

Onset Date: 17/02/2005
Outcome: Recovered

Age: 55
DOB: 26/11/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Hyporeflexia Influenza like illness Pyrexia			

Medicine Details:

MULTIVITAMINS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

PMH: Schizophreniform disorder with somatic delusions, bipolar disorder, intellectual disability, anxiety/panic attacks & hypercholesterolaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214921
Reported: 12/01/2006
Hospitalisation:
Onset Date: 19/02/2005
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 76
DOB: 19/08/1928
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation	Caused or prolonged inpatient hospitalisation	The patient experienced increasing confusion, decreased consciousness, poor oral intake, hyperglycaemia, clonus at the ankles, mild dehydration and inappropriate and disinhibited behaviour.	Risperidone and Temazepam withheld. Risperidone recommenced, then ceased.
Clonus	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OMEPRAZOLE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
TIOTROPIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
POLY-TEARS (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214921
Reported: 12/01/2006

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 19/02/2005

Age: 76

DOB: 19/08/1928

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dehydration	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Disinhibition	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THYROXINE SODIUM (Other drug)			Reason:		
Batch:		Started:		Stopped:	
SIMVASTATIN (Other drug)			Reason:		
Batch:		Started:		Stopped:	
CALTRATE (Other drug)			Reason:		
Batch:		Started:		Stopped:	
OSTELIN 1000 (Other drug)			Reason:		
Batch:		Started:		Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214921
Reported: 12/01/2006

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 19/02/2005

Age: 76

DOB: 19/08/1928

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PARACETAMOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CELECOXIB (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	2.0 Milligram	Daily	
Batch:	Started: 19/02/2005	Stopped: 20/03/2005	
TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligram	Daily	
		Oral	
Batch:	Started: L TERM	Stopped: 20/03/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 214950 **Seq:** 1 **Gender:** F
Reported: 13/01/2006 **Weight:** 50.00
Hospitalisation: Required a visit to the doctor **Age:** 16
Onset Date: 01/11/2005 **DOB:** 05/11/1988
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia Dysarthria Dystonia		The patient experienced alopecia, slurred speech and dystonia.	

Medicine Details:

RISPERDAL (Suspected)	Reason: Otr spec symp psychopathol nec
0.5 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215268 **Seq:** 1 **Gender:** F
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 88
Onset Date: 15/10/2005 **DOB:** 31/12/1916
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation	The patient developed a shuffling gait, had trouble stopping and starting, mask-like faces noted with 'chin shaking' and several weeks of worsening paranoia and delusions.	Sinemet.
Delusion	Caused or prolonged inpatient hospitalisation		
Masked facies	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CEFEPIME HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
DIABEX (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
SOMAC (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215268

Seq: 1

Gender: F

Reported: 24/01/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 88

Onset Date: 15/10/2005

DOB: 31/12/1916

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIGOXIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 15/10/2004	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215308

Seq: 1

Gender: F

Reported: 27/01/2006

Weight: 0.00

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety		The patient experienced increased anxiety, blurred vision, lethargy and rashes.	
Lethargy			
Rash			
Vision blurred			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Injection	Intramuscular
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215414 **Seq:** 1 **Gender:** F
Reported: 31/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 11/01/2006 **DOB:** 03/05/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	Patient developed dyskinesia.	
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped: 06/01/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215539

Seq: 1

Gender: F

Reported: 03/02/2006

Weight: 0.00

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Over a six month period patient experienced a 20kg weight gain.	

Medicine Details:

EPILIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215541

Seq: 1

Gender: F

Reported: 03/02/2006

Weight: 0.00

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced a 16kg weight gain.	Patient started a weight loss program and is now losing weight.

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Intramuscular
Batch:	Started: 15/03/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215901 **Seq:** 1 **Gender:** F
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: 04/03/2005 **DOB:** 22/04/1931
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	? EPSE secondary to Risperidone. ? Neuroleptic malignant syndrome and oversedation with background of dementia.	Withdrawal of therapy.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
OMEPRAZOLE (Other drug)	Reason:
Batch:	Started: Stopped:
TRIMETHOPRIM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215901

Seq: 1

Gender: F

Reported: 16/02/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 73

Onset Date: 04/03/2005

DOB: 22/04/1931

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

DIPHENOXYLATE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 04/03/2006	
MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/03/2005	
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2004	Stopped: 04/03/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215915
Reported: 16/02/2006
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 64Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Incapacity/disability	The patient reports scarcely being able to walk, constant dizziness and eating more than usual. Her physician reports that she experienced postural drop of 10-15 millimeters of mercury.	Risperidone dosage reduced.
Dizziness	Incapacity/disability		
Extrapyramidal disorder	Incapacity/disability		
Gait disturbance	Incapacity/disability		

Medicine Details:

SEROQUEL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215915

Seq: 1

Gender: F

Reported: 16/02/2006

Weight: 0.00

Hospitalisation:

Age: 64Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Increased appetite	Incapacity/disability		

Medicine Details:

SEROQUEL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215948 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 14/10/2004 **DOB:** 09/07/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed myocarditis, fever, hypotension, tachycardia, decreased oxygen saturation, increased troponin, increased LFT's, urine positive for myoglobin. ECHO global LV dysfunction.	Treated with Prednisone, Tritace, Carvedilol, Aldactone, Warfarin, Digoxin and reduced Risperidone gradually to 1.5mg/daily and Frusemide.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2004	Stopped: 30/09/2004	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 26/09/2004	0
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 27/09/2004	0
CLOZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 28/09/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2006	Echocardiogram				Echo: global LV dysfunction. EF about 25%.
16/02/2006	Electrocardiograph				ECG: nil conduction deficits.
16/02/2006	Troponin				Troponin - 0.38.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215948 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 14/10/2004 **DOB:** 09/07/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myoglobinuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 06/10/2004	0
RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 29/09/2004	0
CLOZAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/10/2004	Stopped: 04/10/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215948 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 14/10/2004 **DOB:** 09/07/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oxygen saturation decreased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2004	Stopped: 30/09/2004	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 26/09/2004	0
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 27/09/2004	0
CLOZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 28/09/2004	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 215948 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 14/10/2004 **DOB:** 09/07/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 06/10/2004	0
RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 29/09/2004	0
CLOZAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/10/2004	Stopped: 04/10/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216024 **Seq:** 1 **Gender:** M
Reported: 21/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38Y
Onset Date: 15/11/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Life threatening	The patient experienced a weight increase which "coincides with commencement of Risperidone". He was diagnosed with diabetes.	Metformin 500mg. Risperidone ceased.
Weight increased	Life threatening		

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Daily	
Batch:	Started: 23/03/2005	Stopped: 12/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/02/2006	Serum glucose				BSL of 30.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216209
Reported: 28/02/2006
Hospitalisation:
Onset Date: 11/07/2005
Outcome: Unknown

Seq: 1

Gender: F
Weight: 68.00
Age: 33
DOB: 16/06/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Life threatening	insomnia, agitated depression, headache, increased appetite, pseudo/hallucinations?Risperdal commenced at low dose 0.5 mg daily on about 9th May 2005 by Dr Angela Voita, upon the recommendation of a health worker at Logan clinic Brisbane, 6 months post partum, was the result of misdiagnosis of schizophrenia."Voices" reported and possibly compounded by writing errors from dyslexic psychologist, enforcing the incorrect diagnosis of "schizophrenia" 6 months postpartum.Idiosyncratic reaction ...	continued Risperdal , increased dose to 3 mg daily with Largactil, 25 mg tds, and Valium 5 mg bd/tds, prescribed by Brisbane Hospital staff; required Air transport to Malaysia as no past history available, with confusion in Royal Brisbane Hospital, caused by a dyslexic psychologists report in May 2005.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Capsule	3.0 Milligram Daily Oral
Batch: to be faxed	Started: 11/07/2005 Stopped: 25/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216209
Reported: 28/02/2006
Hospitalisation:
Onset Date: 11/07/2005
Outcome: Unknown

Seq: 1

Gender: F
Weight: 68.00
Age: 33
DOB: 16/06/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation	Life threatening	... of "hallucinations" may have been caused by Risperdal prescribed in depression, with insomnia, and aggitated depression, sleep deprivation and forced taking of Risperdal for misdiagnosed "schizophrenia", which was not in past history, and confused with depression symptoms	
Depression	Life threatening		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Capsule	3.0 Milligram	Daily	Oral
Batch: to be faxed	Started: 11/07/2005	Stopped: 25/07/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216209

Seq: 1

Gender: F

Reported: 28/02/2006

Weight: 68.00

Hospitalisation:

Age: 33

Onset Date: 11/07/2005

DOB: 16/06/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination	Life threatening		
Headache	Life threatening		
Increased appetite	Life threatening		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Capsule	3.0 Milligram	Daily	Oral
Batch: to be faxed	Started: 11/07/2005	Stopped: 25/07/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216402

Seq: 1

Gender: M

Reported: 10/03/2006

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 30/04/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Had severe hallucinations when antidepressant was added to treatment.	Antidepressant separated from risperidone.
Drug interaction			

Medicine Details:

ANTIDEPRESSANT NOS (Interaction)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Interaction)		Reason:	
	8.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216718
Reported: 28/03/2006

Seq: 1

Gender: F
Weight: 0.00
Age: 33Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Patient experienced a psychotic disorder, delusion, somnolence, nausea and vomiting.	Dose increased to 1mg twice daily. Risperdal discontinued. Switched to Aripiprazole 10mg.
Delusion	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216718

Seq: 1

Gender: F

Reported: 28/03/2006

Weight: 0.00

Hospitalisation:

Age: 33Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216768 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 17/07/2005 **DOB:**
Outcome: Recovered 01/09/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	Abnormal liver function.	Fluconazole ceased

Medicine Details:

