



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 92839

Seq: 1

Gender: F

Reported: 09/05/1994

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 08/04/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			
Insomnia			
Nausea			
Somnolence			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
NITRAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ALCOHOL (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	4.0 Milligram	Daily	Oral
Batch:	Started: 05/04/1994	Stopped: 26/04/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 93418

Seq: 1

Gender: M

Reported: 02/06/1994

Weight:

Hospitalisation:

Age: 27Y

Onset Date: 19/05/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

FAMOTIDINE (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 18/05/1994	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 12/05/1994	Stopped:	26/05/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 94396

Seq: 1

Gender: M

Reported: 14/07/1994

Weight: 90.00

Hospitalisation:

Age: 82Y

Onset Date: 01/07/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

Medicine Details:

ASPIRIN (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: CONTIN
ATENOLOL (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: CONTIN
SINEMET (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: CONTIN
INSULIN NOS (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of infection hepatitis b.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 94396

Seq: 1

Gender: M

Reported: 14/07/1994

Weight: 90.00

Hospitalisation:

Age: 82Y

Onset Date: 01/07/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

GLYCERYL TRINITRATE (Other drug)		Reason:
Cream	0.0	Transdermal
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified psychosis
	0.5 Milligram	Daily
Batch:	Started: 20/06/1994	Stopped: 02/07/1994

Laboratory Investigations:

Additional Information:

History of infection hepatitis b.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 95815

Seq: 1

Gender: M

Reported: 09/09/1994

Weight:

Hospitalisation:

Age: 76Y

Onset Date: 13/05/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 96855

Seq: 1

Gender: F

Reported: 01/11/1994

Weight:

Hospitalisation:

Age: 47Y

Onset Date: 15/10/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Increased appetite Weight increased			Commenced on fluphenazine.

Medicine Details:

TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
20.0 Milligram	
Batch:	Started: 25/08/1994 Stopped:
METHOTREXATE (Other drug)	Reason: Other psoriasis
10.0 Milligram	Weekly
Batch:	Started: Stopped:
IMIPRAMINE HYDROCHLORIDE (Other drug)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 22/09/1994 Stopped:
CLONAZEPAM (Other drug)	Reason:
2.0 Milligram	Daily
Batch:	Started: 11/10/1994 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 96855

Seq: 1

Gender: F

Reported: 01/11/1994

Weight:

Hospitalisation:

Age: 47Y

Onset Date: 15/10/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started: 11/10/1994	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	6.0 Milligram	Daily	
Batch:	Started: 22/09/1994	Stopped: 25/10/1994	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 96865

Seq: 1

Gender: F

Reported: 02/11/1994

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Increased appetite		Gained 10kg	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 25/09/1994	Stopped:	CONTIN
BECLOFORTE (Suspected)		Reason:	
Inhalation	4.0 Dose Unspecified	Daily	Inhalation
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 97134

Seq: 1

Gender: F

Reported: 17/11/1994

Weight:

Hospitalisation:

Age: 55

Onset Date: 08/07/1994

DOB: 17/02/1939

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

PANADEINE FORTE (Other drug)		Reason: Pain	
	1.0 Gram	As necessary	
Batch:	Started: 30/03/1994	Stopped:	
FLUPENTHIXOL DECANOATE (Other drug)		Reason:	
Injection	80.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 21/03/1994	Stopped:	
ZANTAC (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 27/03/1994	Stopped: 15/07/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		08/07/1994	3404 MU/L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 97134

Seq: 1

Gender: F

Reported: 17/11/1994

Weight:

Hospitalisation:

Age: 55

Onset Date: 08/07/1994

DOB: 17/02/1939

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZOLOFT (Suspected)

Reason: Depression

Tablet

50.0 Milligram

Daily

Oral

Batch:

Started: 13/05/1994

Stopped: 08/07/1994

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 97579

Seq: 1

Gender: F

Reported: 05/12/1994

Weight: 56.00

Hospitalisation:

Age: 77Y

Onset Date: 21/11/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma		Unable to be aroused.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Total	Oral
Batch:	Started: 20/11/1994	Stopped: 22/11/1994	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	500.0 Microgram	As necessary	
Batch:	Started:	Stopped: 23/11/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 97960

Seq: 1

Gender: M

Reported: 19/12/1994

Weight: 105.00

Hospitalisation:

Age: 47Y

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			
Sudden death			

Medicine Details:

HALDOL DECANOATE (Other drug)		Reason:		
Injection	300.0 Microgram	Monthly	Intramuscular	
Batch:	Started:	L TERM	Stopped:	
PROZAC (Other drug)		Reason: Depression		
Capsule	20.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	1Y
TRITACE (Other drug)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started:		Stopped:	
NATRILIX (Other drug)		Reason:		
Tablet	2.5 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died on the 9/12/94.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 97960

Seq: 1

Gender: M

Reported: 19/12/1994

Weight: 105.00

Hospitalisation:

Age: 47Y

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Other drug)		Reason:	
	240.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	6.0 Milligram	Daily	Oral
Batch:	Started: 29/11/1994	Stopped:	

Laboratory Investigations:

Additional Information:

Patient died on the 9/12/94.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98554
Reported: 23/01/1995
Hospitalisation:
Onset Date: 16/01/1995
Outcome: Recovered

Seq: 1

Gender: M
Weight: 76.00
Age: 73
DOB: 22/02/1921
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Dysarthria Extrapyramidal disorder	Severe		

Medicine Details:

ASPIRIN SOLUBLE (Other drug)	Reason: Chron isch heart dis no hyper
150.0 Milligram Daily Batch:	Started: 01/05/1994 Stopped: CONTIN
PEXID (Other drug)	Reason: Chron isch heart dis no hyper
400.0 Milligram Daily Batch:	Started: 01/04/1994 Stopped: CONTIN
TRANSIDERM-NITRO (Other drug)	Reason: Chron isch heart dis no hyper
50.0 Milligram Daily Batch:	Started: 01/07/1994 Stopped: CONTIN
LITHIUM CARBONATE (Other drug)	Reason:
500.0 Milligram Daily Batch:	Started: 01/12/1993 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	(10-120)	10/01/1995	62	
	Creatine	(10-120)	11/01/1995	66	
	Creatine	(10-120)	12/01/1995	71	
	Creatine	(10-120)	13/01/1995	114	
	Creatine	(10-120)	16/01/1995	179	
	Creatine	(10-120)	17/01/1995	121	
	Creatine	(10-120)	18/01/1995	95	

Additional Information:

Previous history of neuroleptic malignant with haloperidol -gross autonomic instability, fever, ck > 2,000. also pmh gross epse with metoclopramide. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98554

Seq: 1

Gender: M

Reported: 23/01/1995

Weight: 76.00

Hospitalisation:

Age: 73

Onset Date: 16/01/1995

DOB: 22/02/1921

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Manic-depression psycho,manic

4.0 Milligram

Daily

Batch:

Started: 09/01/1995

Stopped: 16/01/1995

Laboratory Investigations:

Additional Information:

Previous history of neuroleptic malignant with haloperidol -gross autonomic instability, fever, ck > 2,000. also pmh gross epse with metoclopramide. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98628

Seq: 1

Gender: F

Reported: 05/12/1994

Weight:

Hospitalisation:

Age:

Onset Date: 20/11/1994

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 15/11/1994	Stopped: 20/11/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98929

Seq: 1

Gender: F

Reported: 13/02/1995

Weight: 110.00

Hospitalisation:

Onset Date: 25/01/1995

Age: 52Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

DEPTRAN (Other drug)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
LITHIUM CARBONATE (Other drug)	Reason: Depression
1.2 Gram Daily	
Batch:	Started: 23/08/1994 Stopped: CONTIN
THYROXINE SODIUM (Other drug)	Reason: Myxedema
200.0 Microgram Daily	
Batch:	Started: L TERM Stopped: CONTIN
RISPERDAL (Suspected)	Reason: Unspecified psychosis
10.0 Milligram Daily	
Batch:	Started: 03/08/1994 Stopped: 05/02/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<60 U/L	25/01/1995	104	
	ALT = SGPT	<60 U/L	31/01/1995	91	
	ALT = SGPT	<60 U/L	06/02/1995	47	
	ALT = SGPT	<60 U/L	20/02/1995	35	
	ALT = SGPT	<60 U/L	13/02/1995	37	
	Bilirubin	<20 MMOL/L	25/01/1995	6	
	Bilirubin	<20 MMOL/L	31/01/1995	9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98929

Seq: 1

Gender: F

Reported: 13/02/1995

Weight: 110.00

Hospitalisation:

Age: 52Y

Onset Date: 25/01/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DEPTRAN (Other drug)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
LITHIUM CARBONATE (Other drug)	Reason: Depression
1.2 Gram Daily	
Batch:	Started: 23/08/1994 Stopped: CONTIN
THYROXINE SODIUM (Other drug)	Reason: Myxedema
200.0 Microgram Daily	
Batch:	Started: L TERM Stopped: CONTIN
RISPERDAL (Suspected)	Reason: Unspecified psychosis
10.0 Milligram Daily	
Batch:	Started: 03/08/1994 Stopped: 05/02/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	<20 MMOL/L	06/02/1995	5	
	Bilirubin	<20 MMOL/L	13/02/1995	7	
	Bilirubin	<20 MMOL/L	20/02/1995	3	
	GGT = SGGT =	<80 U/L	25/01/1995	1016	
	GGT = SGGT =	<80 U/L	31/01/1995	1011	
	GGT = SGGT =	<80 U/L	13/02/1995	562	
	GGT = SGGT =	<80 U/L	20/02/1995	366	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 98929

Seq: 1

Gender: F

Reported: 13/02/1995

Weight: 110.00

Hospitalisation:

Age: 52Y

Onset Date: 25/01/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DEPTRAN (Other drug)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
LITHIUM CARBONATE (Other drug)	Reason: Depression
1.2 Gram Daily	
Batch:	Started: 23/08/1994 Stopped: CONTIN
THYROXINE SODIUM (Other drug)	Reason: Myxedema
200.0 Microgram Daily	
Batch:	Started: L TERM Stopped: CONTIN
RISPERDAL (Suspected)	Reason: Unspecified psychosis
10.0 Milligram Daily	
Batch:	Started: 03/08/1994 Stopped: 05/02/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	<80 U/L	06/02/1995	784	
	SAP = ALP	30-115 U/L	25/01/1995	231	
	SAP = ALP	30-115 U/L	31/01/1995	252	
	SAP = ALP	30-115 U/L	06/02/1995	199	
	SAP = ALP	30-115 U/L	13/02/1995	185	
	SAP = ALP	30-115 U/L	20/02/1995	191	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 100021

Seq: 1

Gender: M

Reported: 04/04/1995

Weight:

Hospitalisation:

Age: 22Y

Onset Date: 24/02/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 26/01/1995	Stopped: 28/02/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 100889

Seq: 1

Gender: M

Reported: 18/05/1995

Weight:

Hospitalisation:

Age: 20Y

Onset Date: 08/05/1995

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		White papular rash	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started: 10/04/1995	Stopped: 08/05/1995	
BENZTROPINE MESYLATE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 30/03/1995	Stopped:	
TEMAZEPAM (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 08/05/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Eczema and itchy before risperidone therapy worsened after starting rispersone



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 100915

Seq: 1

Gender: M

Reported: 19/05/1995

Weight:

Hospitalisation:

Age: 39Y

Onset Date: 10/05/1995

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

TEMAZE (Suspected)		Reason:	
	10.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
COGENTIN (Suspected)		Reason:	
	500.0 Microgram	As necessary	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started: 04/05/1995	Stopped: 10/05/1995	
VALIUM (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

? nms in the past secondary to largactil and haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 102217

Seq: 1

Gender: F

Reported: 17/07/1995

Weight:

Hospitalisation:

Age: 31Y

Onset Date: 08/07/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokinesia Anorexia Anxiety Depression Fatigue Insomnia Pyrexia Thinking abnormal		Psychomotor retardation.	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 05/07/1995 Stopped: 11/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 102651
Reported: 02/08/1995

Seq: 1

Gender: M
Weight: 92.00
Age: 32Y

Hospitalisation:

Onset Date: 15/04/1995
Outcome: Recovered

DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation			
Ejaculation failure			
Gynaecomastia			
Weight increased			

Medicine Details:

LITHICARB (Other drug)		Reason:	
Tablet	1.7 Gram	Daily	Oral
Batch:	Started: 01/02/1995	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 04/04/1995	Stopped: 20/07/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 102769

Seq: 1

Gender: M

Reported: 11/08/1995

Weight: 74.00

Hospitalisation:

Age: 26Y

Onset Date: 02/08/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 30/11/1994	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103027

Seq: 1

Gender: M

Reported: 23/08/1995

Weight: 75.00

Hospitalisation:

Age: 30Y

Onset Date: 14/07/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			
Nausea			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	5.0 Milligram
	Daily
	Oral
Batch:	Started: 30/06/1995
	Stopped: 01/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103382

Seq: 1

Gender: M

Reported: 06/09/1995

Weight:

Hospitalisation:

Age: 57Y

Onset Date: 31/07/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 19/06/1995	Stopped: 19/06/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103464

Seq: 1

Gender: M

Reported: 11/09/1995

Weight: 65.00

Hospitalisation:

Age: 25Y

Onset Date: 31/08/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			
Hyperkinesia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	6.0 Milligram	Daily	
Batch:	Started: 03/07/1995	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103580
Reported: 15/09/1995

Seq: 1

Gender: M
Weight: 77.00

Hospitalisation:

Onset Date: 05/08/1995
Outcome: Recovered

Age: 41Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

WARFARIN SODIUM (Other drug)	Reason: Peptic ulcer nos w/o ment perf
0.0	
Batch:	Started: 01/07/1995 Stopped:
PRO-BANTHINE (Other drug)	Reason: Other diseases of bladder
6.0 Dose Unspecified Daily	
Batch:	Started: 01/04/1995 Stopped:
PROZAC (Other drug)	Reason: Depression
20.0 Milligram Daily	
Batch:	Started: 01/01/1995 Stopped:
ZANTAC (Other drug)	Reason:
300.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103580
Reported: 15/09/1995

Seq: 1

Gender: M
Weight: 77.00
Age: 41Y

Hospitalisation:

Onset Date: 05/08/1995
Outcome: Recovered

DOB:
Causality: Causality probable

Reaction Details:

Medicine Details:

ANDROCUR (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
ESTIGYN (Other drug)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started: 26/07/1995	Stopped:	05/08/1995

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 103738

Seq: 1

Gender: M

Reported: 28/09/1995

Weight: 82.00

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Schizophrenia
8.0 Milligram	Daily
Batch:	Started: 01/04/1995 Stopped: 28/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104163
Reported: 25/10/1995

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 10/10/1995

Age: 73Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

AMOXIL (Other drug)		Reason: Bronchitis,unqualified	
Oral application	1.5 Gram	Daily	Oral
Batch:	Started: 09/10/1995	Stopped: 16/10/1995	
SINEMET (Other drug)		Reason: Paralysis agitans	
Tablet	3.0 Dose Unspecified	Daily	Oral
Batch:	Started: L TERM	Stopped:	
PROPYLTHIOURACIL (Other drug)		Reason: Myxedema	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
BETOPTIC (Other drug)		Reason: Unspecified glaucoma	
Eye Drops	2.0 Dose Unspecified	Daily	Ophthalmic
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104163

Seq: 1

Gender: M

Reported: 25/10/1995

Weight:

Hospitalisation:

Age: 73Y

Onset Date: 10/10/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Hallucinations	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 09/10/1995	Stopped: 15/10/1995	
MODURETIC (Suspected)		Reason: Essential benign hypertension	
	0.5 Dose Unspecified	Daily	
Batch:	Started: L TERM	Stopped: 13/10/1995	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104460

Seq: 1

Gender: F

Reported: 07/11/1995

Weight:

Hospitalisation:

Age: 31Y

Onset Date: 17/10/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome			Fluids, bromocriptine.

Medicine Details:

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started: 11/10/1995	Stopped: 13/10/1995	
HALOPERIDOL (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 03/10/1995	Stopped: 11/10/1995	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 13/10/1995	Stopped: 19/10/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		11/10/1995	1591	
	Creatine		17/10/1995	27352	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104478

Seq: 1

Gender: F

Reported: 08/11/1995

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 29/09/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		Rash around hips, tops of legs, chest, neck	
Angioedema			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	4.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1995	Stopped: 06/10/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104702
Reported: 20/11/1995

Seq: 1

Gender: F

Weight: 80.00

Hospitalisation:

Onset Date: 10/10/1995

Age: 67

DOB: 28/09/1928

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Dehydration Hypertonia Neuroleptic malignant syndrome			Timentin, bromocryptine.