LORAZEPAM (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:
SULFADOXINE (Other drug)	Reason: Other prophylactic procedures
Batch:	Started: Stopped:
NILSTAT (Other drug)	Reason: Moniliasis
Batch:	Started: Stopped:
PENICILLIN NOS (Other drug)	Reason: Syphilis, unspecified
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	ALT = SGPT	7-56	02/07/2005	33	
28/03/2006	ALT = SGPT	7-56	12/07/2005	90	
28/03/2006	ALT = SGPT	7-56	17/07/2005	73	
28/03/2006	ALT = SGPT	7-56	15/07/2005	73	
28/03/2006	ALT = SGPT	7-56	02/08/2005	86	
28/03/2006	ALT = SGPT	7-56	01/09/2005	26	
28/03/2006	ALT = SGPT	7-56	19/08/2005	51	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216768 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 17/07/2005 **DOB:**
Outcome: Recovered 01/09/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

Medication Details:		
METOCLOPRAMIDE HYDROCHLORIDE (Other drug)	Reason:	Nausea and vomiting
Batch:	Started:	Stopped:
TEMAZEPAM (Other drug)	Reason:	Specific disorders of sleep
Batch:	Started:	Stopped:
CENTRUM TABLETS (Other drug)	Reason:	
Batch:	Started:	Stopped:
TRIMETHOPRIM-SULFAMETHOXAZOLE (Suspected)	Reason:	Other prophylactic procedures
	1.0 Dose Unspecified	
Batch:	Started: 09/07/2005	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	ALT = SGPT	7-56	28/07/2005	72	
28/03/2006	ALT = SGPT	7-56	27/07/2005	90	
28/03/2006	Bilirubin	<17	02/07/2005	7	
28/03/2006	Bilirubin	<17	15/07/2005	10	
28/03/2006	Bilirubin	<17	17/07/2005	8	
28/03/2006	Bilirubin	<17	28/07/2005	9	
28/03/2006	Bilirubin	<17	19/08/2005	6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216768 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 17/07/2005 **DOB:**
Outcome: Recovered 01/09/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
2.0 Milligram Daily Oral	
Batch: Started: 01/06/2005 Stopped:	
ISONIAZID (Suspected)	Reason: Pulmonary tuberculosis
300.0 Milligram Daily Oral	
Batch: Started: 11/07/2005 Stopped: 12/07/2005	
RIFAMPICIN (Suspected)	Reason: Pulmonary tuberculosis
600.0 Milligram Daily Oral	
Batch: Started: 11/07/2005 Stopped: 12/07/2005	
ETHAMBUTOL HYDROCHLORIDE (Suspected)	Reason: Pulmonary tuberculosis
600.0 Milligram Daily Oral	
Batch: Started: 11/07/2005 Stopped: 28/07/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	Bilirubin	<17	04/09/2005	7	
28/03/2006	Bilirubin	<17	02/08/2005	9	
28/03/2006	Bilirubin	<17	22/07/2005	7	
28/03/2006	Bilirubin	<17	12/07/2005	8	
28/03/2006	SAP = ALP	30-120	02/07/2005	197	
28/03/2006	SAP = ALP	30-120	12/07/2005	510	
28/03/2006	SAP = ALP	30-120	15/07/2005	709	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216768 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 17/07/2005 **DOB:**
Outcome: Recovered 01/09/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

PYRAZINAMIDE (Suspected)	Reason: Pulmonary tuberculosis
1.0 Gram	Daily Oral
Batch:	Started: 11/07/2005 Stopped: 12/07/2005
PYRIDOXINE HYDROCHLORIDE (Suspected)	Reason: Other prophylactic procedures
25.0 Milligram	Daily Oral
Batch:	Started: 11/07/2005 Stopped: 12/07/2005
FLUCONAZOLE (Suspected)	Reason: Moniliasis
200.0 Milligram	Daily Oral
Batch:	Started: 16/07/2005 Stopped: 27/07/2005 0
RIFABUTIN (Suspected)	Reason: Otr&nos infec&parasit diseases
450.0 Milligram	Daily Oral
Batch:	Started: 13/07/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	SAP = ALP	30-120	17/07/2005	690	
28/03/2006	SAP = ALP	30-120	22/07/2005	1224	
28/03/2006	SAP = ALP	30-120	28/07/2005	961	
28/03/2006	SAP = ALP	30-120	02/08/2005	535	
28/03/2006	SAP = ALP	30-120	19/08/2005	143	
28/03/2006	SAP = ALP	30-120	04/09/2005	97	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216768

Seq: 1

Gender: M

Reported: 29/03/2006

Weight: 40.00

Hospitalisation: Admitted to hospital

Age: 34Y

Onset Date: 17/07/2005

DOB:

Outcome: Recovered

01/09/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

AZITHROMYCIN (Suspected)

Reason:

500.0 Milligram

Daily

Oral

Batch:

Started: 13/07/2005

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 216919

Seq: 1

Gender: F

Reported: 03/04/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 15/02/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Patient experienced hypotension both times after receiving the injections. The patient was flat on the floor as in fainting.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	2 times	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217083

Seq: 1

Gender: M

Reported: 06/04/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose fluctuation	Incapacity/disability	Blood glucose fluctuation.	Risperdal stopped.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217086 **Seq:** 1 **Gender:** F
Reported: 06/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 33
Onset Date: 01/01/2002 **DOB:** 24/05/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Caused or prolonged inpatient hospitalisation	Patient felt indifferent and felt frustrated. Slept all day/night, anxious, did not sleep, confused	Ceased medication. Returned to hospital for medication adjustment. Patient now on Abilify, Seroquel and Lithium.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: L TERM Stopped:
VALIUM (Suspected)	Reason: Anxiety neurosis
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:
HALOPERIDOL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217086 **Seq:** 1 **Gender:** F
Reported: 06/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 33
Onset Date: 01/01/2002 **DOB:** 24/05/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Frustration	Caused or prolonged inpatient hospitalisation		
Insomnia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected)	Reason:
Batch:	Started: Stopped:
LARGACTIL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217295

Seq: 1

Gender: F

Reported: 11/04/2006

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest		Patient experienced a "bordering" respiratory arrest.	

Medicine Details:

HALOPERIDOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
MIDAZOLAM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217388

Seq: 1

Gender: F

Reported: 18/04/2006

Weight: 60.00

Hospitalisation:

Age: 55

Onset Date: 30/01/2001

DOB: 23/02/1945

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced an epileptic fit.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	1 time	
Batch:	Started: 29/01/2001	Stopped: 30/01/2001	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217441

Seq: 1

Gender: F

Reported: 18/04/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced a weight gain of 15-20 kg.	Risperidone was reduced to 2mg daily in an effort to try to reduce the patient's weight, but this had not worked.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217442 **Seq:** 1 **Gender:** M
Reported: 18/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	The patient presented to hospital with chest pain, T-wave inversion and shortness of breath.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Electrocardiogram T wave inversion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRITACE (Other drug)		Reason:	
1.0 Dose Unspecified			
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2006	Echocardiogram				T-wave inversion.
18/04/2006	Troponin				On an unspecified date, Troponin was negative.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217484 **Seq:** 1 **Gender:** M
Reported: 19/04/2006 **Weight:** 95.00
Hospitalisation: Required a visit to the doctor **Age:** 39
Onset Date: 15/03/2004 **DOB:** 01/07/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Condition aggravated and drug-food interaction.	
Food interaction			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
1.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217487

Seq: 1

Gender: M

Reported: 19/04/2006

Weight: 0.00

Hospitalisation:

Age: 22Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Incorrect dose administered and severe akathisia.	Risperdal ceased.
Drug administration error			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection, powder for	75.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217490

Seq: 1

Gender: U

Reported: 19/04/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced an epileptic fit.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Epilepsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217494 **Seq:** 1 **Gender:** F
Reported: 19/04/2006 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 85
Onset Date: 23/03/2006 **DOB:** 19/12/1920
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Caused or prolonged inpatient hospitalisation	Patient developed type 2 diabetes. No PHx, FHx.	Risperidone was withdrawn on 24/03/2006.

Medicine Details:

ALDACTONE (Other drug)	Reason:
Batch:	Started: Stopped:
ASTRIX 100 (Other drug)	Reason:
Batch:	Started: Stopped:
CELEBREX (Other drug)	Reason:
Batch:	Started: Stopped:
CYANOCOBALAMIN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is also taking Ferro-Gradumet, Fosamax, Hydrocortisone, Kapanol, Lanoxin, Lasix, Lipitor, Metoprolol Tartrate, Mivicol, Meo-Mercazole, Neo-Cytamen, Mexium, Panamax, Tegretol, Tofranil, Valium, Vitamin E and Xalatan.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217494

Seq: 1

Gender: F

Reported: 19/04/2006

Weight: 60.00

Hospitalisation: Admitted to hospital

Age: 85

Onset Date: 23/03/2006

DOB: 19/12/1920

Outcome: Unrelated death

Causality: Causality possible

Reaction Details:

Medicine Details:

Medication Details:			
DAIVONEX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ENDEP (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ADVANTAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 30/06/2005	Stopped: 24/03/2006	

Laboratory Investigations:

Additional Information:

Patient is also taking Ferro-Gradumet, Fosamax, Hydrocortisone, Kapanol, Lanoxin, Lasix, Lipitor, Metoprolol Tartrate, Mivicol, Meo-Mercazole, Neo-Cytamen, Mexium, Panamax, Tegretol, Tofranil, Valium, Vitamin E and Xalatan.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 217904
Reported: 02/05/2006
Hospitalisation:
Onset Date: 15/01/2006
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 82
DOB: 14/02/1923
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		Patient developed Pancytopenia, hairy cell leukemia and decreased mental state.	Risperdal discontinued.
Hairy cell leukaemia			
Mental disorder			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Oral	
Batch:	Started:	Stopped:	03/02/2006 0
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
	Tablet	Oral	
Batch:	Started:	Stopped:	0
METFORMIN HYDROCHLORIDE (Suspected)		Reason:	
	Tablet	Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/05/2006	Bone marrow				Bone marrow aspirate showed hairy cell leukemia

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218071 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21Y
Onset Date: 14/01/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient present with tremor, increase tone, low grade fever, irritability, poor oral intake, CK 4672 on 15/1, decrease to 739 prior discharge.	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Batch:		Oral	
Started:		Stopped:	14/01/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218121 **Seq:** 1 **Gender:** M
Reported: 08/05/2006 **Weight:** 100.00
Hospitalisation: Admitted to hospital **Age:** 54
Onset Date: 17/03/2006 **DOB:** 11/11/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retroperitoneal fibrosis	Caused or prolonged inpatient hospitalisation	Patient developed idiopathic retroperitoneal fibrosis, identified on CT scan.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Risperidone is the only medication for previous 2 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218202 **Seq:** 1 **Gender:** M
Reported: 10/05/2006 **Weight:** 67.00
Hospitalisation: Admitted to hospital **Age:** 57Y
Onset Date: 24/04/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Pateint experienced seizure.	

Medicine Details:

TOPAMAX (Other drug)	Reason:
Batch:	Started: Stopped:
VALPRO (Other drug)	Reason:
Batch:	Started: Stopped:
LAMICTAL (Other drug)	Reason:
Batch:	Started: Stopped:
OROXINE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Convulsion.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218202

Seq: 1

Gender: M

Reported: 10/05/2006

Weight: 67.00

Hospitalisation: Admitted to hospital

Age: 57Y

Onset Date: 24/04/2006

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CELEBREX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 21/04/2006	Stopped: 24/04/2006	0

Laboratory Investigations:

Additional Information:

Medical history: Convulsion.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218222 **Seq:** 1 **Gender:** F
Reported: 10/05/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 71
Onset Date: 08/04/2006 **DOB:** 31/12/1934
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria	Life threatening	Urticaria, swelling of face, puffy eyes, itching following Risperdal Consta injection on 07/04/06. Reported mild but similar reaction following the two previous injections. On one occasion had swelling of tongue and difficulty swallowing.	
Dysphagia	Life threatening		
Eye oedema	Life threatening		
Pruritus	Life threatening		

Medicine Details:

CARDIZEM CD (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
DIAMICRON (Other drug)	Reason: Diabetes mellitus
Batch:	Started: Stopped:
SEREVENT ACCUHALER (Other drug)	Reason: Asthma
Batch:	Started: Stopped:
PANAMAX (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. History: Previous allergy to Risperdal. Poorly controlled diabetes mellitus and renal impairment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218222 **Seq:** 1 **Gender:** F
Reported: 10/05/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 71
Onset Date: 08/04/2006 **DOB:** 31/12/1934
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swelling face	Life threatening		
Swollen tongue	Life threatening		

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection, powder for	
Batch:	Started: 07/04/2006 Stopped:

Laboratory Investigations:

Additional Information:

Suspected drug is cert/rechallenge. History: Previous allergy to Risperdal. Poorly controlled diabetes mellitus and renal impairment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218262

Seq: 1

Gender: F

Reported: 12/05/2006

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 12/01/1982

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscular weakness		The patient experienced weak/trembling muscles, pain around the heart, shorthess of breath and headaches/migraines.	
Angina pectoris			
Dyspnoea			
Headache			
Migraine			

Medicine Details:

Abilify (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped: 07/04/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218466

Seq: 1

Gender: F

Reported: 18/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 27/04/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Caused or prolonged inpatient hospitalisation	Patient's prolactin levels were elevated to 2390 milliunits/L.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	5.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218502

Seq: 1

Gender: F

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 14

Onset Date: 02/05/2006

DOB: 17/12/1991

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Pateint developed galactorrhea.	

Medicine Details:

CABERGOLINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Aripiprazole (Other drug)		Reason: Unspecified psychosis	
Batch:	Started:	Stopped:	0
SEROQUEL (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 218503 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218502

Seq: 1

Gender: F

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 14

Onset Date: 02/05/2006

DOB: 17/12/1991

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

QUETIAPINE (Other drug)		Reason: Unspecified psychosis
Batch:	Started:	Stopped:
FLUTICASONE PROPIONATE (Other drug)		Reason: Asthma
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason:
Batch:	Started:	Stopped:
AMISULPRIDE (Suspected)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Report 218503 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218516 **Seq:** 1 **Gender:** M
Reported: 19/05/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 22
Onset Date: 01/04/2006 **DOB:** 04/07/1983
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhinitis		Patient developed rhinitis on Risperidone therapy.	Treated with Drixine.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 19/02/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rhinitis on Risperidone previously.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218745

Seq: 1

Gender: M

Reported: 29/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		It was reported that immediately after taking Risperidone, the patient experienced tardiv dyskinesia, pain in the pancreas, sexual disturbances, difficulties in concentration, a lot of mucus, left side of face paralysed, blurref vision, drowsy (sleedps 12 hours a day), redness behind left eye, welling of the eye lid, constipation, excessive thirst and weight gain.	Risperdal ceased.
Abdominal pain upper			
Constipation			
Eyelid oedema			

Medicine Details:

RISPERDAL (Suspected)	Reason: Explosive personality disorder
1.0 Milligram	Daily
Batch:	Started: 05/05/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218745

Seq: 1

Gender: M

Reported: 29/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ocular hyperaemia			
Somnolence			
Thirst			
Vision blurred			
Weight increased			

Medicine Details:

RISPERDAL (Suspected)	Reason: Explosive personality disorder
1.0 Milligram	Daily
Batch:	Started: 05/05/2006
	Stopped: 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218824

Seq: 1

Gender: M

Reported: 31/05/2006

Weight: 0.00

Hospitalisation:

Age: 80Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall Fall Cerebrovascular accident Orthostatic hypotension		Patient experienced postural hypotension and stroke, resulting in fall (hit his head), and a broken limb.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218873

Seq: 1

Gender: F

Reported: 02/06/2006

Weight: 0.00

Hospitalisation:

Onset Date: 30/04/2006

Age: 78

DOB: 22/07/1927

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation	Fall, confusion and galactorrhoea.	Ceased all meds except Epilim.
Confusional state	Caused or prolonged inpatient hospitalisation		
Galactorrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CALTRATE (Other drug)		Reason:	
Tablet	600.0 Milligram	Oral	
Batch:	Started:	Stopped:	
FLUPENTHIXOL DECANOATE (Other drug)		Reason:	
Injection	80.0 Milligram		
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
	5.0 Milligram		
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218873

Seq: 1

Gender: F

Reported: 02/06/2006

Weight: 0.00

Hospitalisation:

Age: 78

Onset Date: 30/04/2006

DOB: 22/07/1927

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
PROPANTHELINE BROMIDE (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
TRAMAL SR (Suspected)		Reason:	
Tablet, modified release	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 218973

Seq: 1

Gender: F

Reported: 06/06/2006

Weight: 64.00

Hospitalisation:

Age: 99u

Onset Date: 10/05/2006

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction. Severe extrapyramidal effects.	Risperdal ceased.
Extrapyramidal disorder			

Medicine Details:

RISPERDAL (Suspected)	Reason: Hallucinations
1.0 Milligram	Daily
Batch:	Started: Stopped: 16/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219079

Seq: 1

Gender: M

Reported: 09/06/2006

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 05/06/2006

DOB: 10/05/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Incapacity/disability	involuntary movement of jaw - tardive dyskinesia	will aim to reduce dose if clinical situation allows and/or change medication if possible

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	Fortnightly Intramuscular
Batch:	Started: 31/12/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219239
Reported: 19/06/2006
Hospitalisation:
Onset Date: 23/01/2006
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 53
DOB: 06/07/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erythema Eczema Lacrimation increased Periorbital oedema Rash		Generalised pink erythema, scaly crusty eczema (itchy), mainly front of body and face. Some periorbital oedema and rash over left face and eye, crusty, weeping left eye.	Patient given Prednisone orally from 03/02/06 until 06/02/06.

Medicine Details:

RAMIPRIL (Other drug)	Reason:
Batch:	Started: Stopped: 0
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped: 0
QUETIAPINE (Other drug)	Reason:
Batch:	Started: Stopped: Ongoing.
CALTRATE (Other drug)	Reason:
Batch:	Started: Stopped: Ongoing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had eczema in the past years which responded to Corticosteroid ointment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219239

Seq: 1

Gender: M

Reported: 19/06/2006

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date: 23/01/2006

DOB: 06/07/1952

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	Ongoing.
RISPERIDONE (Suspected)		Reason:	
Injection	50.0 Milligram	Fortnightly	
Batch:	Started: 23/08/2005	Stopped:	0

Laboratory Investigations:

Additional Information:

Patient has had eczema in the past years which responded to Corticosteroid ointment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219313 **Seq:** 1 **Gender:** M
Reported: 20/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31
Onset Date: 20/05/2005 **DOB:** 02/02/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tic	Caused or prolonged inpatient hospitalisation	Started with a tic and then contractions of the muscles been very painful, the twisting of the neck and head pushed backwards and locking of jaw 24 hours a day. Involuntary movements. Patient review at hospital - has dystonia.	
Dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM EC 500 (Other drug)		Reason:	
	500.0 Milligram		
Batch:	Started:	Stopped: 27/02/2006	
Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started: 20/05/2005	Stopped: 27/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219313 **Seq:** 1 **Gender:** M
Reported: 20/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31
Onset Date: 20/05/2005 **DOB:** 02/02/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation		
Jaw disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM EC 500 (Other drug)		Reason:	
	500.0 Milligram		
Batch:	Started:	Stopped: 27/02/2006	
Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	25.0 Milligram	Daily	Intramuscular
Batch:	Started: 20/05/2005	Stopped: 27/02/2006	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219320 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 47.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 15/04/2006 **DOB:** 24/02/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Patient had difficulty in swallowing, dribbling, stiffness, falls, staring, found collapsed on 07/05/06 and therapy regimen changed.	
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Drooling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Lexapro (Suspected)		Reason: Unspecified psychosis	
		Oral	
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.5 Milligram	Daily	Oral
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is a nursing home resident.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219320 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 47.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 15/04/2006 **DOB:** 24/02/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Staring	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Lexapro (Suspected)		Reason: Unspecified psychosis	
		Oral	
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet		3.5 Milligram	Daily Oral
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	

Laboratory Investigations:

Additional Information:

Patient is a nursing home resident.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219320 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 47.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 15/04/2006 **DOB:** 24/02/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Lexapro (Suspected)		Reason: Unspecified psychosis	
		Oral	
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet		3.5 Milligram	Daily Oral
Batch:	Started: 15/03/2006	Stopped: 07/05/2006	

Laboratory Investigations:

Additional Information:

Patient is a nursing home resident.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219564

Seq: 1

Gender: F

Reported: 29/06/2006

Weight: 94.00

Hospitalisation:

Age: 51

Onset Date: 28/06/2005

DOB: 08/08/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psoriasis		severe and extensive psoriasis see comments below	steroid and tar creams

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Injection	37.5 Milligram
	Fortnightly
	Intramuscular
Batch: shsk000	Started: 28/06/2005
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219718

Seq: 1

Gender: M

Reported: 05/07/2006

Weight: 0.00

Hospitalisation:

Age: 71

Onset Date: 15/05/2006

DOB: 01/06/1934

Outcome: Recovered

15/08/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	Patient experienced tardive dyskinesia characterised by tongue rolling and lip smacking.	Risperdal withdrawn and quetiapine fumarate initiated.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking citalopram and alcohol.U



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219768

Seq: 1

Gender: F

Reported: 06/07/2006

Weight: 50.00

Hospitalisation:

Onset Date: 05/06/2006

Age: 73

DOB: 11/03/1933

Outcome: Recovered

23/06/2006

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia.	Risperidone ceased.