Medicine Details:

PANAMAX (Other drug)		Reason:	
		2.0 Dose Unspecified As necessary	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
		200.0 Microgram Daily	
Batch:	Started:	Stopped:	
TOLVON (Other drug)		Reason:	
		60.0 Milligram Daily	
Batch:	Started:	Stopped:	
LORAZEPAM (Other drug)		Reason:	
		2.0 Milligram Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	25 - 170 U/L	10/10/1995	328	
	Creatine	25 - 170 U/L	11/10/1995	444	

Additional Information:

Past history of side effects to many anti psychotic drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 104702

Seq: 1

Gender: F

Reported: 20/11/1995

Weight: 80.00

Hospitalisation:

Age: 67

Onset Date: 10/10/1995

DOB: 28/09/1928

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecified schizophrenia

10.0 Milligram

Daily

Batch:

Started: 01/05/1995

Stopped: 10/10/1995

Laboratory Investigations:

Additional Information:

Past history of side effects to many anti psychotic drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 105609

Seq: 1

Gender: M

Reported: 02/01/1996

Weight:

Hospitalisation:

Age: 19Y

Onset Date: 16/12/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema	Severe		

Medicine Details:

PROZAC (Suspected)		Reason: Depression	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started: 14/12/1995	Stopped: 18/12/1995	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 14/12/1995	Stopped: 18/12/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106327

Seq: 1

Gender: F

Reported: 07/02/1996

Weight:

Hospitalisation:

Age: 64Y

Onset Date: 31/01/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Extrapyramidal disorder Hyperkinesia	Severe		

Medicine Details:

COGENTIN (Other drug)	Reason: Paralysis agitans
0.5 Milligram Daily	
Batch:	Started: 12/12/1995 Stopped: 28/01/1996
DIAZEPAM (Other drug)	Reason:
2.5 Milligram Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Presenile dementia
0.5 Milligram Daily	
Batch:	Started: 01/12/1995 Stopped: 28/01/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Moderate dementia of alzheimer type - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106525
Reported: 19/02/1996

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 86Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Dysphagia			
Face oedema			

Medicine Details:

PANAMAX (Other drug)		Reason:	
6.0 Dose Unspecified As necessary			
Batch:	Started:	Stopped:	
COVERSYL (Other drug)		Reason: Essential benign hypertension	
6.0 Milligram Daily			
Batch:	Started: 01/01/1995	Stopped:	
ZOLOFT (Other drug)		Reason: Depression	
100.0 Milligram Daily			
Batch:	Started: 01/08/1995	Stopped:	
ZANTAC (Other drug)		Reason: Ulcer of stomach w/o ment perf	
300.0 Milligram Daily			
Batch:	Started: 01/01/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106525
Reported: 19/02/1996
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 86Y
DOB:
Causality: Causality probable

Reaction Details:

Medicine Details:

PREPULSID (Other drug)		Reason:	
	60.0 Milligram	Daily	
Batch:	Started: 01/01/1995	Stopped:	
MOGADON (Other drug)		Reason: Specific disorders of sleep	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1995	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: L TERM	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Total	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106699

Seq: 1

Gender: M

Reported: 26/02/1996

Weight: 72.00

Hospitalisation:

Age: 53Y

Onset Date: 03/02/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			

Medicine Details:

RISPERDAL (Suspected)		Reason: Schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 30/01/1996	Stopped: 12/02/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106805

Seq: 1

Gender: M

Reported: 01/03/1996

Weight:

Hospitalisation:

Age: 22Y

Onset Date: 18/08/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Staring episodes	
Hypertonia		Stiff arms and legs	Cogentin 2mg iv.
Tremor			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	4.0 Milligram Daily Oral
Batch:	Started: 08/08/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has allergy to largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 106956
Reported: 08/03/1996

Seq: 1

Gender: M
Weight: 66.00
Age: 74Y

Hospitalisation:

Onset Date: 01/03/1996
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			

Medicine Details:

IMDUR (Other drug)	Reason: Angina pectoris w/o hyperten
60.0 Milligram Daily	
Batch:	Started: Stopped:
MADOPAR Q (Other drug)	Reason: Paralysis agitans
3.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Hallucinations
Tablet 1.5 Milligram Daily Oral	
Batch:	Started: 28/02/1996 Stopped: 01/03/1996
CHLORMETHIAZOLE (Suspected)	Reason: Otr spec symp psychopathol nec
192.0 Milligram Daily	
Batch:	Started: 15/02/1996 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck rose to 991

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107160

Seq: 1

Gender: F

Reported: 20/03/1996

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

PEPCIDINE (Other drug)	Reason:
40.0 Milligram	Daily
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
150.0 Microgram	Daily
Batch:	Started: Stopped:
THIAMINE (Other drug)	Reason:
10.0 Milligram	Daily
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started: 03/02/1996 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107160

Seq: 1

Gender: F

Reported: 20/03/1996

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

1.0 Milligram

Daily

Batch:

Started: 09/02/1996

Stopped: 16/02/1996

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107371
Reported: 28/03/1996

Seq: 1

Gender: F
Weight: 71.00

Hospitalisation:

Onset Date: 29/02/1996
Outcome: Unknown

Age: 17Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			

Medicine Details:

LITHICARB (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
VALPRO (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 14/12/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				4/3/96 lithium <0.1 mmol/l valproate 253 mmol/l prolactin 1786 miu/l (32-420) hcg < 2 (0-5)

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107695

Seq: 1

Gender: F

Reported: 03/04/1996

Weight: 50.00

Hospitalisation:

Age: 27Y

Onset Date: 20/03/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema	Required Specialist Consultation		
Gravitational oedema			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason: Depression
	40.0 Milligram	Daily
Batch:	Started: 01/01/1996	Stopped:
TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)		Reason: Unspecified psychosis
	30.0 Milligram	Daily
Batch:	Started: 01/12/1995	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified psychosis
	2.0 Milligram	Daily
Batch:	Started: 10/03/1996	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergic to disprin. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107730

Seq: 1

Gender: M

Reported: 04/04/1996

Weight:

Hospitalisation:

Age: 70Y

Onset Date: 03/11/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
NITRAZEPAM (Other drug)		Reason:	
Oral application	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 01/08/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		03/11/1995	36	
	ALT = SGPT		05/12/1995	84	
	GGT = SGGT =		03/11/1995	349	
	GGT = SGGT =		05/12/1995	489	
	Hepatitis B				Hep b ab+ve
	Radiology				U/s-dilated intrahepatic bile ducts.
	SAP = ALP		03/11/1995	132	

Additional Information:

Hepatitis with jaundice 1969. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107730

Seq: 1

Gender: M

Reported: 04/04/1996

Weight:

Hospitalisation:

Age: 70Y

Onset Date: 03/11/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
NITRAZEPAM (Other drug)		Reason:	
Oral application	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 01/08/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		05/12/1995	138	

Additional Information:

Hepatitis with jaundice 1969. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107912

Seq: 1

Gender: M

Reported: 15/04/1996

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 16/11/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Eosinophilia Hepatic function abnormal Pyrexia Red blood cell sedimentation rate i			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
300.0 Milligram		Daily	
Batch:	Started: 07/11/1995	Stopped: 15/11/1995	
RISPERIDONE (Suspected)		Reason:	
4.0 Milligram		Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		17/11/1995	463	
	ALT = SGPT		20/11/1995	220	
	AST = SGOT		17/11/1995	190	
	AST = SGOT		20/11/1995	59	
	Bilirubin		17/11/1995	48	
	Bilirubin		20/11/1995	17	
	Creatine		18/11/1995	274	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 107912

Seq: 1

Gender: M

Reported: 15/04/1996

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 16/11/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
	300.0 Milligram		Daily
Batch:	Started: 07/11/1995	Stopped:	15/11/1995
RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram		Daily
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils		20/11/1995	0.55	
	Erythrocyte		18/11/1995	29	
	GGT = SGGT =		17/11/1995	341	
	GGT = SGGT =		20/11/1995	353	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 108212

Seq: 1

Gender: M

Reported: 06/05/1996

Weight: 90.00

Hospitalisation:

Onset Date: 01/04/1996

Age: 27Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing Hyperhidrosis			

Medicine Details:

ENDEP (Other drug)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 01/04/1996 Stopped:
ENDEP (Suspected)	Reason: Migraine
10.0 Milligram Daily	
Batch:	Started: 11/03/1996 Stopped: 01/04/1996
RISPERDAL (Suspected)	Reason:
3.0 Dose Unspecified Daily	
Batch:	Started: 12/10/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 108829

Seq: 1

Gender: F

Reported: 30/05/1996

Weight: 70.00

Hospitalisation:

Age: 54

Onset Date: 07/04/1996

DOB: 04/08/1941

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance Hypoaesthesia Paraesthesia	Severe	Altered sensation Numbness of lips, left hand and left foot	

Medicine Details:

PERTOFRAN (Other drug)	Reason: Depression
Tablet	175.0 Milligram
	Daily
	Oral
Batch:	Started:
Stopped:	
RISPERIDONE (Suspected)	Reason: Unspecified psychosis
	4.0 Milligram
	Daily
Batch:	Started: 27/02/1996
Stopped:	07/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 108935
Reported: 03/06/1996
Hospitalisation:
Onset Date: 17/12/1995
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 8Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Oculogyration			
Urinary incontinence			

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
EPILIM (Other drug)		Reason: Other&unspecified epilepsy	
	0.0		
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
Tablet	1.5 Milligram	Daily	Oral
Batch:	Started: 16/12/1995	Stopped: 20/12/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 109274

Seq: 1

Gender: F

Reported: 18/06/1996

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 19/04/1996

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache Nausea	Severe		

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
4.0 Milligram	Daily
Batch:	Started: Stopped: 20/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 109383

Seq: 1

Gender: F

Reported: 20/06/1996

Weight: 55.00

Hospitalisation:

Onset Date: 12/04/1996

Age: 76Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Exacerbation of renal insufficiency	Prednisolone 60mg orally daily, gradually decreasing
Nephritis interstitial			

Medicine Details:

MONOPRIL (Suspected)		Reason: Essential benign hypertension	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/04/1996	Stopped: 23/04/1996	
VOLTAREN (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 30/04/1996	
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 12/04/1996	Stopped:	
MACRODANTIN (Suspected)		Reason: Othr diseases of urinary tract	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped: 14/05/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Renal biopsy =				Renal biopsy revealed granulomatous glomerular nephritis

Additional Information:

See original report for other drugs the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 109383

Seq: 1

Gender: F

Reported: 20/06/1996

Weight: 55.00

Hospitalisation:

Age: 76Y

Onset Date: 12/04/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified schizophrenia

Tablet

3.0 Milligram

Daily

Oral

Batch:

Started: 12/04/1996

Stopped:

Laboratory Investigations:

Additional Information:

See original report for other drugs the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110066

Seq: 1

Gender: M

Reported: 19/07/1996

Weight: 90.00

Hospitalisation:

Age: 26Y

Onset Date: 09/07/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Agitation Blood creatine phosphokinase incr Confusional state Flushing Hepatic function abnormal Neuroleptic malignant syndrome		160/min	

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason: Otr spec symp psychopathol nec	
	200.0 Milligram	1 time	
Batch:	Started: 09/07/1996	Stopped: 09/07/1996	
RIVOTRIL (Suspected)		Reason:	
	1.0 Milligram	1 time	
Batch:	Started: 09/07/1996	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/05/1995	Stopped: 09/07/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		09/07/1996	66	
	Creatine kinase	<10 U/L, <4%	09/07/1996	21, 1%	
	Creatine	25 - 200 U/L	09/07/1996	3238	
	LDH	190 - 395 U/L	09/07/1996	554	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110303
Reported: 29/07/1996

Seq: 1

Gender: F
Weight: 58.00

Hospitalisation:

Onset Date: 28/06/1996
Outcome: Recovered

Age: 54Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Dizziness		Bp 90/50	

Medicine Details:

VALIUM (Other drug)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	As necessary	Oral
Batch:	Started: 12/06/1996	Stopped:	19/06/1996
COGENTIN (Other drug)		Reason:	
Tablet	2.0 Milligram	As necessary	Oral
Batch:	Started: 22/06/1996	Stopped:	05/07/1996
TEMAZE (Other drug)		Reason: Otr spec symp psychopathol nec	
	20.0 Milligram	Daily	
Batch:	Started: 12/06/1996	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 19/06/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110304
Reported: 29/07/1996

Seq: 1

Gender: F
Weight: 58.00
Age: 54Y

Hospitalisation:

Onset Date: 10/07/1996
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Oculogyration			Cogentin iv stat.

Medicine Details:

TEMAZE (Other drug)	Reason: Specific disorders of sleep
20.0 Milligram Daily	
Batch:	Started: 12/06/1996 Stopped: CONTIN
LARGACTIL (Suspected)	Reason: Otr spec symp psychopathol nec
100.0 Milligram As necessary	
Batch:	Started: 04/07/1996 Stopped: CONTIN
RISPERDAL (Suspected)	Reason: Unspecified psychosis
2.0 Milligram Daily	
Batch:	Started: 19/06/1996 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110314

Seq: 1

Gender: M

Reported: 29/07/1996

Weight: 80.00

Hospitalisation:

Age: 54Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Acneiform eruption anterior chest	
Abscess		Has abscesses groin and axillae	

Medicine Details:

HALDOL DECANOATE (Suspected)		Reason: Unspecified schizophrenia	
Injection	100.0 Milligram	Weekly	Intramuscular
Batch:	Started:	L TERM	Stopped: CONTIN
HALOPERIDOL (Suspected)		Reason: Unspecified schizophrenia	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
RISPERIDONE (Suspected)		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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110316
Reported: 29/07/1996

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 25/06/1996

Age: 49Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Oculogyration		Dystonic reaction	

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
TEGRETOL (Other drug)		Reason: Unspecified schizophrenia	
Oral application	900.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
DIAMICRON (Other drug)		Reason: Diabetes mellitus	
Tablet	320.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
LARGACTIL (Suspected)		Reason: Otr spec symp psychopathol nec	
Oral application	100.0 Milligram	As necessary	Oral
Batch:	Started: 22/06/1996	Stopped:	02/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110316

Seq: 1

Gender: F

Reported: 29/07/1996

Weight:

Hospitalisation:

Age: 49Y

Onset Date: 25/06/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RIVOTRIL (Suspected)		Reason: Otr spec symp psychopathol nec	
	500.0 Microgram	As necessary	
Batch:	Started: 20/06/1996	Stopped: 26/06/1996	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 19/06/1996	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110494

Seq: 1

Gender: M

Reported: 05/08/1996

Weight: 63.00

Hospitalisation:

Age: 19Y

Onset Date: 19/07/1996

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Severe		
Epistaxis			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started: 05/07/1996	Stopped: 26/07/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110669

Seq: 1

Gender: M

Reported: 09/08/1996

Weight: 92.00

Hospitalisation:

Onset Date: 01/07/1996

Age: 25Y

DOB:

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Pyrexia			

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified psychosis
275.0 Milligram Daily	
Batch:	Started: 28/06/1996 Stopped: 03/07/1996
FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
20.0 Milligram Daily	
Batch:	Started: Stopped: 26/06/1996
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram Daily	
Batch:	Started: Stopped: 25/06/1996
TETRACYCLINE (Suspected)	Reason:
500.0 Milligram Daily	
Batch:	Started: Stopped: 25/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		02/07/1996	757	

Additional Information:

Suspected neuroleptic malignant syndrome. restarted clozapine on 08/07/96 with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 110878

Seq: 1

Gender: F

Reported: 15/08/1996

Weight: 61.00

Hospitalisation:

Age: 27

Onset Date: 22/07/1996

DOB: 23/04/1969

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Tardive dyskinesia Tremor Goitre Hypothyroidism	Required Specialist Consultation	Flexed upper limbs. Lips twitching with biting of tongue. Pill rolling tremor.	Oroxine.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1995	Stopped:	CONTIN
LITHIUM CARBONATE (Suspected)		Reason: Othr&unspec metabolic diseases	
	1.0 Gram	Daily	
Batch:	Started: 01/03/1995	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Tfts low in late july 1996.

Additional Information:

Risperidone reduced form 4 mg to 2mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 111442

Seq: 1

Gender: M

Reported: 05/09/1996

Weight:

Hospitalisation:

Age: 29

Onset Date: 12/08/1996

DOB: 12/08/1967

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Benztropine

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 05/08/1996	Stopped: 12/08/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 111598

Seq: 1

Gender: F

Reported: 13/09/1996

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Obesity			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 111636
Reported: 16/09/1996

Seq: 1

Gender: F
Weight: 70.00

Hospitalisation:

Onset Date: 01/09/1996
Outcome: Recovered

Age: 60Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence Consciousness fluctuating Hyponatraemia Polydipsia Polyuria Thirst		Incontinent of large amounts of urine. Semi-comatose condition.	Fluid restriction and normal saline

Medicine Details:

SEREPAX (Other drug)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1995	Stopped:	
RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1995	Stopped: 07/09/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality		01/09/1996	257	
	Sodium		01/09/1996	119	
	Urine osmolality		01/09/1996	75	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 111988

Seq: 1

Gender: M

Reported: 02/10/1996

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety Hyperkinesia Increased appetite Paranoia			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The reaction to risperidone was found to be due to a colouring agent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 112239
Reported: 14/10/1996
Hospitalisation:
Onset Date: 26/09/1996
Outcome: Recovered

Seq: 1

Gender: F
Weight: 70.00
Age: 55Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous Headache		Punctate red rash on lower limbs	

Medicine Details:

SURMONTIL (Other drug) Oral application Batch: Started: 06/02/1996	150.0 Milligram Daily Stopped:	Reason: Depression
ROHYPNOL (Other drug) Batch: Started: 26/08/1996	2.0 Milligram Daily Stopped:	Reason:
RISPERDAL (Suspected) Batch: Started: 24/09/1996	0.0 Stopped:	Reason:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset two days after starting risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 112293

Seq: 1

Gender: M

Reported: 16/10/1996

Weight: 90.00

Hospitalisation:

Age: 50Y

Onset Date: 10/10/1996

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hot flush Headache Hyperacusis Nausea Vomiting		Felt hot.	Maxolon.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Depression
Tablet	2.0 Milligram
	Daily
	Oral
Batch:	Started: 10/10/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 112961

Seq: 1

Gender: M

Reported: 08/11/1996

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	3M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 112980

Seq: 1

Gender: M

Reported: 11/11/1996

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 26/09/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression			Sertraline

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 23/05/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113119

Seq: 1

Gender: F

Reported: 13/11/1996

Weight: 52.00

Hospitalisation:

Onset Date: 01/11/1996

Age: 74Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash on trunk, arms and thighs.	Elocon cream.

Medicine Details:

SORBITOL (Other drug)		Reason:	
Oral application	20.0 Millilitre	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 14/08/1996	Stopped: 04/11/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113181

Seq: 1

Gender: M

Reported: 15/11/1996

Weight: 70.00

Hospitalisation:

Age: 36Y

Onset Date: 31/10/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psoriasis		Psoriasis on elbows and face	

Medicine Details:

LITHICARB (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 25/10/1996	Stopped: 31/10/1996	
RISPERDAL (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 11/10/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113205
Reported: 18/11/1996
Hospitalisation:
Onset Date: 07/08/1996
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 55Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state Confusional state Delirium Leukocytosis			Fluids iv.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Oral application	100.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped: 07/08/1996	
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1995	Stopped: 07/08/1996	
THIOPENTONE SODIUM (Suspected)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		08/08/1996	3004	
	Creatine		12/08/1996	1746	
	White blood cells		08/08/1996	15.1	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113205

Seq: 1

Gender: M

Reported: 18/11/1996

Weight:

Hospitalisation:

Age: 55Y

Onset Date: 07/08/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SUXAMETHONIUM CHLORIDE (Suspected)

Reason:

70.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113240

Seq: 1

Gender: F

Reported: 19/11/1996

Weight: 70.00

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Oro-buccal-lingual/severe trunkal dyskinesia	Stop risperidone, re-instate stelazine

Medicine Details:

STELAZINE (Suspected)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started: 23/07/1996	Stopped: 07/11/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on stelazine for 30 years with no problems. patient is now back on stelazine and well.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113426

Seq: 1

Gender: F

Reported: 26/11/1996

Weight: 64.00

Hospitalisation:

Age: 24Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started: 01/09/1996	Stopped:	
BENZTROPINE MESYLATE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 01/09/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113533

Seq: 1

Gender: M

Reported: 29/11/1996

Weight: 101.00

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema			
Periorbital oedema			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged on risperidone with same reaction occurring. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113781
Reported: 09/12/1996

Seq: 1

Gender: F
Weight: 75.00

Hospitalisation:

Onset Date: 08/10/1996
Outcome: Recovered

Age: 27Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute brain syndrome	Cogentin 2mg im, 1mg orally
Dystonia		Dystonia of lower limbs and oral muscles	

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 04/10/1996 Stopped: 09/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has history of problems being stabilised on any antipsychotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113865
Reported: 12/12/1996

Seq: 1

Gender: F
Weight: 78.00

Hospitalisation:

Onset Date: 21/10/1996
Outcome: Recovered

Age:
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema			Risperdal ceased

Medicine Details:

OGEN (Other drug)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
VALIUM (Other drug)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
LITHIUM CARBONATE (Other drug)		Reason:	
	750.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERDAL (Suspected)		Reason:	
	0.0		
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 113867

Seq: 1

Gender: F

Reported: 12/12/1996

Weight:

Hospitalisation:

Age: 79Y

Onset Date: 10/10/1996

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypercalcaemia Stupor			

Medicine Details:

ROCALTROL (Suspected)	Reason: Osteoporosis
0.5 Microgram Daily	
Batch:	Started: Stopped: 10/10/1996
CALTRATE (Suspected)	Reason: Osteoporosis
1.2 Gram Daily	
Batch:	Started: Stopped: 10/10/1996
SODIUM VALPROATE (Suspected)	Reason: Otr&unsp vertebrogen pain synd
200.0 Milligram Daily	
Batch:	Started: Stopped: 20/10/1996
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
1.0 Milligram Daily	
Batch:	Started: Stopped: 28/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed aspiration pneumonia while recovering from hypercalcaemia and died 2 weeks later (11/11/96). patient did not die directly from the hypercalcaemia but it contributed significantly to her death. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114152
Reported: 23/12/1996

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 18/11/1996

Age: 72

DOB: 24/08/1924

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Markedly elevated ggt/alp -->peaks 278/316	
Pyrexia		Spiking fevers-temp peaked at 38.7c on 20/11/96	

Medicine Details:

MYLANTA (Suspected)	Reason: Other diseases of esophagus
20.0 Millilitre	As necessary
Batch:	Started: 18/11/1996 Stopped: 19/11/1996
RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
1.0 Milligram	Daily
Batch:	Started: 15/11/1996 Stopped: 17/11/1996
RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
2.0 Milligram	Daily
Batch:	Started: 17/11/1996 Stopped: 20/11/1996
FUNGILIN (Suspected)	Reason: Moniliasis
Lozenge	4.0 Dose Unspecified Daily Oral
Batch:	Started: 11/11/1996 Stopped: 19/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		08/11/1996	55	
	ALT = SGPT		14/11/1996	39	
	ALT = SGPT		19/11/1996	59	
	AST = SGOT		08/11/1996	39	
	AST = SGOT		14/11/1996	28	
	AST = SGOT		19/11/1996	37	
	Albumin		08/11/1996	36	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114152
Reported: 23/12/1996

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 18/11/1996

Age: 72

Outcome: Recovered

DOB: 24/08/1924

Causality: Causality possible

Reaction Details:

Medicine Details:

MYLANTA (Suspected)	Reason: Other diseases of esophagus
20.0 Millilitre	As necessary
Batch:	Started: 18/11/1996 Stopped: 19/11/1996
RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
1.0 Milligram	Daily
Batch:	Started: 15/11/1996 Stopped: 17/11/1996
RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
2.0 Milligram	Daily
Batch:	Started: 17/11/1996 Stopped: 20/11/1996
FUNGILIN (Suspected)	Reason: Moniliasis
Lozenge	4.0 Dose Unspecified Daily Oral
Batch:	Started: 11/11/1996 Stopped: 19/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Albumin		14/11/1996	25	
	Albumin		19/11/1996	23	
	GGT = SGGT =		08/11/1996	29	
	GGT = SGGT =		14/11/1996	62	
	GGT = SGGT =		19/11/1996	278	
	SAP = ALP		08/11/1996	76	
	SAP = ALP		14/11/1996	105	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114152
Reported: 23/12/1996

Seq: 1

Gender: M

Weight:

Hospitalisation:

Age: 72

Onset Date: 18/11/1996

DOB: 24/08/1924

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

MYLANTA (Suspected)		Reason: Other diseases of esophagus	
	20.0 Millilitre	As necessary	
Batch:	Started: 18/11/1996	Stopped: 19/11/1996	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	1.0 Milligram	Daily	
Batch:	Started: 15/11/1996	Stopped: 17/11/1996	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	2.0 Milligram	Daily	
Batch:	Started: 17/11/1996	Stopped: 20/11/1996	
FUNGILIN (Suspected)		Reason: Moniliasis	
Lozenge	4.0 Dose Unspecified	Daily	Oral
Batch:	Started: 11/11/1996	Stopped: 19/11/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		19/11/1996	316	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114520

Seq: 1

Gender: M

Reported: 13/01/1997

Weight:

Hospitalisation:

Age: 88

Onset Date: 15/07/1996

DOB: 14/09/1907

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	500.0 Microgram	As necessary	
Batch:	Started:	Stopped:	2D
PERICYAZINE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	3.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped:	3D
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason: Otr spec symp psychopathol nec	
	30.0 Milligram	Daily	
Batch:	Started:	Stopped:	5D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114690

Seq: 1

Gender: M

Reported: 23/01/1997

Weight:

Hospitalisation:

Age: 82Y

Onset Date: 15/01/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

AGAROL (Other drug)		Reason: Constipation	
Oral Liquid	20.0 Millilitre	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 24/12/1996	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 06/01/1997	Stopped:	
COLOXYL WITH SENNA (Suspected)		Reason: Constipation	
Tablet	2.0 Dose Unspecified	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114776
Reported: 28/01/1997

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 03/10/1996

Age: 32Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor Coordination abnormal		Coarse hand tremor	

Medicine Details:

COGENTIN (Suspected)		Reason:	
Tablet	2.0 Milligram	As necessary	Oral
Batch:	Started: 23/09/1996	Stopped:	CONTIN
TERIL (Suspected)		Reason:	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 23/09/1996	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 23/09/1996	Stopped:	CONTIN
LITHICARB (Suspected)		Reason:	
Tablet	1.7 Gram	Daily	Oral
Batch:	Started: 23/09/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Carbamazepine level=32umol/l, lithium level=1.23umol/l both therapeutic levels

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114776

Seq: 1

Gender: M

Reported: 28/01/1997

Weight:

Hospitalisation:

Age: 32Y

Onset Date: 03/10/1996

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

AROPAX (Suspected)

Reason: Depression

Tablet

20.0 Milligram

Daily

Oral

Batch:

Started: 26/09/1996

Stopped:

CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114911

Seq: 1

Gender: M

Reported: 03/02/1997

Weight:

Hospitalisation:

Age: 24Y

Onset Date: 20/01/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Monitor bloods.

Medicine Details:

TEGRETOL (Suspected)		Reason: Other&unspecified epilepsy	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 01/01/1995	Stopped: 22/01/1997	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	
RIVOTRIL (Suspected)		Reason:	
Tablet	1.5 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		11/12/1996	3.3	
	Neutrophils		16/12/1996	2.2	
	Neutrophils		20/01/1997	1.3	
	Neutrophils		27/01/1997	1.5	
	Neutrophils		22/01/1997	1.2	
	White blood cells		11/12/1996	5.7	
	White blood cells		16/12/1996	4	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114911

Seq: 1

Gender: M

Reported: 03/02/1997

Weight:

Hospitalisation:

Age: 24Y

Onset Date: 20/01/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

TEGRETOL (Suspected)		Reason: Other&unspecified epilepsy	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 01/01/1995	Stopped: 22/01/1997	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	
RIVOTRIL (Suspected)		Reason:	
Tablet	1.5 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		20/01/1997	3.2	
	White blood cells		22/01/1997	3.0	
	White blood cells		27/01/1997	3.1	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114919

Seq: 1

Gender: M

Reported: 03/02/1997

Weight: 85.00

Hospitalisation:

Onset Date: 28/12/1996

Age: 28Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary movements of upper lip and tongue.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 18/08/1996	Stopped:	
PAROXETINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 19/12/1996	Stopped: 16/01/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 114927

Seq: 1

Gender: M

Reported: 03/02/1997

Weight:

Hospitalisation:

Age: 71Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	CONTIN
UREMIDE (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
DEPTRAN (Other drug)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Depression	
	4.0 Milligram	Daily	
Batch:	Started: 01/02/1996	Stopped:	13/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115051

Seq: 1

Gender: M

Reported: 07/02/1997

Weight: 83.00

Hospitalisation:

Onset Date: 31/01/1997

Age: 40Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema		Puffy inflamed eyelids	
Rhinitis		Stuffy nose	

Medicine Details:

AROPAX (Other drug)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 07/01/1997	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 30/01/1997	Stopped:	02/02/1997
VALIUM (Suspected)		Reason: Anxiety neurosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 29/01/1997	Stopped:	04/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of allergy to stelazine - swollen tongue



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115192

Seq: 1

Gender: M

Reported: 13/02/1997

Weight: 95.00

Hospitalisation:

Age: 37

Onset Date: 29/12/1996

DOB: 06/03/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state Pyrexia	Severe		Icu, drug stopped.

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.7 Gram	Daily	Oral
Batch:	Started: 01/06/1996	Stopped: 31/12/1996	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	8.0 Milligram	Daily	
Batch:	Started: 17/12/1996	Stopped: 31/12/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Cpk up to 800

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115370

Seq: 1

Gender: F

Reported: 18/02/1997

Weight: 100.00

Hospitalisation:

Age: 18Y

Onset Date: 07/02/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain		Sore breasts	
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

AURORIX (Other drug)		Reason: Depression	
	450.0 Milligram	Daily	
Batch:	Started: 01/04/1996	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped: 13/02/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Prolactin level 1785.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115917

Seq: 1

Gender: M

Reported: 12/03/1997

Weight:

Hospitalisation:

Age: 70Y

Onset Date: 22/01/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradykinesia Extrapyramidal disorder Headache Salivary hypersecretion Tremor			

Medicine Details:

TEMAZEPAM (Suspected)		Reason:	
	20.0 Milligram	1 time	
Batch:	Started: 21/01/1997	Stopped: 22/01/1997	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	1.0 Milligram	Daily	
Batch:	Started: 22/01/1997	Stopped: 23/01/1997	
HALOPERIDOL (Suspected)		Reason:	
	6.0 Milligram	Daily	
Batch:	Started: 05/01/1997	Stopped: 19/01/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115934

Seq: 1

Gender: M

Reported: 12/03/1997

Weight:

Hospitalisation:

Age: 78

Onset Date:

DOB: 31/10/1918

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

DIGOXIN (Other drug)	Reason:
62.5 Milligram Daily	
Batch:	Started: L TERM Stopped:
RANITIDINE (Other drug)	Reason:
300.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
FRUSEMIDE (Other drug)	Reason:
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ENALAPRIL MALEATE (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: 22/01/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 115934

Seq: 1

Gender: M

Reported: 12/03/1997

Weight:

Hospitalisation:

Age: 78

Onset Date:

DOB: 31/10/1918

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

1.0 Milligram

Daily

Batch:

Started: 05/02/1997

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 116075

Seq: 1

Gender: F

Reported: 18/03/1997

Weight: 58.00

Hospitalisation:

Age: 36Y

Onset Date: 08/03/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ageusia Somnolence			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 07/03/1997	Stopped: 09/03/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 116683

Seq: 1

Gender: M

Reported: 10/04/1997

Weight:

Hospitalisation:

Age: 75Y

Onset Date: 08/03/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
		3.0 Dose Unspecified Daily	
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 116684

Seq: 1

Gender: M

Reported: 14/04/1997

Weight: 90.00

Hospitalisation:

Onset Date: 04/04/1997

Age: 69Y

Outcome: Recovered

DOB:

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression			
Hyperkinesia			

Medicine Details:

PERMAX (Other drug)	Reason:
0.3 Milligram Daily	
Batch:	Started: Stopped:
ARTANE (Other drug)	Reason:
2.0 Milligram Daily	
Batch:	Started: Stopped:
MADOPAR (Other drug)	Reason:
2.5 Dose Unspecified Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
2.0 Milligram Daily	
Batch:	Started: 20/03/1997 Stopped: 04/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 116968 **Seq:** 1 **Gender:** M
Reported: 21/04/1997 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 12
Onset Date: 22/03/1997 **DOB:** 22/07/1984
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive sedation	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 06/03/1997	Stopped: 22/03/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117343

Seq: 1

Gender: M

Reported: 08/05/1997

Weight:

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Pain			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.0	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Neurologist review: no alteration in tone, minor weakness obduction right little finger, no sensory disturbance.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117489

Seq: 1

Gender: M

Reported: 12/05/1997

Weight:

Hospitalisation:

Age: 45

Onset Date: 14/02/1997

DOB: 27/07/1951

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			

Medicine Details:

PARACETAMOL (Other drug)		Reason: Other disturbance of sensation	
Oral application	1.0 Gram	As necessary	Oral
Batch:	Started:	L TERM	Stopped:
FLUPHENAZINE NOS (Other drug)		Reason: Unspecified psychosis	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 20/01/1997	Stopped: 14/02/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

Age: 62Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Purpura Anaemia Arthralgia Hepatitis Influenza like illness Pyrexia Thrombocytopenia		Splinter haemorrhage,petechial rash on lower limbs	

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 30	25/02/1997	24	
	ALT = SGPT	0 - 30	13/04/1997	50	
	ALT = SGPT	0 - 30	18/04/1997	49	
	ALT = SGPT	0 - 30	14/04/1997	41	
	ALT = SGPT	0 - 30	07/05/1997	20	
	ALT = SGPT	0 - 30	23/04/1997	34	
	AST = SGOT	0 - 30	25/02/1997	28	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0 - 30	13/04/1997	52	
	AST = SGOT	0 - 30	18/04/1997	59	
	AST = SGOT	0 - 30	23/04/1997	26	
	AST = SGOT	0 - 30	14/04/1997	41	
	AST = SGOT	0 - 30	07/05/1997	25	
	Bilirubin	0 - 20	25/02/1997	10	
	Bilirubin	0 - 20	13/04/1997	16	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0 - 20	14/04/1997	12	
	Bilirubin	0 - 20	18/04/1997	7	
	Bilirubin	0 - 20	23/04/1997	7	
	Bilirubin	0 - 20	07/05/1997	11	
	Creatinine	0 - 6MG/L	15/04/1997	218	
	Creatinine	0 - 6MG/L	23/04/1997	3	
	Creatinine	0 - 6MG/L	18/04/1997	58	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	0 - 60	25/02/1997	23	
	GGT = SGGT =	0 - 60	18/04/1997	166	
	GGT = SGGT =	0 - 60	23/04/1997	109	
	GGT = SGGT =	0 - 60	14/04/1997	147	
	GGT = SGGT =	0 - 60	13/04/1997	159	
	GGT = SGGT =	0 - 60	07/05/1997	41	
	Haemoglobin	130 - 175	25/02/1997	153	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin	130 - 175	23/04/1997	139	
	Haemoglobin	130 - 175	18/04/1997	136	
	Haemoglobin	130 - 175	14/04/1997	122	
	Haemoglobin	130 - 175	13/04/1997	129	
	Haemoglobin	130 - 175	17/03/1997	165	
	Platelets	150 - 450	25/02/1997	142	
	Platelets	150 - 450	17/03/1997	199	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	150 - 450	14/04/1997	94	
	Platelets	150 - 450	23/04/1997	248	
	Platelets	150 - 450	18/04/1997	231	
	Platelets	150 - 450	13/04/1997	86	
	SAP = ALP	35 - 120	25/02/1997	90	
	SAP = ALP	35 - 120	13/04/1997	178	
	SAP = ALP	35 - 120	14/04/1997	165	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117527
Reported: 13/05/1997

Seq: 1

Gender: M
Weight: 80.00
Age: 62Y

Hospitalisation:

Onset Date: 11/04/1997
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)		Reason: Diabetes mellitus	
	5.0 Milligram	Daily	
Batch:	Started: 01/01/1997	Stopped:	CONTIN
QUININE (Suspected)		Reason: Pain in limb	
	300.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 07/03/1997	Stopped:	13/04/1997
SODIUM VALPROATE (Suspected)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 04/04/1997	Stopped:	13/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	35 - 120	18/04/1997	218	
	SAP = ALP	35 - 120	23/04/1997	130	
	SAP = ALP	35 - 120	07/05/1997	195	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117605
Reported: 15/05/1997

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Dysarthria Affect lability Depression Headache		Bad stomach pains Word slurring	

Medicine Details:

DEPO-PROVERA (Suspected)		Reason: Contraception	
Injection	150.0 Milligram	Monthly	Intramuscular
Batch:	Started: 01/01/1992	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
VIGABATRIN (Suspected)		Reason:	
Tablet	1.5 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117605
Reported: 15/05/1997

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

OMEPRAZOLE (Suspected)		Reason:	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOBAZAM (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DUPHALAC (Suspected)		Reason:	
Oral Liquid	20.0 Millilitre	Daily	Oral
Batch:	Started:	Stopped:	
PREDNISOLONE (Suspected)		Reason:	
Oral application	5.0 Milligram	Alternate days	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117804

Seq: 1

Gender: F

Reported: 23/05/1997

Weight: 70.00

Hospitalisation:

Onset Date: 10/03/1997

Age: 37Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	NR: 50 - 500			Prolactin level: 5500

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117897

Seq: 1

Gender: F

Reported: 27/05/1997

Weight: 60.00

Hospitalisation:

Onset Date: 21/05/1997

Age: 12Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Continuing risperidone with cogentin

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 20/05/1997	Stopped:	
RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	500.0 Microgram	Daily	Oral
Batch:	Started: 21/05/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous allergy to fluoxetine=urticaria, sertraline=blurred vision.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117973

Seq: 1

Gender: F

Reported: 30/05/1997

Weight: 65.00

Hospitalisation:

Onset Date: 19/05/1997

Age: 70Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria Dysphagia Dyspnoea Face oedema		Difficulty with speech	Benztropine, hydrocortisone, promethazine

Medicine Details:

PARACETAMOL (Other drug)		Reason:
	0.0	As necessary
Batch:	Started:	Stopped:
PHENELZINE SULPHATE (Suspected)		Reason: Depression
	30.0 Milligram	Daily
Batch:	Started: 02/05/1997	Stopped: 21/05/1997
ZOCOR (Suspected)		Reason: Othr&unspec metabolic diseases
	10.0 Milligram	Daily
Batch:	Started: 01/01/1995	Stopped:
RISPERIDONE (Suspected)		Reason: Depression
	1.0 Milligram	Daily
Batch:	Started: 12/05/1997	Stopped: 20/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No known allergies the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 117978

Seq: 1

Gender: M

Reported: 30/05/1997

Weight: 75.00

Hospitalisation:

Age: 53Y

Onset Date: 31/03/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flatulence			
Insomnia			
Nausea			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Schizophrenia
0.0	
Batch:	Started: 12/03/1997 Stopped: 12/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118020

Seq: 1

Gender: F

Reported: 03/06/1997

Weight: 60.00

Hospitalisation:

Age: 32Y

Onset Date: 14/05/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Dizziness		Stiffness	Artane

Medicine Details:

EPILIM (Other drug)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started: 01/04/1997	Stopped:	
PROZAC (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118102 **Seq:** 1 **Gender:** F
Reported: 05/06/1997 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoventilation			Risperidone course ceased

Medicine Details:

EPILIM (Other drug)		Reason:	
	800.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LASIX (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	
TRANSIDERM-NITRO (Other drug)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
	50.0 Microgram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sensitive to serenace/risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118102

Seq: 1

Gender: F

Reported: 05/06/1997

Weight:

Hospitalisation: Admitted to hospital

Age:

Onset Date:

DOB:

Outcome: Recovered with sequelae

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

0.0

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Sensitive to serenace/risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118149
Reported: 06/06/1997

Seq: 1

Gender: F
Weight: 30.00

Hospitalisation:

Onset Date: 25/05/1997
Outcome: Recovered

Age: 79Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression			

Medicine Details:

DIGOXIN (Other drug)	Reason: Congestive heart failure
62.5 Microgram Daily	
Batch:	Started: L TERM Stopped: CONTIN
LISINAPRIL (Other drug)	Reason: Congestive heart failure
2.5 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
RANITIDINE (Other drug)	Reason: Other diseases of esophagus
360.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
HALOPERIDOL (Other drug)	Reason:
1.0 Milligram Daily	
Batch:	Started: 01/05/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118149

Seq: 1

Gender: F

Reported: 06/06/1997

Weight: 30.00

Hospitalisation:

Age: 79Y

Onset Date: 25/05/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

0.0

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118176

Seq: 1

Gender: F

Reported: 11/06/1997

Weight:

Hospitalisation:

Age: 48Y

Onset Date: 04/04/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Dyspnoea with minimal exertion	

Medicine Details:

MODECATE (Other drug)		Reason: Unspecified psychosis	
	37.5 Milligram	Monthly	
Batch:	Started:	L TERM	Stopped:
BENZTROPINE MESYLATE (Other drug)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started: 24/03/1997	Stopped:	11/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Breathlessness investigated - no cause found.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118370

Seq: 1

Gender: M

Reported: 18/06/1997

Weight: 79.00

Hospitalisation:

Age: 17Y

Onset Date: 08/04/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	12.0 Milligram	Daily	
Batch:	Started: 05/02/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118427

Seq: 1

Gender: F

Reported: 20/06/1997

Weight:

Hospitalisation:

Age: 33Y

Onset Date: 07/06/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
50.0 Milligram		Daily	
Batch:	Started: 11/12/1996	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
1.0 Milligram		Daily	
Batch:	Started: 26/05/1997	Stopped: 12/06/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118428

Seq: 1

Gender: F

Reported: 20/06/1997

Weight: 53.00

Hospitalisation:

Age: 67Y

Onset Date: 02/06/1997

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Severe		

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug)		Reason:	
	150.0 Microgram	Daily	
Batch:	Started: 01/01/1991	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 09/05/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history of tarditive dyskinesia the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118491

Seq: 1

Gender: F

Reported: 24/06/1997

Weight:

Hospitalisation:

Age: 47Y

Onset Date: 04/05/1997

DOB:

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice		Mixed hepatocellular & cholestatic jaundice.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 07/04/1997	Stopped: 27/05/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cholelithiasis present when risperdal started. patient rechallenged 2 weeks after initial suspension of drug. Lft raised again.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118537

Seq: 1

Gender: F

Reported: 25/06/1997

Weight:

Hospitalisation:

Age: 32Y

Onset Date: 11/06/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Erythema annulare over trunk and some limbs.	