Medicine Details:

DONEPEZIL HYDROCHLORIDE (Other drug)		Reason: Presenile dementia	
	5.0 Milligram		Oral
Batch:	Started:	Stopped:	
NICOTINE TRANSDERMAL PATCH (Other drug)		Reason:	
Patch, dermal	21.0 Milligram		Transdermal
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2006	Stopped: 06/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took Risperidone 1mg daily oral from 13/06/06 to 21/06/06. Had been on Risperidone 0.5mg for many years without any adverse effect.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219876 **Seq:** 1 **Gender:** F
Reported: 11/07/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 37
Onset Date: **DOB:** 14/11/1968
Outcome: Recovered 29/06/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason: Depression
Tablet	25.0 Milligram	Oral
Batch:	Started: 15/05/2006	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
Tablet	2.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 01/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2006	Prolactin				Prolactin - 3940 ml / U/L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 219971
Reported: 13/07/2006

Seq: 1

Gender: F
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall		Patient experienced a fall which resulted in a subdural hematoma.	
Subdural haematoma			

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220083

Seq: 1

Gender: F

Reported: 17/07/2006

Weight: 0.00

Hospitalisation:

Age: 58Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Patient experienced blood prolactin increased.	

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/07/2006	Prolactin	(25)			Prolactin = 4826 milliunits per liter. High range of (629).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220243

Seq: 1

Gender: F

Reported: 20/07/2006

Weight: 70.00

Hospitalisation:

Age: 93

Onset Date:

DOB: 12/02/1913

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Within 3 days of starting treatment, the patient experienced an excessive sedative effect and fell asleep for 3 days (virtually unconscious/excessively sleepy).	Patient stopped Risperdal for 1 week and then restarted on a reduced dose of 0.25mg every 2 days.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220324

Seq: 1

Gender: M

Reported: 24/07/2006

Weight: 0.00

Hospitalisation:

Onset Date: 24/03/2006

Age: 28

Outcome: Not yet recovered

DOB: 19/11/1977

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced abnormal liver function tests.	Ceased Risperdal Consta and Risperdal.

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	137.0 Milligram	Total	Intramuscular
Batch:	Started: 22/02/2006	Stopped: 20/03/2006	0
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 24/02/2006	Stopped: 26/03/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	ALT = SGPT		20/02/2006	45	
24/07/2006	ALT = SGPT		24/03/2006	168	
24/07/2006	ALT = SGPT		26/03/2006	206	
24/07/2006	ALT = SGPT		03/04/2006	140	
24/07/2006	ALT = SGPT		29/03/2006	160	
24/07/2006	Bilirubin		20/02/2006	20	
24/07/2006	Bilirubin		24/03/2006	56	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220324

Seq: 1

Gender: M

Reported: 24/07/2006

Weight: 0.00

Hospitalisation:

Onset Date: 24/03/2006

Age: 28

DOB: 19/11/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	137.0 Milligram	Total	Intramuscular
Batch:	Started: 22/02/2006	Stopped: 20/03/2006	0

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 24/02/2006	Stopped: 26/03/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	Bilirubin		29/03/2006	43	
24/07/2006	Bilirubin		03/04/2006	26	
24/07/2006	Bilirubin		26/03/2006	78	
24/07/2006	GGT = SGGT =		24/03/2006	260	
24/07/2006	GGT = SGGT =		26/03/2006	305	
24/07/2006	SAP = ALP		20/02/2006	68	
24/07/2006	SAP = ALP		24/03/2006	245	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220324

Seq: 1

Gender: M

Reported: 24/07/2006

Weight: 0.00

Hospitalisation:

Onset Date: 24/03/2006

Age: 28

Outcome: Not yet recovered

DOB: 19/11/1977

Causality: Causality possible

Reaction Details:

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified psychosis	
Injection	137.0 Milligram	Total	Intramuscular
Batch:	Started: 22/02/2006	Stopped: 20/03/2006	0

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 24/02/2006	Stopped: 26/03/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	SAP = ALP		26/03/2006	283	
24/07/2006	SAP = ALP		29/03/2006	220	
24/07/2006	SAP = ALP		03/04/2006	189	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220396 **Seq:** 1 **Gender:** F
Reported: 28/07/2006 **Weight:** 87.00
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Caused or prolonged inpatient hospitalisation	Patient experienced elevated Prolactin levels and probable microadenoma of the pituitary. She has gained weight.	Patient was referred to an Endocrinologist.
Pituitary tumour benign	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection, powder for	50.0 Milligram Alternate weeks Intramuscular
Batch:	Started: 15/12/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2006	Magnetic				MRI revealed probable microadenoma of the pituitary. Prolactin level of 6000 (units unspecified and normal values not provided). Serum prolactin level was reported as 6189 IU (normal values not reported).
28/07/2006	Prolactin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220611

Seq: 1

Gender: F

Reported: 07/08/2006

Weight: 0.00

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes and sexual dysfunction while receiving risperidone 4mg twice daily.	Dose of risperidone reduced to 3 mg twice daily, then switched to Abilify but could not tolerate the side effects, so risperidone was restarted.
Sexual dysfunction			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecifid affective psychosis	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220655

Seq: 1

Gender: F

Reported: 08/08/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia occurred initially with flupenthixol and then worsened with risperidone.	Risperdal discontinued, clozapine substituted.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
FLUPENTHIXOL DECANOATE (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220845

Seq: 1

Gender: M

Reported: 16/08/2006

Weight: 0.00

Hospitalisation:

Age: 82

Onset Date: 15/07/2006

DOB: 31/07/1923

Outcome: Death

06/08/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Within 23 days of being started on risperidone patient was dead - from stroke. Jerky movements of the arms. Sleepy during the daytime (impossible to wake a lot of the time). Missing meals because asleep. Not awake to take any fluids most of the time. Became weak in the legs and eventually unable to walk at all. Extreme loss of weight. Finally unable to swallow.	Nothing could be done. Patient had a stroke and could no longer swallow.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
	Oral
Batch:	Started: 15/07/2006 Stopped: 31/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 220972

Seq: 1

Gender: F

Reported: 23/08/2006

Weight: 0.00

Hospitalisation:

Age: 78

Onset Date: 15/04/2006

DOB: 11/08/1927

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia Akathisia Parkinsonism		Oral and truncal tardive dyskinesia, akathisia and parkinsonism.	Risperdal discontinued.

Medicine Details:

RISPERDAL (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	0.5 Milligram Daily Oral
Batch:	Started: 11/04/2006 Stopped: 09/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221145
Reported: 29/08/2006
Hospitalisation:
Onset Date: 03/08/2006
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 36Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue	Caused or prolonged inpatient hospitalisation	Tongue and lip swelling diagnosed as allergic reaction.	Risperdal withdrawn. hydrocortisone IV, Phenergan and loratidine oral.
Hypersensitivity	Caused or prolonged inpatient hospitalisation		
Lip swelling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)	Reason:		
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 03/08/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history and concurrent conditions included: depression, no illicit drug use. There was no airway compromise and no rash. The patient had previously taken risperidone quicklets and risperidone 2 mg tablets for some time with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221308 **Seq:** 1 **Gender:** M
Reported: 01/09/2006 **Weight:** 100.00
Hospitalisation: Required a visit to the doctor **Age:** 33
Onset Date: 15/07/2006 **DOB:** 24/08/1972
Outcome: Recovered 15/08/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Severe akathesia.	

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection, powder for	25.0 Milligram Daily Intramuscular
Batch:	Started: 15/12/2005 Stopped: 02/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has prior traumatic head iinjury, fronto/temporal area.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221315

Seq: 1

Gender: F

Reported: 04/09/2006

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 11/11/2005

DOB: 17/06/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain upper	Caused or prolonged inpatient hospitalisation	Patient admitted with stomach pains, constipation. Blood test showed raised glucose level of (18.9mmol/L) and High glucose and high ketones in urine.	Treated with Insulin.
Blood glucose increased	Caused or prolonged inpatient hospitalisation		
Constipation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/09/2006	Serum glucose				Glucose level (18.9mmol/L)

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221315

Seq: 1

Gender: F

Reported: 04/09/2006

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 11/11/2005

DOB: 17/06/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glycosuria	Caused or prolonged inpatient hospitalisation		
Ketonuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Tablet	1.0 Milligram
	Daily
	Oral
Batch:	Started: 15/03/2005
	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221323
Reported: 04/09/2006
Hospitalisation:
Onset Date: 15/05/2006
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 43
DOB: 16/04/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level above therapeutic	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MULTIVITAMINS (Other drug)		Reason:	
	1.0 Dose Unspecified		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 28/04/2006	Stopped:	
CLOMIPRAMINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/09/2006	Pharmacokinetics				Clozapine level 4.24, Norchlozapine 2.77 micromol/L 19/05/2006. (recommended level 1.1-1.3). Increased risk of seizure if more then 3micromol/L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221389

Seq: 1

Gender: F

Reported: 05/09/2006

Weight: 0.00

Hospitalisation:

Age: 83Y

Onset Date: 15/02/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Euphoric mood Amnesia Balance disorder		Euphoria, lost balance, amnesic since ceaseing Risperidone.	Risperidone ceased.