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)		Reason: Unspecified psychosis	
0.0			
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1997	Stopped: 19/06/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118680

Seq: 1

Gender: M

Reported: 30/06/1997

Weight:

Hospitalisation:

Age: 61Y

Onset Date: 23/02/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dementia		Organic brain syndrome	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
CLONAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1996	Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason: Other&unspecified epilepsy	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 13/11/1996	Stopped:	05/02/1997
BENZHEXOL HYDROCHLORIDE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 08/02/1997	Stopped:	07/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clopixol-acuphase taken at 50mg every 3 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118680

Seq: 1

Gender: M

Reported: 30/06/1997

Weight:

Hospitalisation:

Age: 61Y

Onset Date: 23/02/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 24/06/1996	Stopped: 04/02/1997	
CLOPIXOL-ACUPHASE (Suspected)		Reason: Unspecified psychosis	
Injection	50.0 Milligram	Cyclical	Intramuscular
Batch:	Started: 07/02/1997	Stopped: 01/03/1997	

Laboratory Investigations:

Additional Information:

Clopixol-acuphase taken at 50mg every 3 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 118835

Seq: 1

Gender: M

Reported: 04/07/1997

Weight: 90.00

Hospitalisation:

Onset Date: 31/05/1997

Age: 33Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	02/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119015

Seq: 1

Gender: F

Reported: 10/07/1997

Weight:

Hospitalisation:

Age: 39Y

Onset Date: 25/06/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Increased appetite Orthostatic hypotension Salivary hypersecretion			Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started: 17/06/1997	Stopped: 27/06/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sob occurred with dosage increase of risperidone from 2mg bd to 3mg bd.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119230

Seq: 1

Gender: M

Reported: 17/07/1997

Weight:

Hospitalisation:

Age: 83

Onset Date:

DOB: 04/09/1913

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Risperidone ceased

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	
AMOXICILLIN-POTASSIUM CLAVULANATE (Other drug)		Reason:	
	3.0 Dose Unspecified	Daily	
Batch:	Started: 16/06/1997	Stopped: 20/06/1997	
NYSTATIN (Other drug)		Reason:	
	4.0 Millilitre	Daily	
Batch:	Started: 16/06/1997	Stopped:	
AMPICILLIN (Other drug)		Reason:	
Injection	3.0 Gram	Daily	Intravenous
Batch:	Started: 13/06/1997	Stopped: 16/06/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119230

Seq: 1

Gender: M

Reported: 17/07/1997

Weight:

Hospitalisation:

Age: 83

Onset Date:

DOB: 04/09/1913

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

1.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119353

Seq: 1

Gender: M

Reported: 23/07/1997

Weight:

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Puffy face	

Medicine Details:

ALCOHOL (Interaction)		Reason:	
		0.0	
Batch:	Started:	Stopped:	
RISPERIDONE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119381

Seq: 1

Gender: F

Reported: 23/07/1997

Weight:

Hospitalisation:

Age: 11Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin discolouration Constipation Epistaxis		Transient unusual discolouration of skin	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 01/12/1996	Stopped: 28/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119442
Reported: 25/07/1997

Seq: 1

Gender: M
Weight: 103.00
Age: 67Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myopathy		Moderately severe proximal muscle weakness	
Extrapyramidal disorder			

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Other drug)	Reason: Disturbance of sleep
125.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram Daily	
Batch:	Started: 01/01/1995 Stopped: 05/02/1997
CLONAZEPAM (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram Daily	
Batch:	Started: 01/01/1994 Stopped: 05/02/1997
PERIACTIN (Suspected)	Reason: Unspecified schizophrenia
8.0 Milligram Daily	
Batch:	Started: 01/01/1995 Stopped: 05/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase				Ck =400 ck returned to normal by 14/05/1997

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119754

Seq: 1

Gender: F

Reported: 08/08/1997

Weight:

Hospitalisation:

Age: 81Y

Onset Date: 25/07/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Cessation of sertraline. observation/symptomatic treatment

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
2.0 Milligram		Daily	
Batch:	Started: 09/07/1997	Stopped: 28/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous history allergic reaction to paroxetine 14/07/1997 truncal rash increased ige



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119760

Seq: 1

Gender: M

Reported: 08/08/1997

Weight: 60.00

Hospitalisation:

Age:

Onset Date: 23/07/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Cessation of risperidone

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	21/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms relieved by cessation. after 1 week resuming again at 0.5mg three times a day. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 119963

Seq: 1

Gender: F

Reported: 15/08/1997

Weight:

Hospitalisation:

Age: 32Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis
Tablet	0.0	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 120324

Seq: 1

Gender: M

Reported: 26/08/1997

Weight:

Hospitalisation:

Age: 76Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria			Ceased risperidone.

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 120325

Seq: 1

Gender: M

Reported: 26/08/1997

Weight:

Hospitalisation:

Age: 76Y

Onset Date: 14/07/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus			Pinetarsol

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 09/07/1997	Stopped: 13/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 120581 **Seq:** 1 **Gender:** F
Reported: 05/09/1997 **Weight:** 84.00
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 16/05/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Hypothermia			Admitted to icu, ventilation and ionotropes, risperdone ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 09/05/1997	Stopped: 16/05/1997	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 21/04/1997	Stopped: 04/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Commenced risperidone 21/4/97 which sertraline was added, on 16/5/97 patient suffered symptoms and was admitted to icu, recovered. readmitted to hospital 24/6/97 suffering same reaction, risperidone was ceased 4/7/97 but only partial improvement.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 120723
Reported: 12/09/1997
Hospitalisation:
Onset Date: 18/05/1997
Outcome: Recovered

Seq: 1

Gender: M
Weight: 65.00
Age: 23Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood pressure fluctuation Supraventricular tachycardia Agitation Blood creatine phosphokinase incr Hallucination Hyperthermia malignant		Increased temperature to over 42c Irregular blood pressure 200/100 to 40/30 Svt 150-170 bpm	

Medicine Details:

PARACETAMOL (Suspected)		Reason:	
Oral application	10.0 Gram	1 time	Oral
Batch:	Started: 17/05/1997	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 14/05/1997	Stopped: 16/05/1997	
EPILIM (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped: 17/05/1997	
COGENTIN (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped: 17/05/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		17/05/1997	213	
	Creatine		18/05/1997	161	
	Creatine		19/05/1997	160	
	Creatine		20/05/1997	471	
	Creatine		21/05/1997	754	
	Creatine		22/05/1997	1142	
	Creatine		24/05/1997	361	

Additional Information:

The patient has a history of neuroleptic malignant syndrome on typical antipsychotics the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 120723

Seq: 1

Gender: M

Reported: 12/09/1997

Weight: 65.00

Hospitalisation:

Age: 23Y

Onset Date: 18/05/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Required intubation, ventilation and paralysis and was treated with dantrolene and bromocriptine, admission to intensive care unit for 6 days.
Tremor			

Medicine Details:

PARVOLEX (Suspected)		Reason: Adv effect aniline derivatives	
Injection	20.0 Gram	Daily	Intravenous
Batch:	Started: 17/05/1997	Stopped: 20/05/1997	
RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped: 12/05/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		25/05/1997	144	
	Creatine		26/05/1997	104	

Additional Information:

The patient has a history of neuroleptic malignant syndrome on typical antipsychotics the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121451

Seq: 1

Gender: F

Reported: 09/10/1997

Weight:

Hospitalisation:

Age:

Onset Date: 15/09/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Seborrhoea		Greasy skin over scalp/forehead/upper chest & back	
Pruritus			Ceased risperdal.
Rash			

Medicine Details:

TRIPHASIL (Other drug)		Reason: Contraception	
Tablet	1.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram Daily	Oral	
Batch:	Started: 09/09/1997	Stopped: 18/09/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121453

Seq: 1

Gender: U

Reported: 09/10/1997

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal seizures.	

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Other&unspecified epilepsy	
	0.0		
Batch:	Started:	Stopped:	CONTIN
PHENYTOIN SODIUM (Other drug)		Reason: Other&unspecified epilepsy	
Capsule	0.0	Oral	
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Grand mal seizures 4 days after increasing risperdal dose from 2mg to 4mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121569

Seq: 1

Gender: M

Reported: 13/10/1997

Weight: 50.00

Hospitalisation:

Age: 13Y

Onset Date: 29/09/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia Confusional state Depersonalisation Drug withdrawal syndrome Fatigue Sensory disturbance			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
	2.0 Milligram Daily
Batch:	Started: 20/08/1997 Stopped: 28/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121680

Seq: 1

Gender: M

Reported: 16/10/1997

Weight:

Hospitalisation:

Age:

Onset Date: 10/09/1997

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			
Left ventricular failure			

Medicine Details:

ZANTAC (Suspected)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
PREDNISOLONE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
PARACETAMOL (Suspected)		Reason:	
	6.0 Gram	Daily	
Batch:	Started:	L TERM	Stopped:
PROGOUT (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had long-standing stable ihd/af. patient died 10/9/97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121680

Seq: 1

Gender: M

Reported: 16/10/1997

Weight:

Hospitalisation:

Age:

Onset Date: 10/09/1997

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

DIGOXIN (Suspected)

Reason:

2.0 Dose Unspecified Daily

Batch:

Started:

L TERM

Stopped:

RISPERIDONE (Suspected)

Reason:

1.0 Milligram Daily

Batch:

Started: 08/09/1997

Stopped:

Laboratory Investigations:

Additional Information:

Patient had long-standing stable ihd/af. patient died 10/9/97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121883
Reported: 24/10/1997

Seq: 1

Gender: F
Weight: 62.00
Age: 82Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Slow onset of muscular rigidity.	Cogentin, valium.

Medicine Details:

CAPTOPRIL (Other drug)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
LASIX (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 07/12/1995	Stopped:	28/02/1997
EPILIM (Suspected)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 07/12/1995	Stopped:	28/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 121969 **Seq:** 1 **Gender:** M
Reported: 28/10/1997 **Weight:** 67.00
Hospitalisation: Admitted to hospital **Age:** 26Y
Onset Date: 08/09/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Polydipsia Rash Skin exfoliation			Ceased risperidone.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: 28/07/1997
CARBAMAZEPINE (Suspected)	Reason:
0.0	
Batch:	Started: 01/08/1997 Stopped: 08/09/1997
CEFACLOX MONOHYDRATE (Suspected)	Reason: Ac upr resp inf,mult,unsp stes
750.0 Milligram Daily	
Batch:	Started: Stopped: 04/09/1997
RISPERIDONE (Suspected)	Reason: Schizophrenia
3.0 Milligram Daily	
Batch:	Started: Stopped: 18/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Skin biopsy				Skin biopsy consistant with drug eruption

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122269

Seq: 1

Gender: F

Reported: 11/11/1997

Weight: 70.00

Hospitalisation:

Onset Date: 14/10/1997

Age: 86Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

FRUSEMIDE (Other drug)		Reason:	
Oral application	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LANOXIN PG (Other drug)		Reason:	
Oral application	62.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CARBAMAZEPINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 36	14/10/1997	14	
	ALT = SGPT	0 - 36	15/10/1997	15	
	ALT = SGPT	0 - 36	24/10/1997	10	
	AST = SGOT	11 - 32	14/10/1997	7	
	AST = SGOT	11 - 32	24/10/1997	11	
	AST = SGOT	11 - 32	15/10/1997	13	
	Bilirubin	0 - 20	14/10/1997	16	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122269

Seq: 1

Gender: F

Reported: 11/11/1997

Weight: 70.00

Hospitalisation:

Age: 86Y

Onset Date: 14/10/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

WARFARIN SODIUM (Other drug)			Reason:		
3.0 Milligram			Daily		
Batch:	Started:		Stopped:		
AMIODARONE HYDROCHLORIDE (Other drug)			Reason:		
100.0 Milligram			Daily		
Batch:	Started: 17/09/1997		Stopped:		
IMDUR (Other drug)			Reason:		
60.0 Milligram			Daily		
Batch:	Started:		Stopped:		
SLOW-K (Other drug)			Reason:		
2.4 Gram			Daily		
Batch:	Started:		Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0 - 20	15/10/1997	14	
	Bilirubin	0 - 20	24/10/1997	16	
	GGT = SGGT =	10 - 37	14/10/1997	417	
	GGT = SGGT =	10 - 37	15/10/1997	444	
	GGT = SGGT =	10 - 37	24/10/1997	242	
	SAP = ALP	30 - 130	14/10/1997	167	
	SAP = ALP	30 - 130	15/10/1997	169	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122269

Seq: 1

Gender: F

Reported: 11/11/1997

Weight: 70.00

Hospitalisation:

Age: 86Y

Onset Date: 14/10/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PARACETAMOL (Other drug)		Reason:	
	4.0 Gram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 03/10/1997	Stopped: 21/10/1997	
METOLAZONE (Suspected)		Reason:	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started:	Stopped: 17/09/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30 - 130	24/10/1997	114	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122641

Seq: 1

Gender: M

Reported: 20/11/1997

Weight: 100.00

Hospitalisation:

Age: 30Y

Onset Date: 24/10/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Hyperkinesia		Stiff arms and sense of restlessness.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	0.0		
Batch:	Started:	Stopped: 22/10/1997	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 23/10/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122765

Seq: 1

Gender: M

Reported: 25/11/1997

Weight: 51.00

Hospitalisation:

Onset Date: 17/11/1997

Age: 34Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic tongue, curling upwards and protruding	Cogentin imi 2mg.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started: 14/11/1997	Stopped:	
RISPERDAL (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 16/11/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122913

Seq: 1

Gender: F

Reported: 01/12/1997

Weight: 50.00

Hospitalisation:

Age: 68Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus Rash maculo-papular		Rash all areas of body.	Ceased risperidone.

Medicine Details:

OESTROGENS NOS (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
CAPTOPRIL (Other drug)	Reason:
150.0 Milligram Daily	
Batch:	Started: Stopped:
METOPROLOL TARTRATE (Other drug)	Reason:
300.0 Milligram Daily	
Batch:	Started: Stopped:
IMDUR (Other drug)	Reason:
60.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 122913

Seq: 1

Gender: F

Reported: 01/12/1997

Weight: 50.00

Hospitalisation:

Age: 68Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

OROXINE (Other drug)		Reason:	
	100.0 Microgram	Daily	
Batch:	Started:	Stopped:	
ORUVAIL SR (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Paranoia	
	1.0 Milligram	Daily	
Batch:	Started: 01/06/1997	Stopped: 28/11/1997	

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123544 **Seq:** 1 **Gender:** M
Reported: 18/12/1997 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 51
Onset Date: 15/08/1997 **DOB:** 11/07/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified neurosis
3.0 Milligram	Daily
Batch:	Started: 14/08/1997 Stopped: 15/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Priapism developed after the second dose of risperdal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123771

Seq: 1

Gender: F

Reported: 05/01/1998

Weight: 77.00

Hospitalisation:

Age: 46Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Bronchopneumonia	
Pulmonary oedema			

Medicine Details:

MS CONTIN (Other drug)		Reason: Pain	
Oral application	320.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
STELAZINE (Other drug)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 01/10/1997	
LARGACTIL (Other drug)		Reason:	
Oral application	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 01/10/1997	
ZOLOFT (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient died in october 1997.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123771

Seq: 1

Gender: F

Reported: 05/01/1998

Weight: 77.00

Hospitalisation:

Age: 46Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ALODORM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ANTENEX (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 02/10/1997	Stopped: 05/10/1997	

Laboratory Investigations:

Additional Information:

The patient died in october 1997.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123771

Seq: 1

Gender: F

Reported: 05/01/1998

Weight: 77.00

Hospitalisation:

Age: 46Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason:

Tablet

4.0 Milligram

Daily

Oral

Batch:

Started: 05/10/1997

Stopped:

Laboratory Investigations:

Additional Information:

The patient died in october 1997.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123810 **Seq:** 1 **Gender:** M
Reported: 05/01/1998 **Weight:** 25.00
Hospitalisation: Admitted to hospital **Age:** 7Y
Onset Date: 06/09/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Malaise Pyrexia			G-csf and antibiotics.

Medicine Details:

RITALIN (Other drug)	Reason:
30.0 Milligram Daily	
Batch:	Started: 01/02/1997 Stopped: CONTIN
CARBAMAZEPINE (Suspected)	Reason:
200.0 Milligram Daily	
Batch:	Started: 15/08/1997 Stopped: 26/08/1997
CARBAMAZEPINE (Suspected)	Reason:
300.0 Milligram Daily	
Batch:	Started: 26/08/1997 Stopped: 06/09/1997
RISPERIDONE (Suspected)	Reason:
2.0 Milligram Daily	
Batch:	Started: 06/08/1997 Stopped: 08/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 123910

Seq: 1

Gender: M

Reported: 13/01/1998

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Tachycardia		Prolonged qt interval	Atenolol

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 15/05/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 124574

Seq: 1

Gender: F

Reported: 02/02/1998

Weight:

Hospitalisation:

Age: 18Y

Onset Date: 22/10/1997

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Galactorrhoea		Elevated prolactin	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 15/09/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	50-500 MIU/L	22/10/1997	2739	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 124579
Reported: 02/02/1998

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 15/07/1997

Age: 36

DOB: 23/11/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain			
Hyperprolactinaemia			

Medicine Details:

CYCLOPHOSPHAMIDE (Suspected)	Reason: Systemic lupus erythematosus
0.0	
Batch:	Started: Stopped:
MOCLOBEMIDE (Suspected)	Reason: Depression
Tablet 450.0 Milligram Daily Oral	
Batch: Started: 01/10/1996 Stopped: CONTIN	
RISPERDAL (Suspected)	Reason: Unspecified psychosis
Tablet 500.0 Microgram Daily Oral	
Batch: Started: 01/10/1996 Stopped: CONTIN	
PREDNISONE (Suspected)	Reason: Systemic lupus erythematosus
50.0 Milligram Daily	
Batch: Started: Stopped: CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(46-622)	15/07/1997	838	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 124586

Seq: 1

Gender: F

Reported: 02/02/1998

Weight: 72.00

Hospitalisation:

Age: 29

Onset Date: 15/04/1996

DOB: 08/11/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Amenorrhoea		Prolactin increased	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/04/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(70-566)	26/03/1997	2259	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 124673

Seq: 1

Gender: M

Reported: 04/02/1998

Weight: 56.00

Hospitalisation:

Age: 17Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Dyskinesia Dizziness Dyspnoea Dystonia		Hr - 160 Tongue protruding from mouth	Benztropine 1mg

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
Oral application	2.0 Milligram Daily Oral
Batch:	Started: 07/10/1997 Stopped: 09/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125013

Seq: 1

Gender: F

Reported: 16/02/1998

Weight:

Hospitalisation:

Age: 37

Onset Date: 31/03/1997

DOB: 03/04/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia Dry skin Visual disturbance		Hair loss	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 15/03/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No obvious thinning on examination; no loss of other facial hair. differential diagnosis: 1. within normal range of hair loss with family history of early hair loss in maternal grandmother; 2. drug effect; 3. exclude hypothyroidism. history of irritable bowel syndrome. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125140

Seq: 1

Gender: F

Reported: 20/02/1998

Weight:

Hospitalisation:

Age: 28Y

Onset Date: 15/08/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder		Increased and prolonged menstrual bleeding	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	0.0
Batch:	Started: 15/08/1997
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125317
Reported: 23/02/1998

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 47

Onset Date:

DOB: 21/06/1950

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Dizziness		Low bp	Ceased lasix, nefazodone and risperidone

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	10.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	50.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
OESTROGENS CONJUGATED (Other drug)		Reason: Menopausal symptoms	
Tablet	625.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
MS CONTIN (Other drug)		Reason: Pain	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has chronic back pain. stopped nefazodone and risperidone. reduced lasix to 20mg mane. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125317
Reported: 23/02/1998
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 47
DOB: 21/06/1950
Causality: Causality possible

Reaction Details:

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
LASIX (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 09/12/1997
NEFAZODONE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 09/12/1997	Stopped:	28/01/1998
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.0	Daily	Oral
Batch:	Started: 18/12/1997	Stopped:	20/12/1997

Laboratory Investigations:

Additional Information:

Has chronic back pain. stopped nefazodone and risperidone. reduced lasix to 20mg mane. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125373

Seq: 1

Gender: M

Reported: 27/02/1998

Weight: 18.00

Hospitalisation:

Age: 4Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epistaxis		Recurrent nose bleeds	
Anaemia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125484

Seq: 1

Gender: M

Reported: 03/03/1998

Weight: 65.00

Hospitalisation:

Age: 19Y

Onset Date: 19/06/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia Breast pain		Gynaecomastia bilateral	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
4.0 Milligram	Daily
Batch:	Started: 20/03/1996 Stopped: 19/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125543

Seq: 1

Gender: U

Reported: 05/03/1998

Weight:

Hospitalisation:

Age:

Onset Date: 31/01/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125601

Seq: 1

Gender: F

Reported: 06/03/1998

Weight: 61.00

Hospitalisation:

Age: 46Y

Onset Date: 31/01/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthritis		Bilateral shoulder capsulitis	Cortisol injection.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started: 02/05/1997	Stopped: 11/02/1998	
RISPERIDONE (Suspected)		Reason:	
	6.0 Milligram	Daily	
Batch:	Started: 09/05/1997	Stopped: 01/01/1998	
BENZTROPINE MESYLATE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 02/05/1997	Stopped: 02/01/1998	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt allergic to penicillin - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125658
Reported: 09/03/1998
Hospitalisation:
Onset Date: 31/12/1998
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 79Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Postural hypotension resulting in falls.	Risperidone ceased

Medicine Details:

INDERAL (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
COLGOUT (Other drug)		Reason:	
	3.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped:	02/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125879 **Seq:** 1 **Gender:** F
Reported: 17/03/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 77Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state Hepatic function abnormal Hypertonia Hypochloraemia Hypomagnesaemia Hyponatraemia Neuroleptic malignant syndrome Pyrexia			Treatment: valium, gentamicin and ciproxin

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 25/02/1998
TRYPTANOL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 25/02/1998
HALOPERIDOL (Suspected)	Reason: Reactive confusion
2.0 Milligram Daily	
Batch:	Started: 25/02/1998 Stopped: 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<30 U/L	13/03/1994	8	
	ALT = SGPT	<30 U/L	22/02/1998	30	
	ALT = SGPT	<30 U/L	02/03/1998	42	
	AST = SGOT	<30 U/L	13/03/1994	17	
	AST = SGOT	<30 U/L	22/02/1998	48	
	AST = SGOT	<30 U/L	02/03/1998	70	
	Bilirubin	<20 UMOL/L	13/03/1994	5	

Additional Information:

Patient was treated for uti. died on 08/03/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125879

Seq: 1

Gender: F

Reported: 17/03/1998

Weight:

Hospitalisation: Admitted to hospital

Age: 77Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped: 25/02/1998	
TRYPTANOL (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped: 25/02/1998	
HALOPERIDOL (Suspected)		Reason: Reactive confusion	
2.0 Milligram		Daily	
Batch:	Started: 25/02/1998	Stopped: 26/02/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	<20 UMOL/L	22/02/1998	27	
	Bilirubin	<20 UMOL/L	02/03/1998	12	
	Chloride	100 - 111	13/03/1994	92	
	Chloride	100 - 111	22/02/1998	85	
	Chloride	100 - 111	02/03/1998	122	
	Creatine	<200 U/L	22/02/1998	1190	
	Creatine	<200 U/L	02/03/1998	1159	

Additional Information:

Patient was treated for uti. died on 08/03/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125879 **Seq:** 1 **Gender:** F
Reported: 17/03/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 77Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 25/02/1998
TRYPTANOL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 25/02/1998
HALOPERIDOL (Suspected)	Reason: Reactive confusion
2.0 Milligram Daily	
Batch:	Started: 25/02/1998 Stopped: 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	<200 U/L	04/03/1998	1875	
	Creatine	<200 U/L	01/03/1998	831	
	GGT = SGGT =	<35 U/L	13/03/1994	25	
	GGT = SGGT =	<35 U/L	02/03/1998	57	
	GGT = SGGT =	<35 U/L	22/02/1998	65	
	LDH	<400 U/L	22/02/1998	652	
	LDH	<400 U/L	04/03/1998	677	

Additional Information:

Patient was treated for uti. died on 08/03/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125879

Seq: 1

Gender: F

Reported: 17/03/1998

Weight:

Hospitalisation: Admitted to hospital

Age: 77Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped: 25/02/1998	
TRYPTANOL (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped: 25/02/1998	
HALOPERIDOL (Suspected)		Reason: Reactive confusion	
2.0 Milligram		Daily	
Batch:	Started: 25/02/1998	Stopped: 26/02/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Magnesium	0.70 - 1.00	22/02/1998	0.63	
	SAP = ALP	35 - 120 U/L	13/03/1994	127	
	SAP = ALP	35 - 120 U/L	02/03/1998	68	
	SAP = ALP	35 - 120 U/L	22/02/1998	87	
	Sodium	136 - 145	13/03/1994	134	
	Sodium	136 - 145	22/02/1998	124	
	Sodium	136 - 145	02/03/1998	156	

Additional Information:

Patient was treated for uti. died on 08/03/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 125952

Seq: 1

Gender: M

Reported: 20/03/1998

Weight: 76.00

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Chewing movements	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 30/07/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 126363

Seq: 1

Gender: M

Reported: 01/04/1998

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 30/03/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia		Bradyarrhythmia	

Medicine Details:

TRANSIDERM-NITRO (Other drug)		Reason: Chron isch heart dis no hyper	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
PERMAX (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
TEGRETOL (Other drug)		Reason:	
	750.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 126363

Seq: 1

Gender: M

Reported: 01/04/1998

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 30/03/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecified schizophrenia

0.5 Dose Unspecified Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 126765

Seq: 1

Gender: M

Reported: 17/04/1998

Weight:

Hospitalisation:

Age: 19

Onset Date: 21/03/1998

DOB: 05/12/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Clonic tonic seizure	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 01/03/1997	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 15/03/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has no history of seizures. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127152

Seq: 1

Gender: M

Reported: 05/05/1998

Weight:

Hospitalisation:

Age: 27Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Lingual tardive dyskinesia	Risperdal ceased and olanzapine commenced

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started: 01/10/1997	Stopped: 13/03/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127200

Seq: 1

Gender: F

Reported: 06/05/1998

Weight: 98.00

Hospitalisation:

Onset Date: 31/08/1997

Age: 29Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Grossly raised prolactin levels.	
Menstrual disorder		Oligomenorrhoea	
Weight increased			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	
Batch:	Started: 01/02/1997	Stopped: 28/03/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recent negative mri scan excludes pituitary tumor. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127208

Seq: 1

Gender: M

Reported: 06/05/1998

Weight: 123.00

Hospitalisation:

Age: 31Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Genital ulceration		Penile meatus	
Hypertonia		Spasm in left leg and arm.	
Rash			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 24/04/1998	Stopped: 25/04/1998	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127345

Seq: 1

Gender: M

Reported: 13/05/1998

Weight:

Hospitalisation:

Age: 22

Onset Date: 25/03/1998

DOB: 28/07/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Neck spasms.	Benztropine 2mg and imi cogentin 2 mg regularly

Medicine Details:

SALBUTAMOL (Other drug)		Reason:	
Inhalation	2.0 Dose Unspecified	As necessary	Inhalation
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
	150.0 Milligram	1 time	
Batch:	Started: 23/03/1998	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	6.0 Milligram	Daily	
Batch:	Started: 18/03/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127395

Seq: 1

Gender: F

Reported: 12/05/1998

Weight:

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis Abdominal pain Anorexia Malaise Vomiting		Increased wcc's	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127398 **Seq:** 1 **Gender:** M
Reported: 12/05/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Bowel obstruction	Bowel surgery, needed colostomy.
Abscess			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	
Batch:	Started: 01/11/1996	Stopped:	CONTIN
PAROXETINE HYDROCHLORIDE (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started: 29/09/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127399 **Seq:** 1 **Gender:** M
Reported: 12/05/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 28Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Anorexia			
Nausea			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Paranoia	
	1.0 Milligram	Daily	
Batch:	Started: 17/01/1996	Stopped:	CONTIN
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
	25.0 Milligram	Daily	
Batch:	Started: 11/02/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127403
Reported: 13/05/1998
Hospitalisation:
Onset Date: 23/10/1997
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 86Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Severe	Increasing hypertension	
Extrapyramidal disorder		Severe parkinsonism	
Drug ineffective			

Medicine Details:

FERRO-GRADUMET (Other drug)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
EFEXOR (Other drug)		Reason: Depression	
	150.0 Milligram	Daily	
Batch:	Started: 17/05/1997	Stopped: 28/01/1998	
MOGADON (Other drug)		Reason: Specific disorders of sleep	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
TENORMIN (Other drug)		Reason: Essential benign hypertension	
	50.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127403

Seq: 1

Gender: M

Reported: 13/05/1998

Weight:

Hospitalisation:

Age: 86Y

Onset Date: 23/10/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified psychosis

0.0

Batch:

Started: 16/10/1997

Stopped:

Laboratory Investigations:

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127450

Seq: 1

Gender: F

Reported: 15/05/1998

Weight: 65.00

Hospitalisation:

Age: 35Y

Onset Date: 28/04/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Raised prolactin	
Galactorrhoea			
Hepatic function abnormal			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
Oral application	2.0 Milligram Daily Oral
Batch:	Started: 12/04/1998 Stopped: 05/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127461

Seq: 1

Gender: M

Reported: 18/05/1998

Weight: 80.00

Hospitalisation:

Age: 17Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharospasm	Required Visit to Doctor	Blepharospasm and frowning	
Tardive dyskinesia	Required Visit to Doctor	Movements of tongue, grimacing.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Other atyp forms schizophrenia	
	4.0 Milligram	Daily	
Batch:	Started: 01/01/1994	Stopped: 28/05/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127608

Seq: 1

Gender: F

Reported: 20/05/1998

Weight: 90.00

Hospitalisation:

Onset Date: 08/11/1997

Age: 18Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Stopped risperidone, will try nefazodone.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 01/10/1997	Stopped: 28/12/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		08/11/1997	121	
	AST = SGOT		08/11/1997	74	
	Creatine		08/11/1997	124	
	Creatinine		08/11/1997	85-> 90	
	GGT = SGGT =		08/11/1997	98	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127731

Seq: 1

Gender: M

Reported: 25/05/1998

Weight: 55.00

Hospitalisation:

Age: 22Y

Onset Date: 07/05/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Depersonalised feelings	Kemadrin 5mg bd.

Medicine Details:

NORDETTE NOS (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
3.0 Milligram Daily	
Batch:	Started: 05/05/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127734

Seq: 1

Gender: F

Reported: 25/05/1998

Weight:

Hospitalisation:

Age: 18Y

Onset Date: 08/11/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
KEMADRIN (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1997	Stopped:	28/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127736

Seq: 1

Gender: F

Reported: 25/05/1998

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder Metrorrhagia			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was started on risperidone one year ago. risperidone was increased to 16mg/day. dose was then steadily reduced to 6 mg/day. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127738

Seq: 1

Gender: M

Reported: 25/05/1998

Weight:

Hospitalisation:

Age: 16Y

Onset Date: 15/01/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
0.0	
Batch:	Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Oct 97: risperidone was started for psychosis in a 16 years old male patient. early 1998. memory impairment found on neurological testing. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127857

Seq: 1

Gender: F

Reported: 27/05/1998

Weight: 82.00

Hospitalisation:

Onset Date: 19/05/1998

Age: 54

DOB: 04/07/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash over abdomen and back - itchy redish rash.	Benadryl 50mg po tds
Pruritus			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
AMOXICILLIN SODIUM (Suspected)		Reason: Othr diseases of urinary tract	
Tablet	1.5 Gram	Daily	Oral
Batch:	Started: 19/05/1998	Stopped: 20/05/1998	
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 127898
Reported: 28/05/1998

Seq: 1

Gender: M
Weight: 54.00

Hospitalisation:

Onset Date: 15/05/1998
Outcome: Recovered

Age: 18Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Marked postural hypotension - 125/85 - 70/40	

Medicine Details:

RIVOTRIL (Other drug)	Reason:
Tablet	0.5 Milligram Daily Oral
Batch:	Started: 07/05/1998 Stopped:
COGENTIN (Other drug)	Reason:
Tablet	1.0 Milligram Daily Oral
Batch:	Started: 12/05/1998 Stopped:
SERENACE (Other drug)	Reason:
	5.0 Milligram Daily
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
	4.0 Milligram Daily
Batch:	Started: 14/05/1998 Stopped: 15/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128010

Seq: 1

Gender: M

Reported: 01/06/1998

Weight:

Hospitalisation:

Age: 30

Onset Date:

DOB: 10/10/1967

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Risperidone ceased

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
Tablet	0.0	Oral
Batch:	Started:	Stopped: 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128052

Seq: 1

Gender: M

Reported: 03/06/1998

Weight:

Hospitalisation:

Age: 44Y

Onset Date: 04/06/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Flushing		Recurrant hot flushes	Risperdal ceased

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 22/04/1997	Stopped: 08/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128269 **Seq:** 1 **Gender:** M
Reported: 10/06/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: 09/09/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal disorder		Crohn's disease	Total colectomy with formation of an ileostomy.

Medicine Details:

RISPERDAL (Suspected)	Reason: Schizophrenia
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 07/05/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128350 **Seq:** 1 **Gender:** F
Reported: 11/06/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 27
Onset Date: 28/03/1998 **DOB:** 14/12/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Opisthotonus Hypertonia Urinary retention Purpura Pyrexia Blood creatine phosphokinase incr Encephalopathy Leukocytosis Neuroleptic malignant syndrome		Arched back Muscle rigidity, arched back and jaw clenched No voiding Spontaneous bruising Up to 37.5 degrees	Dantrolene, amantadine and benzotropine.

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		28/03/1998	94000	
	Creatine		29/03/1998	41000	
	Creatinine		29/03/1998	0.17	
	Neutrophils		29/03/1998	13.3	
	White blood cells		29/03/1998	16.9	

Additional Information:

Pt has mild intellectual disability the dosage start date is not accurate but indicates that start occurred sometime during the year.
the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128350 **Seq:** 1 **Gender:** F
Reported: 11/06/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 27
Onset Date: 28/03/1998 **DOB:** 14/12/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment			

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	

Laboratory Investigations:

Additional Information:

Pt has mild intellectual disability the dosage start date is not accurate but indicates that start occurred sometime during the year.
the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128492

Seq: 1

Gender: F

Reported: 18/06/1998

Weight:

Hospitalisation:

Age: 75

Onset Date:

DOB: 17/10/1922

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue Dizziness		Lethargy Pre-syncope	Ceased thioridazine

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Unspecified psychosis
0.0	
Batch:	Started: Stopped:
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep
10.0 Milligram	As necessary
Batch:	Started: Stopped:
ATENOLOL (Suspected)	Reason: Otr&nos disord of heart rhythm
50.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN
CARTIA (Suspected)	Reason: Otr&nos disord of heart rhythm
100.0 Milligram	Daily
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128492

Seq: 1

Gender: F

Reported: 18/06/1998

Weight:

Hospitalisation:

Age: 75

Onset Date:

DOB: 17/10/1922

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Paranoia

1.0 Milligram

Daily

Batch:

Started:

Stopped:

CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128646

Seq: 1

Gender: F

Reported: 23/06/1998

Weight:

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Amenorrhoea		Raised prolactin: 2169	

Medicine Details:

RISPERDAL (Suspected)		Reason: Schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiology				Ct scan indicated possibility of 5mm. microadenoma in pituitary.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 128783

Seq: 1

Gender: M

Reported: 24/06/1998

Weight:

Hospitalisation:

Age: 62Y

Onset Date: 10/06/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Hypertonia Blood creatine phosphokinase incr Neuroleptic malignant syndrome Pyrexia		Clouding of consciousness Rigidity	Ceased risperdal and sertraline

Medicine Details:

PROPOFOL (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
FENTANYL CITRATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/04/1998	Stopped: 10/06/1998	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1998	Stopped: 10/06/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		10/06/1998	1800	

Additional Information:

09/06/98 - patient had a cystoscopy and bladder neck incision. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 129097

Seq: 1

Gender: M

Reported: 10/07/1998

Weight: 72.00

Hospitalisation:

Age: 58Y

Onset Date: 14/06/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Prothrombin level increased			

Medicine Details:

WARFARIN SODIUM (Interaction)		Reason: Phleb&thrombophleb lowr extrem	
	0.0	Daily	
Batch:	Started: 06/05/1998	Stopped:	CONTIN
RISPERIDONE (Interaction)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Batch:	Started: 14/06/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International normalized ratio				Inr of 2.2 on 8mg warfrin, after 3 days of 8mg and 3 days of 10mg pt inr was only 1.4.

Additional Information:

Pt is now on 10mg daily of warfrin and his inr is fluctuating from 3.1 - 4.0.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 129719
Reported: 30/07/1998

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 27/07/1998

Age: 21Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonia (involuntary spasm of masseters)	Reaction occurred on 27/07/98 when risperidone was increased treated with cogentin 2mg im.