Medicine Details:

PLAVIX (Other drug)	Reason:
Batch:	Started: Stopped:
ZOLOFT (Other drug)	Reason:
Batch:	Started: Stopped:
NORMISON (Other drug)	Reason:
Batch:	Started: Stopped:
LOSEC (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221389

Seq: 1

Gender: F

Reported: 05/09/2006

Weight: 0.00

Hospitalisation:

Age: 83Y

Onset Date: 15/02/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIDROCAL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Depression	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started: 15/02/2006	Stopped: 15/03/2006	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221390

Seq: 1

Gender: M

Reported: 05/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2006

Age: 83Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Balance disorder	Caused or prolonged inpatient hospitalisation	Lost balance, collapsed in shower, low muscle ton, parkinsonism posture, vague and speech- dysarthria.	
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medication Details:		
CIPRAMIL (Other drug)	Reason:	Depression
Batch:	Started:	Stopped:
VERAPAMIL HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)	Reason:	Anxiety neurosis
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221390

Seq: 1

Gender: M

Reported: 05/09/2006

Weight: 0.00

Hospitalisation:

Age: 83Y

Onset Date: 15/07/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Hypotonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medication Details:		
CIPRAMIL (Other drug)	Reason:	Depression
Batch:	Started:	Stopped:
VERAPAMIL HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)	Reason:	Anxiety neurosis
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221491
Reported: 07/09/2006
Hospitalisation:
Onset Date: 02/08/2006
Outcome: Recovered

Seq: 1

Gender: M
Weight: 61.20
Age: 16
DOB: 19/07/1990
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration	Caused or prolonged inpatient hospitalisation	Oculogyric crisis after dose increased from 1.5mg to 1.5mg bd.	Decreased dose to 1mg daily
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 30/07/2006	Stopped: 03/08/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221563

Seq: 1

Gender: M

Reported: 12/09/2006

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 16/08/2006

DOB: 02/03/1961

Outcome: Death, maybe drug

16/08/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Sudden death	

Medicine Details:

Risperdal Consta (Suspected)

Reason:

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history of diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221585

Seq: 1

Gender: M

Reported: 13/09/2006

Weight: 0.00

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pituitary tumour benign		Pituitary adenoma and elevated prolactin levels.	
Blood prolactin increased			

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified schizophrenia

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221605

Seq: 1

Gender: F

Reported: 13/09/2006

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 23/08/2006

DOB: 31/07/1945

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Abnormal LFT's and severe EPSE.	Withdrew promethazine, Lipitor, olanzapine and risperidone. Small doses benztropine prn.
Extrapyramidal disorder			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:
Batch:	Started:	Stopped:
THYROXINE SODIUM (Other drug)		Reason:
Batch:	Started:	Stopped:
TEMAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
ALENDRONATE SODIUM (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221605

Seq: 1

Gender: F

Reported: 13/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 23/08/2006

Age: 61

Outcome: Not yet recovered

DOB: 31/07/1945

Causality: Causality possible

Reaction Details:

Medicine Details:

LIPITOR (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
PROMETHAZINE HYDROCHLORIDE (Suspected)		Reason:	
	25.0 Milligram	As necessary	Oral
Batch:	Started:	S TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221677

Seq: 1

Gender: F

Reported: 18/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 03/11/2005

Age: 76

DOB: 17/04/1929

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extrapyramidal disorder, neck stiffness, increased rigidity, decreasing mobility, shaking of arms, dysphagia, resting and essential tremor and cogwheel rigidity.	risperidone, sodium valproate, donepezil, diclofenac, oxazepam and temazepam all ceased. quetiapine commenced 25mg bd prn.
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SIMVASTATIN (Other drug)		Reason:	
20.0 Milligram			
Batch:	Started:	Stopped: 05/11/2005	
CALCITRIOL (Other drug)		Reason:	
250.0 Microgram Daily			
Batch:	Started:	L TERM Stopped:	
COLOXYL WITH SENNA (Other drug)		Reason: Constipation	
Tablet	2.0 Dose Unspecified Daily	Oral	
Batch:	Started:	L TERM Stopped:	
RISPERIDONE (Suspected)		Reason: Explosive personality disorder	
2.0 Milligram Daily			
Batch:	Started: 05/09/2005	Stopped: 03/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221677

Seq: 1

Gender: F

Reported: 18/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 03/11/2005

Age: 76

DOB: 17/04/1929

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason: Explosive personality disorder
	1.0 Gram	Daily
Batch:	Started:	Stopped:
DONEPEZIL HYDROCHLORIDE (Suspected)		Reason: Presenile dementia
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped: 12/11/2005
DICLOFENAC SODIUM (Suspected)		Reason: Osteoarthritis
	50.0 Milligram	Daily
Batch:	Started:	Stopped: 03/11/2005
OXAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec
Tablet	7.5 Milligram	Daily Oral
Batch:	Started: 05/09/2005	Stopped: 04/11/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221677

Seq: 1

Gender: F

Reported: 18/09/2006

Weight: 0.00

Hospitalisation:

Age: 76

Onset Date: 03/11/2005

DOB: 17/04/1929

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/11/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221735 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 22
Onset Date: 24/07/2006 **DOB:** 30/04/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Peripheral (pitting) oedema, subsequently complicated by cellulitis.	antibiotics and frusemide 40mg.
Cellulitis			

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: 03/07/2006 Stopped:
Risperdal Consta (Other drug)	Reason: Unspecified schizophrenia
37.5 Milligram	Daily
Batch:	Started: 28/06/2006 Stopped: 0
FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Obsessive compulsive neurosis
80.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
RISPERIDONE (Suspected)	Reason:
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 28/06/2006 Stopped: 04/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221907
Reported: 26/09/2006

Seq: 1

Gender: F

Weight: 69.00

Hospitalisation:

Onset Date: 03/08/2006

Age: 32

DOB: 04/04/1974

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Premature baby Foetal movements decreased		Baby born 6 weeks premature Each time she has her injection of Risperdal Consta she experiences decreased foetal movements.	

Medicine Details:

EPILIM (Suspected)		Reason:	
	3.3 Gram	Daily	
Batch:	Started:	Stopped:	0
Risperdal Consta (Suspected)		Reason:	
Injection, powder for	37.5 Milligram	Alternate weeks	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See report 221907 for reaction in baby



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221952

Seq: 1

Gender: M

Reported: 26/09/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation	Chest pain from a lower respiratory tract infection	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221955
Reported: 26/09/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/09/2006
Outcome: Recovered

Age: 23Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Febrile neutropenia	Caused or prolonged inpatient hospitalisation	Febrile neutropenia, lethargic, dizzy, hypotensive, flu-like symptoms.	Risperidone and sertraline were ceased, treated with granulocyte stimulating factor (GSF) and antibiotics.
Dizziness	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 24/08/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/09/2006	Neutrophils		30/08/2006	0.4	
26/09/2006	Platelets		30/08/2006	148	
26/09/2006	White blood cells		30/08/2006	2.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 221955
Reported: 26/09/2006

Seq: 1

Gender: F
Weight: 0.00
Age: 23Y

Hospitalisation:

Onset Date: 01/09/2006
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 24/08/2006	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222012

Seq: 1

Gender: M

Reported: 27/09/2006

Weight: 150.00

Hospitalisation:

Onset Date: 15/10/2005

Age: 39

DOB: 06/07/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus, increased appetite.	Diabetic medication
Increased appetite			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	1.7 Gram		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Schizoaffective disorder. smoker



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222045

Seq: 1

Gender: F

Reported: 28/09/2006

Weight: 0.00

Hospitalisation:

Age: 86

Onset Date:

DOB: 25/08/1920

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Worsening of heart failure and swelling of legs.	Risperidone cease. Frusemide started.
Oedema peripheral			

Medicine Details:

AVAPRO (Other drug)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 11/05/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Cardiac failure.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222301

Seq: 1

Gender: F

Reported: 10/10/2006

Weight: 0.00

Hospitalisation:

Age: 92Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia.	Reduced the dose of risperidone and introduced Cogentin.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tardive dyskinesia for several years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222331

Seq: 1

Gender: U

Reported: 10/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		Suspected pancytopenia.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222400

Seq: 1

Gender: M

Reported: 12/10/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Cerebrovascular accident	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222417
Reported: 12/10/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 27/09/2006

Age: 34

DOB: 03/06/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes, Risperdal 25mg increased to 37.5mg on 06/05/2006.	Commenced diabetic treatment, diet, Diamicon.
Therapy regimen changed			

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	1.0 Milligram		Oral
Batch:	Started:	Stopped:	
Aripiprazole (Other drug)		Reason:	
Tablet	15.0 Milligram		Oral
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SODIUM VALPROATE (Other drug)		Reason:	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Wt gain on Lithium carbonate, antipsychotics and valproate - but recent increase of risperidal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222417

Seq: 1

Gender: M

Reported: 12/10/2006

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 27/09/2006

DOB: 03/06/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

SIMVASTATIN (Other drug)			Reason:	
Tablet	10.0	Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:	
Risperdal Consta (Suspected)			Reason:	
Injection	37.5	Milligram	Fortnightly	Intramuscular
Batch:	Started: 06/05/2006		Stopped:	

Laboratory Investigations:

Additional Information:

Wt gain on Lithium carbonate, antipsychotics and valproate - but recent increase of risperidal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222534

Seq: 1

Gender: M

Reported: 18/10/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222579

Seq: 1

Gender: F

Reported: 19/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Caused or prolonged inpatient hospitalisation	Abnormal coordination, patient developed very severe uncoordinated movement. Unable to to coordinate to touch his finger, unable to walk	

Medicine Details:

RISPERDAL (Suspected)		Reason:		
Tablet	2.0 Milligram	1 time	Oral	
Batch:	Started:	Stopped:	0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222598

Seq: 1

Gender: F

Reported: 19/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Death	Parkinson's like effect. One week later she fell resulting in a lower and upper limb fracture. Died due to "domino like effects of health issues".	
Death	Death		
Fall	Death		

Medicine Details:

RISPERDAL (Other drug)		Reason:	
	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram		
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222631

Seq: 1

Gender: F

Reported: 23/10/2006

Weight: 70.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 29/03/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Incapacity/disability	Increased blood prolactin level	

Medicine Details:

RAMIPRIL (Other drug)		Reason: Essential benign hypertension	
	1.3 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:	0
EFEXOR-XR (Suspected)		Reason: Depression	
	375.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2006	Prolactin				3395

Additional Information:

Not yet recovered but recovering



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222653

Seq: 1

Gender: M

Reported: 24/10/2006

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 16/03/1976

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Incapacity/disability	Spasms of the flexor muscle of his forearms and akathisia	
Akathisia			

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Paranoia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222685

Seq: 1

Gender: F

Reported: 25/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cleft palate	Congenital anomaly / birth defect	Cleft Palate	
Cleft palate	Congenital anomaly / birth defect		
Drug exposure during pregnancy	Congenital anomaly / birth defect		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started:
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222838

Seq: 1

Gender: M

Reported: 01/11/2006

Weight: 166.00

Hospitalisation:

Age: 43Y

Onset Date: 20/10/2006

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation	Hepatic enzyme increased. 4x elevation in alkaline phosphatase, alanine aminotransferase and gamma-glutamyl transferase.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Intramuscular	
Batch:	Started: 17/10/2006	Stopped:	0
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	Oral
Batch:	Started: 11/10/2006	Stopped:	20/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222841

Seq: 1

Gender: M

Reported: 01/11/2006

Weight: 100.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual acuity reduced	Incapacity/disability	developed myopia and decreased visual acuity	
Myopia	Incapacity/disability		

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222910
Reported: 06/11/2006
Hospitalisation:
Onset Date: 06/10/2006
Outcome: Unknown

Seq: 1

Gender: F
Weight:
Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Apnoea	Caused or prolonged inpatient hospitalisation	Neonate with possible drug withdrawal (48 hrs of increased apnoea, myoclonic jerks and jitteriness.	Transferred to another hospital
Drug withdrawal syndrome neonate	Caused or prolonged inpatient hospitalisation		
Feeling jittery	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222910

Seq: 1

Gender: F

Reported: 06/11/2006

Weight:

Hospitalisation:

Age: 99U

Onset Date: 06/10/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 222980 **Seq:** 1 **Gender:** M
Reported: 09/11/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 17Y
Onset Date: 15/08/2006 **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation	Developed headaches and found to have a blockage in the cerebrospinal fluid system. Intracranial hypertension.	
Intracranial pressure increased			

Medicine Details:

RISPERDAL (Suspected)	Reason: Obsessive compulsive neurosis
1.0 Milligram	1 time Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223104

Seq: 1

Gender: M

Reported: 14/11/2006

Weight: 73.00

Hospitalisation:

Age: 52

Onset Date: 20/10/2006

DOB: 27/09/1954

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevated blood prolactin levels	
Intentional drug misuse			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	75.0 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2006	Prolactin		20/10/2006	1367	

Additional Information:

History of schizophrenia and "hypogonadal failure"



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223329 **Seq:** 1 **Gender:** M
Reported: 17/11/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 26
Onset Date: 15/04/2006 **DOB:** 18/07/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Generalised pruritis - scratching and pustules.	Ceased Risperdal.

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection, powder for	300.0 Milligram Daily Intravenous
Batch:	Started: 15/08/2005 Stopped: 15/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223701

Seq: 1

Gender: F

Reported: 01/12/2006

Weight: 0.00

Hospitalisation:

Age: 57Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		tardive dyskinesia involving mouth and tongue	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223785

Seq: 1

Gender: F

Reported: 05/12/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		blood prolactin level increased	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223787

Seq: 1

Gender: M

Reported: 05/12/2006

Weight: 101.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 25/04/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased	Life threatening	Baseline LFT's were normal. 2 days into admission, oral risperidone was commenced, with the depot also given 6 days after. 10 days after admission, LFT's had increased dramatically.	Risperidone, quetiapine and chlorpromazine ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	25.0 Milligram	1 time	
Batch:	Started: 17/10/2006	Stopped: 20/10/2006	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason: Otr spec symp psychopathol nec	
	100.0 Milligram	As necessary	
Batch:	Started: 10/10/2006	Stopped: 20/10/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 11/10/2006	Stopped: 20/10/2006	
QUETIAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 20/10/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2006	ALT = SGPT		20/10/2006	ALTx30	
05/12/2006	GGT = SGGT =		20/10/2006	GGT x 30	
05/12/2006	SAP = ALP		20/10/2006	Alk Phos x 4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223849

Seq: 1

Gender: F

Reported: 06/12/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		weight increased	

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified schizophrenia

Batch:

Started:

Stopped:

discontinued

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

medical history : multiple sclerosis



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223853

Seq: 1

Gender: M

Reported: 06/12/2006

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 14/06/1951

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide		completed suicide	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223890

Seq: 1

Gender: F

Reported: 07/12/2006

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 12/10/1971

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Incapacity/disability	Breakthrough positive symptoms including hallucinations, usually 12 days after injections	
Delusion	Incapacity/disability		
Hallucination	Incapacity/disability		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	50.0 Milligram Intramuscular
Batch:	Started: 24/10/2005 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient uses cannabis, is a non-smoker, non alcohol drinker



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223928

Seq: 1

Gender: F

Reported: 08/12/2006

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 15/05/2006

DOB: 27/07/1973

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		increased blood prolactin and amenorrhoea	
Amenorrhoea			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 15/12/2005	Stopped: 11/08/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/12/2006	Prolactin		22/05/2006	1910	
08/12/2006	Prolactin		12/07/2006	3528	
08/12/2006	Prolactin		20/10/2006	2968	
08/12/2006	Prolactin		29/11/2006	1870	

Additional Information:

Prolactin coming down



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223962 **Seq:** 1 **Gender:** M
Reported: 01/12/2006 **Weight:** 100.00
Hospitalisation: Required a visit to the doctor **Age:** 39
Onset Date: 12/09/2006 **DOB:** 27/06/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertriglyceridaemia		Severe hypertriglyceridaemia temporally associated with conversion from oral risperidone (poor compliance) to depot risperidone.	

Medicine Details:

Risperdal Quicklet (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Tablet 1.5 Gram	Oral
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
15.0 Milligram	
Batch:	Started: Stopped:
RANITIDINE (Other drug)	Reason:
300.0 Milligram	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	Other data				Other cases of triglycerides not demonstrated no significant alcohol intake. (N) TFT HbA1c 7st. Pre-depot total chol: 6.9 post-depot total chol: 21.1 Triglyceride: 92.0 (@RBH) trig: 9.2

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223962

Seq: 1

Gender: M

Reported: 01/12/2006

Weight: 100.00

Hospitalisation: Required a visit to the doctor

Age: 39

Onset Date: 12/09/2006

DOB: 27/06/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

75.0 Milligram

Weekly

Batch:

Started: 15/01/2006

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 223965

Seq: 1

Gender: M

Reported: 11/12/2006

Weight: 0.00

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		weight increase, 30 kg in 8 months	dose reduced to every 3 weeks
Fatigue			
Loss of libido			
Sedation	Incapacity/disability		

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection		Fortnightly	Intramuscular
Batch:	Started: 15/04/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224127
Reported: 15/12/2006

Seq: 1

Gender: M

Weight: 49.00

Hospitalisation:

Onset Date: 09/12/2006

Age: 13

DOB: 27/12/1992

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		acute dystonic reaction	Benztropine 2mg IM and then regular benztropine 1mg orally since as well as reduction in dose

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 20/11/2006	Stopped: 08/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 07/12/2006	Stopped: 09/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 08/12/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2006	Other data				genetic testing for CYP2D6 phenotyping maybe done

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224201 **Seq:** 1 **Gender:** M
Reported: 19/12/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 70Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Cardiac arrest.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prior to the start of the aripiprazole therapy, the patient was admitted to the hospital while receiving risperidone. He was then switched to aripiprazole 10mg, and within 24 hours had experienced cardiac arrest. Medical history: included cardiovascular disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224231 **Seq:** 1 **Gender:** F
Reported: 20/12/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 18Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis	Caused or prolonged inpatient hospitalisation	Choreoathetosis, weight increased, dysphagia, tic. swallowing difficulty described as if there were 1000 earthworms moving. Also gained 15-20 kg.	Patient taken off risperidone and switched to aripiprazole.
Dysphagia	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug)	Reason:
Batch:	Started: Stopped:
TETRABENAZINE (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Other drug)	Reason:
Batch:	Started: Stopped:
Lexapro (Other drug)	Reason:
Batch:	10.0 Milligram Daily Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

(CERT: RECHALL). Yet to exclude other causes such as bulber nerve problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224231 **Seq:** 1

Reported: 20/12/2006

Hospitalisation: Admitted to hospital

Onset Date:

Outcome: Not yet recovered

Gender: F

Weight: 0.00

Age: 18Y

DOB:

Causality: Causality certain

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason:

Tablet

2.0 Milligram

Daily

Oral

Batch:

Started: 15/05/2005

Stopped: 08/12/2006 0

Laboratory Investigations:

Additional Information:

(CERT: RECHALL). Yet to exclude other causes such as bulber nerve problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224494 **Seq:** 1 **Gender:** M
Reported: 09/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 27/12/2006 **DOB:** 05/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	On day after the third injections of risperidone, the subject experienced a relapse of psychosis with agitation, prolonged QTc interval, elevated creatine phosphokinase of 10,000, (troponin I normal) and an injured tendon.(self-injury)	risperidone LAI discontinued
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2007	Creatine		02/01/2007	1465	
09/01/2007	Creatine		27/12/2006	10000	
09/01/2007	Creatine		01/02/2007	1465	
09/01/2007	QT interval		27/12/2006	491	
09/01/2007	QT interval		28/12/2006	471	
09/01/2007	QT interval		09/02/2007	451	
09/01/2007	Troponin		27/12/2006	normal	