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:
Batch:	2.0 Dose Unspecified As necessary
Started: 01/01/1996	Stopped:
PROZAC (Other drug)	Reason:
Batch:	60.0 Milligram Daily
Started: 01/01/1996	Stopped:
VALIUM (Other drug)	Reason:
Batch:	60.0 Milligram Daily
Started: 01/01/1996	Stopped:
RISPERIDONE (Suspected)	Reason:
Batch:	8.0 Milligram Daily
Started: 21/07/1998	Stopped: 27/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has had previous dystonic reactions with phenothiazines. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 129853

Seq: 1

Gender: F

Reported: 03/08/1998

Weight:

Hospitalisation:

Age: 32Y

Onset Date: 28/01/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Schizophrenia
7.0 Milligram Daily	
Batch:	Started: 01/07/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(56-500)	28/01/1998	2324	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130287 **Seq:** 1 **Gender:** F
Reported: 17/08/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia			Flucloxacillin and prednisone. risperidone ceased.
Infection			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred on three occasions after commencing risperidone. hypothermia induced by risperidone and olanzapine in a patient with prader- willi syndrome. mja vol 169 17/8/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130655

Seq: 1

Gender: F

Reported: 31/08/1998

Weight:

Hospitalisation:

Age: 31Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania			Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when zoloft was added to therapy. zoloft ceased and reaction resolved.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130794

Seq: 1

Gender: M

Reported: 02/09/1998

Weight:

Hospitalisation:

Age: 77

Onset Date: 24/06/1998

DOB: 06/09/1920

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Extrapyramidal disorder			Risperidone ceased.

Medicine Details:

CARTIA (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	
FAMOTIDINE (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
PRAZOSIN HYDROCHLORIDE (Other drug)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130794

Seq: 1

Gender: M

Reported: 02/09/1998

Weight:

Hospitalisation:

Age: 77

Onset Date: 24/06/1998

DOB: 06/09/1920

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)

Reason: Unspecified psychosis

500.0 Microgram Daily

Batch:

Started:

Stopped:

2M

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130823 **Seq:** 1 **Gender:** M
Reported: 04/09/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 32Y
Onset Date: 18/05/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Headache Hyperkinesia Insomnia			Ceased risperdal and sertraline.

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
Oral application	20.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
PARACETAMOL (Other drug)		Reason: Headache	
Oral application	4.0 Gram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
Oral application	125.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 27/02/1998	Stopped:	17/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130823

Seq: 1

Gender: M

Reported: 04/09/1998

Weight:

Hospitalisation: Admitted to hospital

Age: 32Y

Onset Date: 18/05/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason: Depression

Tablet

50.0 Milligram

Daily

Oral

Batch:

Started: 18/05/1998

Stopped: 17/06/1998

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 130921
Reported: 08/09/1998

Seq: 1

Gender: M
Weight: 76.00

Hospitalisation:

Onset Date: 12/08/1998
Outcome: Recovered

Age: 65Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Neuroleptic malignant syndrome Tremor			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/04/1997	Stopped: 12/08/1998	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 08/08/1998	Stopped: 12/08/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck - 1960

Additional Information:

Possible previous short exposure to combination. no side effects on risperdal alone over several months. after 4 doses of zoloft rapid development of reactions. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131013

Seq: 1

Gender: M

Reported: 04/09/1998

Weight: 68.00

Hospitalisation:

Age: 34Y

Onset Date: 29/07/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 27/07/1998	Stopped: 28/07/1998	
RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 29/07/1998	Stopped: 31/07/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131143

Seq: 1

Gender: M

Reported: 11/09/1998

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 01/06/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		110/80 bp	
Tachycardia			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1997	Stopped:	CONTIN
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 01/06/1998	
RISPERIDONE (Suspected)		Reason: Anxiety neurosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 27/05/1998	Stopped: 28/05/1998	
RISPERIDONE (Suspected)		Reason: Neuroses	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 28/05/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131328

Seq: 1

Gender: M

Reported: 16/09/1998

Weight: 60.00

Hospitalisation:

Onset Date: 01/09/1998

Age: 77Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Jaundice	Severe	Raised eosinophils	Discontinued all medication and used midazolam im for agitation.

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 27/07/1998	Stopped: 01/09/1998	
PARALGIN (Suspected)		Reason: Pain	
Tablet	3.0 Gram	Daily	Oral
Batch:	Started: 16/07/1998	Stopped: 03/09/1998	
SERENACE (Suspected)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1998	Stopped: 03/09/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	U/L	17/07/1998	41	
	ALT = SGPT	U/L	01/09/1998	530	
	ALT = SGPT	U/L	03/09/1998	517	
	ALT = SGPT	U/L	09/09/1998	414	
	AST = SGOT	U/L	17/07/1998	30	
	AST = SGOT	U/L	01/09/1998	261	
	AST = SGOT	U/L	09/09/1998	192	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131328

Seq: 1

Gender: M

Reported: 16/09/1998

Weight: 60.00

Hospitalisation:

Age: 77Y

Onset Date: 01/09/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 27/07/1998	Stopped: 01/09/1998	
PARALGIN (Suspected)		Reason: Pain	
Tablet	3.0 Gram	Daily	Oral
Batch:	Started: 16/07/1998	Stopped: 03/09/1998	
SERENACE (Suspected)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1998	Stopped: 03/09/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	U/L	03/09/1998	238	
	Bilirubin	UMOL/L	17/07/1998	4	
	Bilirubin	UMOL/L	01/09/1998	97	
	Bilirubin	UMOL/L	09/09/1998	183	
	Bilirubin	UMOL/L	03/09/1998	125	
	Biochemistry		17/07/1998	8	Total bilirubin umol/l
	Biochemistry		01/09/1998	107	Total bilirubin umol/l

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131328

Seq: 1

Gender: M

Reported: 16/09/1998

Weight: 60.00

Hospitalisation:

Age: 77Y

Onset Date: 01/09/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 27/07/1998	Stopped: 01/09/1998	
PARALGIN (Suspected)		Reason: Pain	
Tablet	3.0 Gram	Daily	Oral
Batch:	Started: 16/07/1998	Stopped: 03/09/1998	
SERENACE (Suspected)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1998	Stopped: 03/09/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry		03/09/1998	134	Total bilirubin umol/l
	Biochemistry		09/09/1998	211	Total bilirubin umol/l
	GGT = SGGT =	U/L	17/07/1998	67	
	GGT = SGGT =	U/L	01/09/1998	2018	
	GGT = SGGT =	U/L	09/09/1998	1471	
	GGT = SGGT =	U/L	03/09/1998	1798	
	SAP = ALP	U/L	17/07/1998	199	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131328

Seq: 1

Gender: M

Reported: 16/09/1998

Weight: 60.00

Hospitalisation:

Age: 77Y

Onset Date: 01/09/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 27/07/1998	Stopped: 01/09/1998	
PARALGIN (Suspected)		Reason: Pain	
Tablet	3.0 Gram	Daily	Oral
Batch:	Started: 16/07/1998	Stopped: 03/09/1998	
SERENACE (Suspected)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1998	Stopped: 03/09/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	U/L	01/09/1998	1507	
	SAP = ALP	U/L	03/09/1998	1457	
	SAP = ALP	U/L	09/09/1998	1451	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131458

Seq: 1

Gender: F

Reported: 23/09/1998

Weight: 59.00

Hospitalisation:

Age: 27

Onset Date: 16/09/1998

DOB: 14/08/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Redish rash over stomach, back, forearms & thighs	Risperidone ceased
Pruritus			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
Oral application	2.0 Milligram Daily Oral
Batch:	Started: 12/09/1998 Stopped: 18/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergy to aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131598

Seq: 1

Gender: F

Reported: 30/09/1998

Weight: 52.00

Hospitalisation:

Age: 71Y

Onset Date: 31/12/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hypertonia			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Nervousness
3.0 Milligram	Daily
Batch:	Started: 09/12/1997 Stopped: 03/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increased tone upper and lower limbs, legs have developed contractures secondary to low mobility. pt suffers from dementia - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131713

Seq: 1

Gender: M

Reported: 28/09/1998

Weight: 76.00

Hospitalisation:

Age: 21

Onset Date: 08/09/1998

DOB: 26/04/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Benztropine 2mg im

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started: 31/08/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131934
Reported: 12/10/1998

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 15/06/1997

Age: 36

DOB: 08/10/1960

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Testicular disorder			Risperidone changed to olanzapine

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 15/03/1997	Stopped: 15/07/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	<20	24/06/1997	30	
	Prolactin	<20	11/07/1997	31	
	Prolactin	<20	20/08/1997	8	
	Prolactin	<20	19/10/1998	11	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131982
Reported: 13/10/1998

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 26/08/1998

Age: 13Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

RISPERDAL (Interaction)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 21/08/1998	Stopped:	CONTIN
LAMOTRIGINE (Interaction)		Reason: Other&unspecified epilepsy	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 15/12/1996	Stopped:	CONTIN
TOPIRAMATE (Interaction)		Reason: Other&unspecified epilepsy	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1997	Stopped:	CONTIN
NORIMIN (Other drug)		Reason: Contraception	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 15/11/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131992
Reported: 15/10/1998
Hospitalisation:
Onset Date: 16/09/1998
Outcome: Unknown

Seq: 1

Gender: F
Weight:
Age: 71
DOB: 08/02/1927
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Frozen state	Cogentin 2mg imi given on 11/09/98 pt felt better. risperidone reduced on 21/09/98 to 1mg at night.

Medicine Details:

FAMOTIDINE (Other drug)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped: CONTIN
SALBUTAMOL (Other drug)		Reason:	
	30.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped: CONTIN
GLYCERYL TRINITRATE (Other drug)		Reason:	
Cream	50.0 Milligram	Daily	Transdermal
Batch:	Started:	S TERM	Stopped: CONTIN
SODIUM BICARBONATE (Other drug)		Reason:	
	40.0 Millilitre	Daily	
Batch:	Started:	S TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 131992

Seq: 1

Gender: F

Reported: 15/10/1998

Weight:

Hospitalisation:

Age: 71

Onset Date: 16/09/1998

DOB: 08/02/1927

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

SORBILAX (Other drug)		Reason: Constipation	
	40.0 Millilitre	Daily	
Batch:	Started:	S TERM	Stopped: CONTIN
SENOKOT (Other drug)		Reason: Constipation	
Oral application	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	S TERM	Stopped: CONTIN
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132117

Seq: 1

Gender: F

Reported: 19/10/1998

Weight:

Hospitalisation:

Age: 38Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Headache Hepatitis		Elevated temperature 40 degrees	

Medicine Details:

NEO-CYTAMEN (Other drug)		Reason: Other vitamin b deficiency	
Injection	1.0 Milligram	Weekly	Intravenous
Batch:	Started: 02/10/1998	Stopped:	CONTIN
FEFOL (Other drug)		Reason: Unspecified anemia	
Capsule	350.0 Milligram	Daily	Oral
Batch:	Started: 27/09/1998	Stopped:	CONTIN
TEMAZE (Other drug)		Reason: Otr spec symp psychopathol nec	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started: 02/10/1998	Stopped:	CONTIN
LITHICARB (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		06/10/1998	725	
	ALT = SGPT		07/10/1998	600	
	ALT = SGPT		14/10/1998	173	
	ALT = SGPT		08/10/1998	398	
	Bilirubin		06/10/1998	11	
	Bilirubin		07/10/1998	25	
	Bilirubin		08/10/1998	19	

Additional Information:

Pt currently has a urinary tract infection



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132117

Seq: 1

Gender: F

Reported: 19/10/1998

Weight:

Hospitalisation:

Age: 38Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LARGACTIL (Suspected)		Reason: Otr spec symp psychopathol nec
	100.0 Milligram	As necessary
Batch:	Started: 26/09/1998	Stopped: 06/10/1998
RISPERDAL (Suspected)		Reason: Manic-depression psycho,manic
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 26/09/1998	Stopped: 07/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin		14/10/1998	11	
	GGT = SGGT =		06/10/1998	51	
	GGT = SGGT =		07/10/1998	76	
	GGT = SGGT =		14/10/1998	59	
	GGT = SGGT =		08/10/1998	84	
	SAP = ALP		06/10/1998	125	
	SAP = ALP		07/10/1998	143	

Additional Information:

Pt currently has a urinary tract infection



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132117

Seq: 1

Gender: F

Reported: 19/10/1998

Weight:

Hospitalisation:

Age: 38Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

NEO-CYTAMEN (Other drug)		Reason: Other vitamin b deficiency	
Injection	1.0 Milligram	Weekly	Intravenous
Batch:	Started: 02/10/1998	Stopped:	CONTIN
FEFOL (Other drug)		Reason: Unspecified anemia	
Capsule	350.0 Milligram	Daily	Oral
Batch:	Started: 27/09/1998	Stopped:	CONTIN
TEMAZE (Other drug)		Reason: Otr spec symp psychopathol nec	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started: 02/10/1998	Stopped:	CONTIN
LITHICARB (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		08/10/1998	143	
	SAP = ALP		14/10/1998	118	

Additional Information:

Pt currently has a urinary tract infection



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132117

Seq: 1

Gender: F

Reported: 19/10/1998

Weight:

Hospitalisation:

Age: 38Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LARGACTIL (Suspected)		Reason: Otr spec symp psychopathol nec	
	100.0 Milligram	As necessary	
Batch:	Started: 26/09/1998	Stopped: 06/10/1998	
RISPERDAL (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 26/09/1998	Stopped: 07/10/1998	

Laboratory Investigations:

Additional Information:

Pt currently has a urinary tract infection



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132315

Seq: 1

Gender: F

Reported: 22/10/1998

Weight:

Hospitalisation:

Age: 36

Onset Date: 15/04/1998

DOB: 16/02/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Hyperprolactinaemia			

Medicine Details:

EFEXOR (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)		Reason: Unspecified psychosis	
Tablet	1.6 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
LITHIUM CARBONATE (Other drug)		Reason: Unspecified psychosis	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				20/08/98 - ct scan was suspicious of 4-5mm microadenoma.
	Prolactin	70-570 MU/L	15/07/1998	2278	
	Prolactin	70-570 MU/L	26/08/1998	3482	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132398

Seq: 1

Gender: F

Reported: 29/10/1998

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia		General aches and pains	
Pyrexia		Raised temperature	
Hepatic function abnormal			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	40.0 Milligram	As necessary	Oral
Batch:	Started: 26/09/1998	Stopped:	
MIDAZOLAM (Other drug)		Reason:	
Injection	30.0 Milligram	As necessary	Intramuscular
Batch:	Started: 26/09/1998	Stopped:	
FERROUS SULPHATE (Other drug)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 27/09/1998	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<30	26/09/1998	17	
	ALT = SGPT	<30	06/10/1998	725	
	ALT = SGPT	<30	07/10/1998	600	
	ALT = SGPT	<30	14/10/1998	173	
	ALT = SGPT	<30	08/10/1998	398	
	Bilirubin	<18	26/09/1998	16	
	Bilirubin	<18	06/10/1998	19	

Additional Information:

See original report for more drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132398

Seq: 1

Gender: F

Reported: 29/10/1998

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecifid affective psychosis

Tablet

2.0 Milligram

Daily

Oral

Batch:

Started: 26/09/1998

Stopped: 07/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	<18	07/10/1998	25	
	Bilirubin	<18	14/10/1998	11	
	Bilirubin	<18	08/10/1998	19	
	GGT = SGGT =	<35	26/09/1998	11	
	GGT = SGGT =	<35	06/10/1998	51	
	GGT = SGGT =	<35	08/10/1998	84	
	GGT = SGGT =	<35	14/10/1998	59	

Additional Information:

See original report for more drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132398

Seq: 1

Gender: F

Reported: 29/10/1998

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	40.0 Milligram	As necessary	Oral
Batch:	Started: 26/09/1998	Stopped:	
MIDAZOLAM (Other drug)		Reason:	
Injection	30.0 Milligram	As necessary	Intramuscular
Batch:	Started: 26/09/1998	Stopped:	
FERROUS SULPHATE (Other drug)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 27/09/1998	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	<35	07/10/1998	76	
	SAP = ALP	(30-100)	26/09/1998	52	
	SAP = ALP	(30-100)	06/10/1998	125	
	SAP = ALP	(30-100)	07/10/1998	143	
	SAP = ALP	(30-100)	08/10/1998	143	
	SAP = ALP	(30-100)	14/10/1998	118	

Additional Information:

See original report for more drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132398

Seq: 1

Gender: F

Reported: 29/10/1998

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 06/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecifid affective psychosis

Tablet

2.0 Milligram

Daily

Oral

Batch:

Started: 26/09/1998

Stopped: 07/10/1998

Laboratory Investigations:

Additional Information:

See original report for more drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132914
Reported: 06/11/1998
Hospitalisation:
Onset Date: 03/11/1998
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 76Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		Raised red wheelts on back & thighs for 2 days	Risperidone ceased

Medicine Details:

LARGACTIL (Other drug)	Reason: Otr spec symp psychopathol nec
1.0 Dose Unspecified As necessary	
Batch:	Started: 29/10/1998 Stopped:
MADOPAR M (Other drug)	Reason: Paralysis agitans
Oral application 4.0 Dose Unspecified Daily Oral	
Batch:	Started: Stopped:
ATROMID-S (Other drug)	Reason:
Oral application 1.0 Gram Daily Oral	
Batch:	Started: Stopped:
ZYLOPRIM (Other drug)	Reason: Gout
300.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132914

Seq: 1

Gender: M

Reported: 06/11/1998

Weight:

Hospitalisation:

Age: 76Y

Onset Date: 03/11/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

ZOCOR (Other drug)		Reason:	
		1.0 Dose Unspecified Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
		1.0 Milligram Daily	
Batch:	Started: 29/10/1998	Stopped: 03/11/1998	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 132918

Seq: 1

Gender: M

Reported: 02/11/1998

Weight:

Hospitalisation:

Age: 77Y

Onset Date: 21/08/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Risperdal ceased

Medicine Details:

TEMAZE (Other drug)		Reason:	
Tablet	10.0 Milligram	As necessary	Oral
Batch:	Started: 13/08/1998	Stopped: 26/08/1998	
DYMADON (Other drug)		Reason: Pain	
Tablet	4.0 Gram	Daily	Oral
Batch:	Started: 19/08/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 17/08/1998	Stopped: 25/08/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Principal diagnosis: extrapyramidal disorder



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133033 **Seq:** 1 **Gender:** M
Reported: 02/11/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 19/10/1998 **DOB:** 27/12/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life threatening		Patient requiring iv antibiotics.
Leukopenia	Life threatening		
Pancytopenia			
Sepsis			
Thrombocythaemia			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bone marrow				Bone marrow on 3 nov 98: hypocellular marrow with maturation arrest of myelocytes.
	Haemoglobin		22/10/1998	14.2	
	Haemoglobin		25/11/1998	9.5	
	Neutrophils		03/07/1998	6.8	
	Neutrophils		19/10/1998	0.0	
	Neutrophils		25/11/1998	1.64	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133033

Seq: 1

Gender: M

Reported: 02/11/1998

Weight:

Hospitalisation: Admitted to hospital

Age: 39

Onset Date: 19/10/1998

DOB: 27/12/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

700.0 Milligram

Daily

Oral

Batch:

Started: 14/08/1996

Stopped: 19/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/10/1998	1.01	
	Platelets		22/10/1998	275	
	Platelets		25/11/1998	21	
	White blood cells		03/07/1998	9.6	
	White blood cells		19/10/1998	1.0	
	White blood cells		22/10/1998	1.2	
	White blood cells		25/11/1998	2.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133135

Seq: 1

Gender: M

Reported: 12/11/1998

Weight:

Hospitalisation:

Age: 68Y

Onset Date: 17/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Leukocytosis Neuroleptic malignant syndrome			Ceased risperidone on 18/10/98 given ceftriaxone 1gm and metronidazole 500mg iv

Medicine Details:

RENITEC (Other drug)	Reason:
5.0 Milligram	Daily
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
40.0 Milligram	Daily
Batch:	Started: Stopped:
POTASSIUM CHLORIDE (Other drug)	Reason:
600.0 Milligram	Daily
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
50.0 Microgram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		18/10/1998	-	
	AST = SGOT		19/10/1998	53	
	Creatine		18/10/1998	879	
	Creatine		19/10/1998	1118	
	Creatinine		18/10/1998	-	
	Creatinine		19/10/1998	0.15	
	LDH		18/10/1998	-	

Additional Information:

All drugs started on admission



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133135

Seq: 1

Gender: M

Reported: 12/11/1998

Weight:

Hospitalisation:

Age: 68Y

Onset Date: 17/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SALBUTAMOL (Other drug)		Reason:	
Inhalation	800.0 Milligram	Daily	Inhalation
Batch:	Started:	Stopped:	
METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	Stopped:	
GLICLAZIDE (Other drug)		Reason:	
	320.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	LDH		19/10/1998	268	
	White blood cells		17/10/1998	16.1	

Additional Information:

All drugs started on admission



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133135

Seq: 1

Gender: M

Reported: 12/11/1998

Weight:

Hospitalisation:

Age: 68Y

Onset Date: 17/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

1.0 Milligram

Daily

Batch:

Started:

Stopped: 14/10/1998

Laboratory Investigations:

Additional Information:

All drugs started on admission



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133231

Seq: 1

Gender: M

Reported: 13/11/1998

Weight:

Hospitalisation:

Age: 30

Onset Date: 31/07/1997

DOB: 16/05/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Chest pain Hyperkinesia		Increased muscle tone	Ceased risperidone

Medicine Details:

RISPERIDONE (Suspected)	Reason: Schizophrenia
0.0	
Batch:	Started: Stopped: 28/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133295

Seq: 1

Gender: M

Reported: 18/11/1998

Weight: 75.00

Hospitalisation:

Age: 33Y

Onset Date: 23/10/1998

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Sexual dysfunction	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started: 23/10/1998	Stopped: 25/10/1998	
RISPERDAL (Suspected)		Reason: Unspecifid affective psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 13/10/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133522

Seq: 1

Gender: F

Reported: 20/11/1998

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 09/10/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion Extrapyramidal disorder Paranoia Psychotic disorder			Ceased risperidone.

Medicine Details:

TENOPT (Other drug)		Reason:	
Eye Drops	2.0 Dose Unspecified Daily	Ophthalmic	
Batch:	Started:	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram Daily		
Batch:	Started: 01/10/1998	Stopped:	09/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133574
Reported: 23/11/1998

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 16Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Micturition disorder Urinary incontinence		Urinary urgency	Zoloft was discontinued.

Medicine Details:

ZOLOFT (Suspected)		Reason: Schizo-affective type psychos	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 28/11/1998	
RISPERDAL (Suspected)		Reason: Schizo-affective type psychos	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient with schizo-affective disorder for 1 year. no other cause of her urinary symptoms could be identified. no urinary infection was found. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133629

Seq: 1

Gender: M

Reported: 23/11/1998

Weight: 75.00

Hospitalisation:

Age: 50Y

Onset Date: 31/08/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombosis mesenteric vessel			Operaton and small bowel resection.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
0.0	
Batch:	Started: 01/01/1998
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133659

Seq: 1

Gender: F

Reported: 24/11/1998

Weight: 64.00

Hospitalisation:

Age: 33Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Hyperprolactinaemia			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason: Depression	
	100.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	8.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Prolactin 4000 ml/l.
	Histology				Microadenoma of pituitary gland.

Additional Information:

Sequalae: patient has reduced bone density.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133763

Seq: 1

Gender: F

Reported: 27/11/1998

Weight:

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder		Menstrual disturbances.	

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133822

Seq: 1

Gender: F

Reported: 30/11/1998

Weight:

Hospitalisation:

Age: 38Y

Onset Date: 13/10/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itching on the arm and thighs.	
Rash		Rash and general redness on the arm and thighs.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 15/02/1998	Stopped:	28/10/1998
PHENYTOIN SODIUM (Suspected)		Reason: Other&unspecified epilepsy	
Oral application	330.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 15/03/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133824

Seq: 1

Gender: M

Reported: 30/11/1998

Weight:

Hospitalisation:

Age: 12Y

Onset Date: 15/11/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Nocturnal enuresis	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	500.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	1W
RISPERIDONE (Suspected)		Reason: Alcoholism	
Tablet	1.0 Milligram	Daily	Oral
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133825

Seq: 1

Gender: F

Reported: 30/11/1998

Weight:

Hospitalisation:

Age: 17

Onset Date: 15/01/1998

DOB: 25/07/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms some months after starting risperidone. when risperidone was stopped and replaced by olanzapine, symptoms continued. it also continued when risperidone was restarted.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 133843

Seq: 1

Gender: F

Reported: 02/12/1998

Weight:

Hospitalisation:

Age: 24Y

Onset Date: 15/10/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neurosis		Siriperidone ceased, symptoms settled spontaneously	28 oct 97 thioridazine 100mg/day and risperidone gradually discontinued.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	8.0 Milligram	Daily	
Batch:	Started: 01/10/1997	Stopped: 28/10/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

While the patient was taking risperidone she developed obsessional thoughts and images (no rituals). the risperidone dose varried from 1mg/day to 6mg/day. olanzapine was started jan 98 in addition to thioridazine and was increased gradually to a dose of 20mg/day. olanzapine was ceased 28 sep 98. ocd symptoms also occurred during olanzapine treatment. periciazine was started once olanzapine had been ceased. ssri started 3 weeks ago for ocd symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134007

Seq: 1

Gender: F

Reported: 04/12/1998

Weight: 88.00

Hospitalisation:

Age: 71Y

Onset Date: 11/06/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lichenoid keratosis Oedema peripheral Weight increased			Ceased risperidone

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Tablet	0.5 Dose Unspecified Daily	Oral	
Batch:	Started: L TERM	Stopped:	
DIGOXIN (Other drug)		Reason:	
	125.0 Microgram Daily		
Batch:	Started: L TERM	Stopped:	
LASIX (Other drug)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started: L TERM	Stopped:	
SLOW-K (Other drug)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ongoing oedema, lichen-planus, weight gain.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134007

Seq: 1

Gender: F

Reported: 04/12/1998

Weight: 88.00

Hospitalisation:

Age: 71Y

Onset Date: 11/06/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

0.0

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Ongoing oedema, lichen-planus, weight gain.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134503

Seq: 1

Gender: F

Reported: 22/12/1998

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 08/12/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression			

Medicine Details:

RISPERDAL (Interaction)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 24/09/1998	Stopped:	
METHADONE HYDROCHLORIDE (Interaction)		Reason:	
Oral Liquid	10.0 Milligram	Daily	Oral
Batch:	Started: 04/12/1998	Stopped: 08/12/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134507
Reported: 23/12/1998

Seq: 1

Gender: F
Weight: 73.00
Age: 27Y

Hospitalisation:

Onset Date: 01/12/1998
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Ears & neck at hairline & waist, thigh area.	
Urticaria		Including palms, soles of feet & face.	
Angioedema		Severe facial & mild on rest of body.	
Bronchospasm			
Face oedema			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Depression	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 24/11/1998	Stopped: 01/12/1998	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 27/11/1998	Stopped: 01/12/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to pethidine. risperidone 2mg po nocte 20/10/98 to 29/10/98 the 1mg nocte till 2/11/98. no previous exposure to zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134564 **Seq:** 1 **Gender:** M
Reported: 21/12/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 21/11/1998 **DOB:** 01/06/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	21/11/98 benztropine(oral) then cogentin (imi)
Chest pain			
Dyspnoea			

Medicine Details:

FOLIC ACID (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: Stopped:
DILANTIN (Other drug)	Reason:
400.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
ZUCLOPENTHIXOL ACETATE (Suspected)	Reason: Otr spec symp psychopathol nec
100.0 Microgram 1 time	
Batch:	Started: 20/11/1998 Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram Daily	
Batch:	Started: 20/11/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134866

Seq: 1

Gender: M

Reported: 06/01/1999

Weight: 96.00

Hospitalisation:

Age: 17Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue		Tiredness	Changed to zyprexa

Medicine Details:

ZOLOFT (Other drug)		Reason: Other atyp forms schizophrenia	
	100.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
CLARATYNE (Other drug)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:		Stopped:
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/02/1997		Stopped: 10/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 134974

Seq: 1

Gender: F

Reported: 07/01/1999

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 08/12/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression			

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
NALTREXONE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified psychosis
4.0 Milligram Daily	
Batch:	Started: 01/08/1998 Stopped: CONTIN
METHADONE HYDROCHLORIDE (Suspected)	Reason:
10.0 Milligram Daily	
Batch:	Started: 04/12/1998 Stopped: 08/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Urinary drug screen collected of dec 98=methadone, metoclopramide and naltre- xone.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 135206

Seq: 1

Gender: F

Reported: 18/01/1999

Weight: 64.00

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		14kg gained in 18/12.	

Medicine Details:

NORMISON (Other drug)		Reason: Specific disorders of sleep	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/06/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 135716

Seq: 1

Gender: F

Reported: 01/02/1999

Weight:

Hospitalisation:

Age: 81Y

Onset Date: 22/12/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Bilateral leg oedema	Ceased respiridone and keflex
Rash			

Medicine Details:

WARFARIN SODIUM (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
OESTRADIOL (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
AMLODIPINE (Other drug)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:
CALTRATE (Other drug)	Reason:
3.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 135716

Seq: 1

Gender: F

Reported: 01/02/1999

Weight:

Hospitalisation:

Age: 81Y

Onset Date: 22/12/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

AMIODARONE HYDROCHLORIDE (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FERRO-GRADUMET (Other drug)		Reason:	
	2.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 21/12/1998	Stopped: 22/12/1998	
KEFLEX (Suspected)		Reason:	
	1.5 Gram	Daily	
Batch:	Started: 21/12/1998	Stopped: 22/12/1998	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 136172

Seq: 1

Gender: M

Reported: 15/02/1999

Weight:

Hospitalisation:

Age: 16

Onset Date:

DOB: 13/08/1982

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
		0.0	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	275.0 Milligram	Daily	Oral
Batch:	Started: 07/07/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 136528

Seq: 1

Gender: F

Reported: 23/02/1999

Weight:

Hospitalisation:

Age: 19Y

Onset Date: 09/02/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Gynaecomastia			

Medicine Details:

PULMICORT (Other drug)		Reason:	
Inhalation	4.0 Dose Unspecified Daily	Inhalation	
Batch:	Started: 21/01/1999	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram Daily		
Batch:	Started: 04/02/1999	Stopped: 09/02/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt had been on 1mg bd of risperidone 21/1/99 to 4/2/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 136573

Seq: 1

Gender: M

Reported: 24/02/1999

Weight:

Hospitalisation:

Age: 71

Onset Date: 29/01/1999

DOB: 22/07/1927

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Ck from 1538 to 11474	Ceasing risperidone ck decreased.

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 29/01/1999	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason: Depression	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started: 29/01/1999	Stopped:	31/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient originally on 0.5mg nocte. increased to 1mg nocte from 01/02/99 to 04/02/99. increased again to 2mg nocte from 05/02/99 to 09/02/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 136862

Seq: 1

Gender: M

Reported: 01/03/1999

Weight:

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Breathlessness, first on exertion, & later at rest	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	
Oral application	1.5 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 07/12/1998	Stopped:	30/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 136932

Seq: 1

Gender: F

Reported: 05/03/1999

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 28/03/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Risperidone ceased.

Medicine Details:

LITHICARB (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
OROXINE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Schizophrenia
2.0 Milligram Daily	
Batch:	Started: 01/11/1997 Stopped: 28/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		01/04/1998	233	
	GGT = SGGT =		01/04/1998	477	
	SAP = ALP		01/04/1998	135	

Additional Information:

Progressive increased in lfts whilst on risperidone, which seems to reverse when risperidone ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 138655
Reported: 22/04/1999

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 08/03/1999

Age: 81

DOB: 26/10/1917

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion			Ceased risperidone

Medicine Details:

RISPERDAL (Suspected)	Reason: Hallucinations
1.0 Milligram	Daily
Batch:	Started: 04/03/1999 Stopped: 12/03/1999
MORPHINE SULPHATE (Suspected)	Reason: Otr spec symp psychopathol nec
4.0 Millilitre	Daily
Batch:	Started: Stopped: 08/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

? bradykinesia. no known allergies. see original report for details of other drugs - amiodarone, sodium valproate, ramipril, famotidine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 139514

Seq: 1

Gender: M

Reported: 14/05/1999

Weight: 85.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Gynaecomastia		Increased prolactin levels	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/01/1999	Stopped:	
SODIUM VALPROATE (Suspected)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 01/01/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history other drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 139645

Seq: 1

Gender: F

Reported: 19/05/1999

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			Zoloft ceased, cipramil commenced.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Anxiety neurosis	
Tablet	100.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 139656 **Seq:** 1 **Gender:** F
Reported: 24/05/1999 **Weight:** 85.00
Hospitalisation: Admitted to hospital **Age:** 70Y
Onset Date: 01/04/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state			Ceased risperidone

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 01/03/1999	Stopped: 01/04/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck increased to 1002.

Additional Information:

See original report for details on other drug therapy: sertraline. patient history of depression and obsessive compulsive disorder. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 140324

Seq: 1

Gender: M

Reported: 07/06/1999

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 140401

Seq: 1

Gender: M

Reported: 10/06/1999

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 18/05/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Difficulty breathing.	
Dysphagia		Difficulty in swallowing.	
Rash		Rash on hands.	Calamine lotion & pheneregan oral
Face oedema		Swollen lip & eyelids.	

Medicine Details:

HALOPERIDOL (Suspected)		Reason:	
Tablet	5.0 Milligram	1 time	Oral
Batch:	Started: 18/05/1999	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 18/05/1999	Stopped: 18/05/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed rash on 18.5.99. unsure if is due to risperidone or haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 140581

Seq: 1

Gender: F

Reported: 23/06/1999

Weight:

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Risperidone discontinued.

Medicine Details:

RISPERIDONE (Suspected)		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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 140898

Seq: 1

Gender: F

Reported: 28/06/1999

Weight: 62.00

Hospitalisation:

Age: 75Y

Onset Date: 08/06/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Risperadone ceased & fluid restriction.
Inappropriate antidiuretic hormone			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 18/05/1999	Stopped: 09/06/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality				Sos 254
	Sodium		18/05/1999	131	
	Sodium		24/05/1999	136	
	Sodium		08/06/1999	123	
	Sodium		09/06/1999	121	
	Sodium		13/06/1999	124	
	Sodium		17/06/1999	126	

Additional Information:

Please see original report for details of other drugs - indapamide, enalapril, amlodipine, pravastatin, quinine bisulfate, imdur.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 140898

Seq: 1

Gender: F

Reported: 28/06/1999

Weight: 62.00

Hospitalisation:

Age: 75Y

Onset Date: 08/06/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 18/05/1999	Stopped: 09/06/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium Urine osmolality		21/06/1999	130	Vos 308

Additional Information:

Please see original report for details of other drugs - indapamide, enalapril, amlodipine, pravastatin, quinine bisulfate, imdur.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141299

Seq: 1

Gender: M

Reported: 08/07/1999

Weight:

Hospitalisation:

Age:

Onset Date: 21/06/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Myositis			
Respiratory depression			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase				4000-5000

Additional Information:

Patient history of mild chronic renal failure, diabetes, hypertension.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141362

Seq: 1

Gender: M

Reported: 09/07/1999

Weight:

Hospitalisation:

Age: 18Y

Onset Date: 31/12/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Pt began to experience epileptic fits everyday.	Zoloft discontinued.

Medicine Details:

TEGRETOL (Interaction)		Reason: Other&unspecified epilepsy	
	0.0		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Interaction)		Reason: Other&unspecified epilepsy	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Interaction)		Reason: Unspecified schizophrenia	
	0.0		
Batch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141467

Seq: 1

Gender: M

Reported: 13/07/1999

Weight: 82.00

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

FLUPHENAZINE HYDROCHLORIDE (Suspected)		Reason:	
0.0			
Batch:	Started:	L TERM	Stopped: 28/07/1994
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
0.0			
Batch:	Started:	L TERM	Stopped: 28/07/1994
RISPERIDONE (Suspected)		Reason:	
6.0 Milligram		Daily	
Batch:	Started: 01/02/1994	Stopped: 08/07/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - metoprolol. had previous tardive dyskinesia 1993-1994 which seemed to resolve after change to clozapine, then reappeared. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141728

Seq: 1

Gender: F

Reported: 19/07/1999

Weight:

Hospitalisation:

Age: 16

Onset Date: 31/03/1999

DOB: 14/05/1982

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	0.0	Oral	
Batch:	Started: 01/03/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(50-500)	19/04/1999	3500	Prolactin level=3737 mlu/l

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141774

Seq: 1

Gender: F

Reported: 21/07/1999

Weight:

Hospitalisation:

Age: 84Y

Onset Date: 17/06/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
11.0 Milligram	Total
Batch:	Started: 24/05/1999 Stopped: 08/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: frusemide, chlorvescent, coloxyl with senna, digoxin, & warfarin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141886

Seq: 1

Gender: M

Reported: 23/07/1999

Weight:

Hospitalisation:

Age: 54Y

Onset Date: 13/07/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Nocturnal urinary incontinence	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 06/07/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: nitrazepam, clonazepam. risperidone was started at 1mg on 30/6/99, increased to 3mg 6/7/99 reduced to 2mg on 13/7/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 141934

Seq: 1

Gender: F

Reported: 26/07/1999

Weight: 73.00

Hospitalisation:

Onset Date: 31/03/1999

Age: 58Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Gained 9 kg.	
Alopecia		Hair falling out	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142427 **Seq:** 1 **Gender:** F
Reported: 05/08/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 54Y
Onset Date: 10/06/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphadenopathy Hepatomegaly Abdominal pain Dizziness Hepatic function abnormal Nausea Pyrexia Vomiting		Enlarged lymphnodes Liver mildly tender and edge palpable. Tender I upper quadrant	Recovery with supportive measures and cessation of risperidone.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 04/06/1999	Stopped: 07/06/1999	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 07/06/1999	Stopped: 10/06/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		17/06/1999	241	
	Bilirubin		17/06/1999	76	
	GGT = SGGT =		17/06/1999	135	
	SAP = ALP		17/06/1999	305	

Additional Information:

See original report for details of other drug therapy: luvox, voltaren, nitrazepam and paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142428

Seq: 1

Gender: M

Reported: 05/08/1999

Weight:

Hospitalisation:

Age:

Onset Date: 28/03/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1999	Stopped: 12/05/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	24 - 467	12/05/1999	568	
	Prolactin	24 - 467	02/06/1999	NORMAL	

Additional Information:

Patient was also on valproate. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142453