Additional Information:

The subject claimed to be having about 2 grams of marijuana daily for three weeks prior to Christmas. Recovered from most reactions but still recovering from the psychotic episode.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224494 **Seq:** 1 **Gender:** M
Reported: 09/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 27/12/2006 **DOB:** 05/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation		
Self injurious behaviour	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2007	Troponin		31/12/2006	<0.015	

Additional Information:

The subject claimed to be having about 2 grams of marijuana daily for three weeks prior to Christmas. Recovered from most reactions but still recovering from the psychotic episode.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224494 **Seq:** 1 **Gender:** M
Reported: 09/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 27/12/2006 **DOB:** 05/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tendon injury	Admitted to Hospital		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped: 0

Laboratory Investigations:

Additional Information:

The subject claimed to be having about 2 grams of marijuana daily for three weeks prior to Christmas. Recovered from most reactions but still recovering from the psychotic episode.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224510 **Seq:** 1 **Gender:** M
Reported: 10/01/2007 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 34Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Suicidal ideation, depression, insomnia, thinking abnormal, anger.	
Anger	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection, powder for	37.5 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224510

Seq: 1

Gender: M

Reported: 10/01/2007

Weight: 0.00

Hospitalisation: Hospitalisation prolonged

Age: 34Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection, powder for	37.5 Milligram	Daily	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224511

Seq: 1

Gender: F

Reported: 10/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 24/11/2006

Age: 44

DOB: 24/01/1962

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Incorrect dose administered	Death	Given more than recommended dose of Risperdal Consta IM.	NA
Sudden death	Death	On an unknown date, while on risperidone and risperidone long-acting injection, the patient "died suddenly in the hospital car park". The reporter stated, "Autopsy so far showed no cause of death, toxicology results still unknown."	
Abnormal behaviour	Death		
Prescribed overdose	Death		
Sedation	Death		

Medicine Details:

SOLIAN (Other drug)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	Stopped:	0
DOSTINEX (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	100.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 15/05/2005	Stopped:	0
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
	100.0 Milligram	Alternate weeks	Oral
Batch:	Started: L TERM	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 224876

Seq: 1

Gender: F

Reported: 19/01/2007

Weight: 0.00

Hospitalisation:

Age: 18Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Patient had trouble swallowing and chewing.	Drug discontinued, started Escitalopram oxalate
Mastication disorder	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Batch:	Started:	Stopped: 08/12/2006	
TETRABENAZINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started: 01/08/2006	Stopped: 07/12/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225084

Seq: 1

Gender: F

Reported: 25/01/2007

Weight: 90.00

Hospitalisation:

Age: 47

Onset Date: 15/10/2006

DOB: 26/07/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle injury		Rubbery muscle at injection site. Blood sometimes comes out when injecting.	Event required intervention to prevent permanent damage. The plan is to medically review with the intention of changing to the Risperdal oral formulation, however there is difficulty with compliance.
Injection site haemorrhage			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Occassional use of marijuana.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225120 **Seq:** 1 **Gender:** M
Reported: 29/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 67Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia Irritability		diet refusal	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225306

Seq: 1

Gender: F

Reported: 02/02/2007

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 20/01/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hirsutism Polycystic ovaries Amenorrhoea Blood testosterone increased Breast enlargement Dizziness Galactorrhoea Menstruation irregular Psychotic disorder Rash pruritic Skin odour abnormal		excessive facial and body hair polycystic ovary syndrome	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Batch:	Started:	L TERM	Stopped: 0
EFEXOR (Suspected)		Reason:	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225306

Seq: 1

Gender: F

Reported: 02/02/2007

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 20/01/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Batch:	Started:	L TERM	Stopped: 0
EFEXOR (Suspected)		Reason:	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225382 **Seq:** 1 **Gender:** M
Reported: 02/02/2007 **Weight:** 95.00
Hospitalisation: Required a visit to the doctor **Age:** 21
Onset Date: 04/01/2007 **DOB:** 18/11/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Development of oro- buccal dyskinesia-low grade. Grade low- noticed by patient & girlfriend release phenoma present.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)		Reason:	
Batch:	Started:	Stopped: 0	
Abilify (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past exposure to other antipsychotics-risperidone, amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225646

Seq: 1

Gender: F

Reported: 08/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 29/07/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred		After about 18months, blurred vision, excess salivation, 50% vision lost in right eye.	
Salivary hypersecretion			

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified psychosis

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225669
Reported: 12/02/2007

Seq: 1

Gender: F
Weight: 80.00

Hospitalisation:

Onset Date: 15/11/2006
Outcome: Unknown

Age: 41Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Schizophrenia		Breakthrough psychotic symptoms medically significant hyperprolactinaemia and galactorrhoea.	
Drug ineffective		Breakthrough psychotic symptoms after several months	
Hyperprolactinaemia		medically significant hyperprolactinaemia	
Galactorrhoea		soon after starting	

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 15/06/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/02/2007	Prolactin	50-570	24/01/2007	2820	
12/02/2007	Prolactin	50-570	25/01/2007	2820	

Additional Information:

No alcohol use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225729 **Seq:** 1 **Gender:** U
Reported: 13/02/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 26
Onset Date: 15/11/2006 **DOB:** 28/01/1980
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Migraine with aura		The patient was treated with an unknown dose of risperidone long-acting injection (microspheres, intramuscular) initiated in Nov-2006, having been on oral risperidone for 6 months prior to the adverse event. 5 hours following the first dose of risperidone long-acting injection and to lesser extent subsequent injections, the patient experienced frontal occipital migraine headache with aura, muscle tremors, left eye droop, and general fatigue.	
Eyelid ptosis			

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Fortnightly Intramuscular
Batch:	Started: 01/11/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cert:rechall



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225729 **Seq:** 1 **Gender:** U
Reported: 13/02/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 26
Onset Date: 15/11/2006 **DOB:** 28/01/1980
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue Tremor			

Medicine Details:

Risperdal Consta (Suspected)	Reason:
Injection	Fortnightly Intramuscular
Batch:	Started: 01/11/2006 Stopped: 0

Laboratory Investigations:

Additional Information:

Cert:rechall



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225843

Seq: 1

Gender: F

Reported: 14/02/2007

Weight: 0.00

Hospitalisation: Required a visit to the doctor

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Elevated prolactin levels;no visible side effects	Risperidone discontinued
Prescribed overdose			

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	75.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2007	Prolactin				Prolactin levels increased from 1100 on 50mg risperidone and 6000 on 75mg.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225869

Seq: 1

Gender: F

Reported: 15/02/2007

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date: 22/01/2007

DOB: 09/07/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extraagramidal symptom, sweating, parkinsonism, rigidity and poor mobility.	Given bentropine.
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:
Batch:	Started:	Stopped:
NEXIUM (Other drug)		Reason:
Batch:	Started:	Stopped:
ACTOS (Other drug)		Reason:
Batch:	Started:	Stopped:
GLICLAZIDE (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of weight gain, drooling, slurred speech, movement problems with risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225869

Seq: 1

Gender: F

Reported: 15/02/2007

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date: 22/01/2007

DOB: 09/07/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation		
Parkinsonism	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/01/2007	
RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 23/01/2007	

Laboratory Investigations:

Additional Information:

History of weight gain, drooling, slurred speech, movement problems with risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225970 **Seq:** 1 **Gender:** F
Reported: 20/02/2007 **Weight:** 66.00
Hospitalisation: Required a visit to the doctor **Age:** 36
Onset Date: 01/11/2006 **DOB:** 15/10/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drop attacks		Patient has 2-3 drop attacks with altered consciousness per day. Possible secondary generalised seizure, absences.	Drug discontinued.
Partial seizures with secondary generalisation			
Simple partial seizures			

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
PAXAM (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Other drug)	Reason:
Batch:	Started: Stopped:
Risperdal Consta (Suspected)	Reason:
Batch:	Started: 15/08/2006 Stopped: 01/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

+VE DECHALLENGE. Seizures disappeared when drug discontinued.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 225995

Seq: 1

Gender: M

Reported: 21/02/2007

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date: 18/01/2007

DOB: 27/09/1954

Outcome: Unrelated death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	death	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	75.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is morbidly obese.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226047 **Seq:** 1 **Gender:** F
Reported: 22/02/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 03/12/2006 **DOB:** 02/03/1931
Outcome: Recovered 05/12/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Patient admitted with delirium, fractured right wrist from fall, orthostatic hypotension and myoclonus.	Risperidone ceased.
Fall	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PERINDOPRIL (Other drug)		Reason:	
Tablet	5.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ALLOPURINOL (Other drug)		Reason:	
Tablet	100.0 Milligram	Oral	
Batch:	Started:	Stopped:	
MELOXICAM (Other drug)		Reason:	
Tablet	7.5 Milligram	Oral	
Batch:	Started:	Stopped:	
RALOXIFENE (Other drug)		Reason:	
Tablet	60.0 Milligram	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226047 **Seq:** 1 **Gender:** F
Reported: 22/02/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 03/12/2006 **DOB:** 02/03/1931
Outcome: Recovered 05/12/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Tablet	100.0 Milligram	Oral	
Batch:	Started:	Stopped:	
FRUSEMIDE (Other drug)		Reason:	
Tablet	40.0 Milligram	Oral	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	03/12/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226068

Seq: 1

Gender: F

Reported: 23/02/2007

Weight: 0.00

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		myocardial infarction	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	50.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226206
Reported: 28/02/2007

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 21/12/2006

Age: 57

DOB: 29/04/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Patient had 3 episodes of bilateral lower leg and ankle oedema.	Initially on Subutex changed to Suboxone. Suboxone ceased.

Medicine Details:

MAGMIN (Other drug)	Reason:
Batch:	Started: Stopped:
VALTREX (Other drug)	Reason:
Batch:	Started: Stopped:
GABAPENTIN (Other drug)	Reason: Pain
Batch:	Started: Stopped:
LOVAN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2007	Cortisol (serum)				Cortisol = 33mmol/L.
28/02/2007	Other data				CT and MRI scans subsequently normal.
28/02/2007	Thyroxine				T4 =7pmol/L.

Additional Information:

Started Subutex on 12/12/06, changed to Suboxone 4mg on 20/12/06 - developed ankle oedema by 21/12/06. Ceased Suboxone on 21/12/06. Ankle oedema on the 24/12/06 plus risperidone ceased by 26/12/06. Recommended Subutex again - 27/12/06 and ceased on 08/01/07 ankle oedema - methadone and risperidone on 11/01/07.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226206
Reported: 28/02/2007

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 21/12/2006

Age: 57

DOB: 29/04/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ROXITHROMYCIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Suboxone (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 20/12/2006	Stopped: 21/12/2006	0
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 26/12/2006	0

Laboratory Investigations:

Additional Information:

Started Subutex on 12/12/06, changed to Suboxone 4mg on 20/12/06 - developed ankle oedema by 21/12/06. Ceased Suboxone on 21/12/06. Ankle oedema on the 24/12/06 plus risperidone ceased by 26/12/06. Recommended Subutex again - 27/12/06 and ceased on 08/01/07 ankle oedema - methadone and risperidone on 11/01/07.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226233

Seq: 1

Gender: M

Reported: 01/03/2007

Weight: 0.00

Hospitalisation:

Age: 10Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of nearly 3 stone and tiredness in the morning (cannot stay away at school).	
Fatigue			

Medicine Details:

RISPERDAL (Suspected)		Reason: Other atyp forms schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226372

Seq: 1

Gender: F

Reported: 06/03/2007

Weight: 68.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 02/10/1985

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		hyperprolactineamia ammenorheoa	
Amenorrhoea			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Fortnightly	Intramuscular
Batch:	Started: 22/06/2006	Stopped: 01/03/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/03/2007	Other data				patient weight 68kg and height 158cm
06/03/2007	Prolactin		16/02/2007	4089 ml U/L	

Additional Information:

patient is a smoker and drinks alcohol



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226469

Seq: 1

Gender: F

Reported: 08/03/2007

Weight: 0.00

Hospitalisation:

Age: 41Y

Onset Date: 15/11/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia	Caused or prolonged inpatient hospitalisation	Hyperprolactinaemia and galactorrhoea.	
Galactorrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)	Reason: Unspecified schizophrenia
Injection	37.5 Milligram Fortnightly Intramuscular
Batch:	Started: Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226562 **Seq:** 1 **Gender:** M
Reported: 13/03/2007 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 54Y
Onset Date: 24/01/2007 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Patient had acute urinary retention on the background of mild prostatomegaly.	Panadeine forte and ibuprofen given. Catheter installed. Risperidone ceased.

Medicine Details:

ZYPREXA (Other drug)		Reason: Otr spec symp psychopathol nec	
	5.0 Milligram	Daily	
Batch:	Started: 23/01/2007	Stopped:	0
RISPERDAL (Suspected)		Reason: Unspecified neurosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 23/01/2007	Stopped:	24/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: mild enlarged prostate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226653

Seq: 1

Gender: F

Reported: 15/03/2007

Weight: 0.00

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/03/2007	Prolactin				The maximum prolactin level reading was around 3000. After dosage reduction the levels reduced to around 1500

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226793
Reported: 26/09/2006

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 07/10/2006

Age: 32

DOB: 04/04/1974

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Premature baby Drug withdrawal syndrome neonate Feeling jittery Myoclonus Sepsis		Premature baby (6 weeks early) who on day 7 changed abruptly with irritability, recurrent myoclonic jerks and jitteriness. Consistent with a drug withdrawal syndrome and also signs of sepsis	

Medicine Details:

EPILIM (Other drug)		Reason:	
	3.3 Gram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	Oral
Batch:	Started: 28/06/2006	Stopped: 28/08/2006	
Risperdal Consta (Suspected)		Reason:	
Injection, powder for	37.5 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 28/06/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See report 221907 for reaction in mother



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226810

Seq: 1

Gender: F

Reported: 21/03/2007

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Patient experienced galactorrhea.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/03/2007	Creatine kinase		17/01/2007	Normal	
21/03/2007	Creatine		17/01/2007	Normal	
21/03/2007	Echocardiogram		17/01/2007	Normal	
21/03/2007	Electrocardiograph		17/01/2007	Normal	
21/03/2007	Neutrophils				01/2007 slight rise.
21/03/2007	Troponin		17/01/2007	Normal	
21/03/2007	White blood cells				Normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 226875

Seq: 1

Gender: F

Reported: 22/03/2007

Weight: 0.00

Hospitalisation:

Age: 80Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia		asthenia	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227225

Seq: 1

Gender: M

Reported: 02/04/2007

Weight: 78.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 17/10/1983

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased			

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2007	Prolactin				801 IU/L

Additional Information:

At time of report no evidence of lactation or breast development



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227229

Seq: 1

Gender: M

Reported: 02/04/2007

Weight: 84.50

Hospitalisation:

Age: 20

Onset Date:

DOB: 22/03/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		blood prolactin increased to 1560 IU/L	

Medicine Details:

Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
Injection	37.5 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2007	Prolactin				1560 IU/L

Additional Information:

At time of reporting there was no breast development or lactation



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227344 **Seq:** 1 **Gender:** M
Reported: 04/04/2007 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 30Y
Onset Date: 12/11/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand Mal Convulsion: risperidone microspheres , intramuscular commenced on 5 Nov 2006, every 2 weeks, Within days of his first injection the patient experianced grand mal fits. Has had 14 GM fits in 3 months . 12 of these have been in the first week after his injection, and only 2 have been in the second week . Also in only 2 of the first weeks after injection has he NOT had a fit . After first injection "psychosis+++" 10 Nov 2006 After fourth injection ...	risperidone injections stopped

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 05/11/2006	Stopped:	02/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227344 **Seq:** 1 **Gender:** M
Reported: 04/04/2007 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 30Y
Onset Date: 12/11/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		... "behavioural disturbance ++" last injection 02 Feb 2007, fits on Feb3,4,5,11,12,13 Now unmedicated	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	25.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 05/11/2006	Stopped:	02/02/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227649

Seq: 1

Gender: F

Reported: 17/04/2007

Weight: 0.00

Hospitalisation:

Age: 34Y

Onset Date: 15/12/2007

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		she was not able to do everyday things like driving	
Depressed mood			
Feeling abnormal			
Suicidal ideation			

Medicine Details:

Risperdal Quicklet (Suspected)		Reason:	
	2.0 Milligram	Daily	Oral
Batch: 6LG0195X 08/08	Started: 24/12/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227654
Reported: 17/04/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose Constipation Depressed mood Pain in extremity Suicidal ideation	Caused or prolonged inpatient hospitalisation	he took a total of 9 mg in one day (prescribed dose is 2mg daily)	

Medicine Details:

BENZTROPINE MESYLATE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	08/04/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227821

Seq: 1

Gender: F

Reported: 23/04/2007

Weight: 0.00

Hospitalisation:

Age: 47Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		She did not have a menstrual period for 3-4 years, when dosage was reduced to 2mg daily her periods became more regular	
Weight increased		gained approximately 30kg	
Blood prolactin increased			

Medicine Details:

VITAMINS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Oral	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 227931

Seq: 1

Gender: M

Reported: 26/04/2007

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood triglycerides increased		Blood triglycerides increased.	Treated with other medications.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/04/2007	Triglyceride				On an unspecified date, the patient experienced very high triglyceride levels (in the 40's), his triglyceride levels have since decreased into the 20's.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228150 **Seq:** 1 **Gender:** F
Reported: 02/05/2007 **Weight:** 70.00
Hospitalisation: Required a visit to the doctor **Age:** 37
Onset Date: **DOB:** 05/10/1969
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Insidious onset tardive dyskinesia - gradual since late 2005.	Gradual lowering of dose of risperidone.

Medicine Details:

RISPERIDONE (Other drug)		Reason: As necessary Oral	
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason: Unspecified schizophrenia	
	75.0 Milligram	Fortnightly	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228280

Seq: 1

Gender: F

Reported: 08/05/2007

Weight: 0.00

Hospitalisation:

Age: 61Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Dizziness Hot flush Restless legs syndrome		2-3 per week	

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	
Tablet	100.0 Microgram	Oral	
Batch:	Started:	Stopped:	
DILANTIN (Other drug)		Reason:	
	300.0 Milligram	Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had previously been on many different anti-epileptic medications without adequate control of seizures



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228379

Seq: 1

Gender: M

Reported: 10/05/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		possible aggravation of psychosis	
Hallucination, visual		vivid visual hallucinations	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228380

Seq: 1

Gender: M

Reported: 10/05/2007

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 20/04/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rheumatoid arthritis	Incapacity/disability	experiencing sore neck when moving his head, sore feet	
Weight increased	Incapacity/disability	since commencing risperidone patient gained 20kg	
Muscular weakness	Incapacity/disability	weakness in the hands, he finds it hard to use knife and fork and finds it hard to lift things	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	2.0 Milligram 2 times Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is mentally delayed (mental age is 10 years)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228417 **Seq:** 1 **Gender:** M
Reported: 11/05/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	his symptoms remained uncontrolled and he was unable to be managed at home	
Drug interaction	Caused or prolonged inpatient hospitalisation	possible interaction between risperidone and nicotine, patient has been smoking 3 to 4 packs per day	
Aggression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	Milligram	Intramuscular	
Batch:	Started:	Stopped:	0
NICOTINE (Suspected)		Reason:	
		Inhalation	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously received zuclopenthixol which had not controlled his symptoms



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 228417 **Seq:** 1 **Gender:** M
Reported: 11/05/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		
Sleep phase rhythm disturbance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection	Milligram	Intramuscular	
Batch:	Started:	Stopped:	0
NICOTINE (Suspected)		Reason:	
		Inhalation	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient had previously received zuclopenthixol which had not controlled his symptoms