Seq: 1

Gender: M

Reported: 06/08/1999

Weight: 50.00

Hospitalisation:

Onset Date: 23/07/1999

Age: 82Y

Outcome: Death, maybe drug

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Pneumonia			
Respiratory failure			
Sepsis			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	3.0 Milligram	Weekly	
Batch:	Started:	Stopped:	6M
DIAZEPAM (Suspected)		Reason:	
	2.5 Milligram	As necessary	
Batch:	Started:	Stopped:	
SINEMET (Suspected)		Reason: Paralysis agitans	
	3.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells				White cell count of 1.5

Additional Information:

Date of death: 23/7/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142453

Seq: 1

Gender: M

Reported: 06/08/1999

Weight: 50.00

Hospitalisation:

Age: 82Y

Onset Date: 23/07/1999

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

NORMISON (Suspected)

Reason:

10.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Date of death: 23/7/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142459

Seq: 1

Gender: M

Reported: 09/08/1999

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 12/10/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Abnormal lft.	Risperdal therapy ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 21/09/1998	Stopped: 18/10/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Alt 277 units/l (n<50) ast 112 u/l (n<41)

Additional Information:

See original report for details of other drug. - antenex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142502

Seq: 1

Gender: M

Reported: 09/08/1999

Weight:

Hospitalisation:

Age: 20Y

Onset Date: 31/12/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Macular degeneration			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142947

Seq: 1

Gender: F

Reported: 24/08/1999

Weight: 65.00

Hospitalisation:

Age: 42Y

Onset Date: 17/05/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Galactorrhoea		Prolactin rise	Risperidone ceased

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		17/05/1999	993	
	Prolactin		20/06/1999	3238	
	Prolactin		27/07/1999	4710	
	Prolactin		04/08/1999	128	

Additional Information:

Patient has a long psych history. has had 2 overdose attempts with the drugs ducene, zoloft, codeine phos and brufen on 31/5/99 and 12/6/99.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 142948

Seq: 1

Gender: M

Reported: 24/08/1999

Weight: 0.00

Hospitalisation:

Age: 22Y

Onset Date: 31/07/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast mass		Nodular breast lump	

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
3.0 Milligram	Daily
Batch:	Started: 01/06/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. The dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 143260

Seq: 1

Gender: M

Reported: 31/08/1999

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal disorder		See additional information for description.	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis
	0.0	
Batch:	Started:	Stopped:
GLIMEL (Suspected)		Reason: Diabetes mellitus
	0.0	
Batch:	Started:	Stopped:
CYANOCOBALAMIN (Suspected)		Reason:
Injection	0.0	Intravenous
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mild hypopigmentation and punctate choroiditis within 1 disc diameter of left macula in retina.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 143948

Seq: 1

Gender: M

Reported: 23/09/1999

Weight: 65.00

Hospitalisation:

Age: 35Y

Onset Date: 11/09/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 143950

Seq: 1

Gender: U

Reported: 23/09/1999

Weight:

Hospitalisation:

Age: 72

Onset Date: 15/08/1999

DOB: 11/08/1927

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp has dropped from 160/100 to 60/40.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application	500.0 Microgram	Daily	Oral
Batch:	Started: 15/08/1999	Stopped:	15/08/1999
PHENERGAN (Suspected)		Reason:	
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started: 14/08/1999	Stopped:	15/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 144024

Seq: 1

Gender: F

Reported: 24/09/1999

Weight: 60.00

Hospitalisation:

Age: 67Y

Onset Date: 04/09/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Severe		Ceased risperdal

Medicine Details:

LITHICARB (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ASIG (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ENDEP (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 20/08/1999 Stopped: 17/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 144140

Seq: 1

Gender: F

Reported: 28/09/1999

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 144594

Seq: 1

Gender: F

Reported: 12/10/1999

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 03/09/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Patient complained of itch (without rash).	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started: 27/08/1999	Stopped: 03/09/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - clonazepam, haloperidol & temazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 144894

Seq: 1

Gender: M

Reported: 19/10/1999

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 11/06/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Cease risperidone, changed to olanzapine then clopixol depot 400mg.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Oral application	3.0 Milligram Daily Oral
Batch:	Started: 07/06/1999 Stopped: 11/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nil previous adr's.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 144937

Seq: 1

Gender: M

Reported: 20/10/1999

Weight:

Hospitalisation:

Age: 41Y

Onset Date: 26/08/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema		Oedema in hands.	Clozapine dose had been reduced from 550mg/day to 525mg/day in 6/99 and then further reduced to 500mg/day in 7/99.

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Other drug)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped: 28/07/1999	
LIPEX (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1999	Stopped:	CONTIN
CLOZAPINE (Suspected)		Reason: Schizophrenia	
	550.0 Milligram	Daily	
Batch:	Started: 01/02/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Schizophrenia	
	8.0 Milligram	Daily	
Batch:	Started: 01/10/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145436
Reported: 04/11/1999

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Leaking of fluid from both breasts.	Stopped risperidone and changed to olanzapine 5mg.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Manic-depression psycho,manic
	2.0 Milligram	Daily
Batch:	Started: 02/09/1999	Stopped: 16/09/1999
RISPERIDONE (Suspected)		Reason: Manic-depression psycho,manic
	4.0 Milligram	Daily
Batch:	Started: 16/09/1999	Stopped: 28/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145442

Seq: 1

Gender: M

Reported: 04/11/1999

Weight:

Hospitalisation:

Age: 6Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Mother and teacher noticed oral-buccal movements	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Oral application	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Risperdal given for adhd. when risperdal was discontinued, reaction occurred. reaction stopped when risperdal was started again. patient has developmental delay. see original report for details of other drug - ritalin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145446

Seq: 1

Gender: F

Reported: 04/11/1999

Weight:

Hospitalisation:

Age: 22Y

Onset Date: 31/01/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1998	Stopped: 01/03/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Patient's prolactin level was 2838 miu/l.

Additional Information:

Dose has been reduced on 2/3/99, to 1mg daily. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145447

Seq: 1

Gender: F

Reported: 04/11/1999

Weight:

Hospitalisation:

Age: 38Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea Hyperprolactinaemia			Risperdal dose has been reduced.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Oral application	4.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1998	Stopped: 28/06/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Prolactin level at the end of june 99 was 2683 miu/l.

Additional Information:

Dose reduced to 3mg daily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145448

Seq: 1

Gender: F

Reported: 04/11/1999

Weight:

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain Breast enlargement Galactorrhoea Pollakiuria Urinary incontinence		Tenderness	

Medicine Details:

MEDROXYPROGESTERONE ACETATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
DOXYCYCLINE HYDROCHLORIDE (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a cardiac murmur.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145576

Seq: 1

Gender: F

Reported: 09/11/1999

Weight:

Hospitalisation:

Age: 20Y

Onset Date: 23/04/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Bizaqrre movements/gestures.	Risperidone ceased and changed to olanzepine and melleril.
Depersonalisation		Patient states she felt strange.	
Speech disorder		Speech slow and childlike.	
Hypertonia			

Medicine Details:

PROZAC (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 20/04/1998	Stopped: 30/04/1998	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 21/04/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - lithium. patient history: older brother has scz, abused by father and husband, depression.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145929 **Seq:** 1 **Gender:** M
Reported: 16/11/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 30/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Hypertonia			Cogentin 2mg orally.

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified psychosis	
Injection	150.0 Milligram	1 time	Intramuscular
Batch:	Started: 27/10/1999	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 27/10/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 145961

Seq: 1

Gender: M

Reported: 18/11/1999

Weight:

Hospitalisation:

Age: 33Y

Onset Date: 28/12/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 28/12/1998	Stopped: 30/04/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4 - 11	28/12/1998	17.5	
	White blood cells	4 - 11	20/01/1999	20.4	
	White blood cells	4 - 11	10/05/1999	14.8	

Additional Information:

Medical conditions include asthma. risperdal reduced to 1mg then ceased 5/99. see original report for details of other drug therapy: moclobemide



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 146443

Seq: 1

Gender: M

Reported: 02/12/1999

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 08/10/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevation of prolactin serum level	
Blood testosterone decreased		Reduction of the serum testosterone level	Risperdal dose reduced to 2mg.
Mastitis			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	3.5 Milligram	Daily	Oral
Batch:	Started: 12/02/1998	Stopped: 10/09/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data	9.5 - 35.0 mIU/L	08/09/1999	6.6	Testosterone level
	Prolactin	50 - 300mIU/L	08/09/1999	704	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 146836

Seq: 1

Gender: M

Reported: 13/12/1999

Weight:

Hospitalisation:

Age: 61

Onset Date: 20/11/1999

DOB: 24/10/1938

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			Cogentin

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	Started: 06/11/1999	Stopped:	CONTIN
ZUCLOPENTHIXOL DECANOATE (Suspected)		Reason: Unspecified psychosis	
	100.0 Milligram	Daily	
Batch:	Started: 18/11/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking sodium valproate, salbutamol, clonazepam, benztropine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 147034

Seq: 1

Gender: M

Reported: 16/12/1999

Weight: 75.00

Hospitalisation:

Age: 58

Onset Date: 16/09/1999

DOB: 15/09/1941

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Severe akathisia	Benzthopine, diazapam, indoral 40mg bd.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
12.0 Milligram	Daily
Batch:	Started: 30/03/1999 Stopped: 04/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 147084

Seq: 1

Gender: F

Reported: 17/12/1999

Weight: 44.00

Hospitalisation:

Age: 17Y

Onset Date: 08/12/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Increased irritability	
Coordination abnormal		Very unsteady, unable to walk.	
Hallucination			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 08/12/1999	Stopped: 08/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 147308

Seq: 1

Gender: M

Reported: 23/12/1999

Weight: 51.00

Hospitalisation:

Age: 14Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertrichosis		Fine hair on face and neck	

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
	1.0 Gram	Daily	
Batch:	Started: 01/04/1999	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 01/05/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking dexamphetamine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 147317

Seq: 1

Gender: F

Reported: 23/12/1999

Weight:

Hospitalisation:

Age: 43Y

Onset Date: 31/10/1999

DOB:

Outcome: Not yet recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		No menstruation	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/04/1999	Stopped: 28/10/1999	
RISPERDAL (Suspected)		Reason: Specific disorders of sleep	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 147505

Seq: 1

Gender: M

Reported: 24/12/1999

Weight: 90.00

Hospitalisation:

Onset Date: 31/08/1999

Age: 18Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngitis			Antibiotic therapy amoxil, rulide, abbocillin.

Medicine Details:

RISPERDAL (Suspected)	Reason: Explosive personality disorder
Oral application	1.0 Milligram Daily Oral
Batch:	Started: 01/08/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148015
Reported: 14/01/2000

Seq: 1

Gender: F
Weight: 71.00

Hospitalisation:

Onset Date: 31/10/1999
Outcome: Recovered

Age: 61Y

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperventilation			Dose of risperdal reduced from 4mg to 2mg daily.

Medicine Details:

RENITEC (Other drug)	Reason: Essential benign hypertension
10.0 Milligram Daily	
Batch:	Started: 01/06/1999 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified psychosis
4.0 Milligram Daily	
Batch:	Started: 01/09/1999 Stopped: 28/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148239

Seq: 1

Gender: F

Reported: 20/01/2000

Weight:

Hospitalisation:

Age: 49Y

Onset Date: 20/10/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal		Hair has become very hard and like straw.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 20/10/1999	Stopped:	CONTIN
NIZATIDINE (Suspected)		Reason:	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking trisequens. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148240

Seq: 1

Gender: F

Reported: 20/01/2000

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 28/06/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		28/06/1999	1670	

Additional Information:

Patient also taking modecate, temazepam, serepax, benztropine and diane 35.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148274

Seq: 1

Gender: F

Reported: 24/01/2000

Weight:

Hospitalisation:

Age: 86Y

Onset Date: 31/12/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			Zoloft reduced

Medicine Details:

RISPERDAL (Suspected)		Reason:	
		0.0	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
		50.0 Milligram Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148454

Seq: 1

Gender: M

Reported: 31/01/2000

Weight:

Hospitalisation:

Age: 20Y

Onset Date: 02/07/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharospasm			The patient had some relief with benztropine and a reduction of the dose of risperidone.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 08/09/1998	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/08/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148836

Seq: 1

Gender: F

Reported: 11/02/2000

Weight: 75.00

Hospitalisation:

Age: 20

Onset Date: 02/07/1999

DOB: 08/06/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw tightness	Cogentin

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/07/1999	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 01/07/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking zoloft and panamax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 148981

Seq: 1

Gender: M

Reported: 14/02/2000

Weight: 50.00

Hospitalisation:

Onset Date: 31/10/1999

Age: 09Y

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
	2.0 Milligram	Daily	
Batch:	Started: 01/10/1999	Stopped: 03/02/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increase in weight from 30-40kg over four months. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 149751

Seq: 1

Gender: F

Reported: 29/02/2000

Weight:

Hospitalisation:

Age: 32Y

Onset Date: 20/01/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia		Creamy discharche from nipples.	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aropax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 150369
Reported: 10/03/2000

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 01/02/2000

Age: 16Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Risperidone and diazepam ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 20/01/2000	Stopped: 01/02/2000	
DIAZEPAM (Suspected)		Reason: Specific disorders of sleep	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Increased lft's detected about 10 days after commencing risperidone. drugs ceased and lft's repeated in 2 days - levels decreased.

Additional Information:

Amobarbited 0.1mg ?frequency and bromoual erylurea 0.15mg ?frequency - reported on discharge summary when he first became psychotic on 20.1.00. allergies to some foods.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 150836

Seq: 1

Gender: F

Reported: 27/03/2000

Weight:

Hospitalisation:

Age: 84Y

Onset Date: 24/02/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erythema multiforme			Ceased zoloft and risperidone.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 150906

Seq: 1

Gender: F

Reported: 28/03/2000

Weight: 105.00

Hospitalisation:

Onset Date: 20/10/1999

Age: 30

DOB: 02/07/1969

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Weight decreased			

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
Oral application	1.0 Milligram
Batch:	Daily
Started: 31/03/1998	Oral
Stopped:	
ALDAZINE (Suspected)	Reason: Specific disorders of sleep
Tablet	200.0 Milligram
Batch:	Daily
Started: 24/06/1998	Oral
Stopped:	
AROPAX (Suspected)	Reason: Depression
Tablet	30.0 Milligram
Batch:	Daily
Started: 31/03/1998	Oral
Stopped:	
SODIUM VALPROATE (Suspected)	Reason:
Tablet	1.0 Gram
Batch:	Daily
Started: 07/04/1998	Oral
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Lost a lot of weight 15-20 kgs.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 150939 **Seq:** 1 **Gender:** M
Reported: 28/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 78
Onset Date: 15/02/2000 **DOB:** 27/11/1921
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokinesia Confusional state Fatigue Urinary incontinence Dizziness Hypotension		Decreased mobility. Increased confusion. Increased lethargy. Increased urinary incontinence.	Ceasing risperidone. madopar dose has since been decreased to 5 x day ceasing last dose of the day. chlormethiazole been introduced.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking warfarin, ranitidine, madopar and paroxetine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 150992

Seq: 1

Gender: F

Reported: 28/03/2000

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 04/01/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Disturbance in attention Somnolence			Risperdal decreased then ceased, aricept ceased and started on olanzapine therapy.

Medicine Details:

ARICEPT (Suspected)	Reason: Presenile dementia
0.0	
Batch:	Started: 01/06/1999 Stopped: 28/09/1999
RISPERDAL (Suspected)	Reason: Paranoia
3.0 Milligram Daily	
Batch:	Started: 01/06/1999 Stopped: 04/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 151049
Reported: 28/03/2000
Hospitalisation:
Onset Date: 27/10/1998
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 20Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Saliva altered		Difficulty with salivation and tongue movements.	
Dystonia			Benztropine 2mg given orally. thioridazine reduced to 150mg/d.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason: Unspecified psychosis	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 26/10/1998	Stopped: 27/10/1998	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 23/10/1998	Stopped:	CONTIN
DIAZEPAM (Suspected)		Reason: Anxiety neurosis	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 24/10/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 151287

Seq: 1

Gender: F

Reported: 06/04/2000

Weight: 72.00

Hospitalisation:

Age: 81Y

Onset Date: 21/02/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Altered mental state	
Convulsion		Clonic tonic seizure	Phenytoin
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 10/02/2000	Stopped: 21/02/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking thyroxine, temazeapm, lactulose, paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 151790

Seq: 1

Gender: M

Reported: 18/04/2000

Weight:

Hospitalisation:

Age: 16Y

Onset Date: 09/07/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Tongue feeling increasingly swollen.	Benztrapine. risperidone slowly withdrawn over 1 week. olanzapine slowly introduced in place of risperidone.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Oral application	6.0 Milligram Daily Oral
Batch:	Started: 01/05/1999 Stopped: 12/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient found it difficult to speak properly and move tongue. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 151811

Seq: 1

Gender: F

Reported: 17/04/2000

Weight:

Hospitalisation:

Age: 52Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Swollen feet.	Risperdal therapy ceased more than 5 years ago.
Weight increased		Weight gain.	

Medicine Details:

RISPERDAL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking multiple concomitant medications.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 152154 **Seq:** 1 **Gender:** M
Reported: 26/04/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 19/04/2000 **DOB:** 31/10/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 152326

Seq: 1

Gender: M

Reported: 03/05/2000

Weight:

Hospitalisation:

Age: 29Y

Onset Date: 02/03/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Generalised tonic-clonic movements.	

Medicine Details:

CLOPIXOL (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 29/02/2000	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 21/02/2000	Stopped:	21/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 152327
Reported: 03/05/2000
Hospitalisation:
Onset Date: 04/02/2000
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 84Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Plaques with central grey blue discolouration.	Sorbolene cream, oatmeal baths and olive oil to scalp.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	07/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Biopsy was taken, which suggested toxic pustuloderma or agep (acute generalised exanthematous pustulosis).

Additional Information:

Patient was also taking ssri which was discontinued on 7.2.00, verapamil, folic acid, atorvastatin, aspirin and coloxyl with senna. reaction: the patches commenced in the intramammary regions, spreading over the next few days to trunk, neck, back, arms, groin, thighs and legs, sparing the face. it progressed to skin exfoliation and redness of skin, but no oedema.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 152438 **Seq:** 1 **Gender:** M
Reported: 08/05/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 82Y
Onset Date: 17/04/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Tachycardia		Bp 56/38	Dose reduced to 0.5mg and slowly increased on subsequent nights.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 17/04/2000	Stopped: 17/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking oxazepam, temazepam, droperidol, panadeine, lactulose, olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 152716 **Seq:** 1 **Gender:** F
Reported: 18/05/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 33Y
Onset Date: 14/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope Amnesia Arrhythmia Convulsion Palpitations		Loss of consciousness.	Treated with sodium valproate

Medicine Details:

MELLERIL (Other drug)		Reason:	
		1.0 Dose Unspecified As necessary	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 13/11/1998	Stopped: 22/08/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Ecg showed qtc from 0.47 to 0.45. ct scan in mar-00 showed no abnormalities. eeg on 8/3/00 showed temporal lobe activity.

Additional Information:

Patient history of palpitations whilst taking risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153176

Seq: 1

Gender: F

Reported: 10/05/2000

Weight: 72.00

Hospitalisation:

Age: 16Y

Onset Date: 17/04/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms Drug withdrawal syndrome Dysphagia Headache Insomnia Nausea Nervousness Tremor Vomiting		Cramping legs/feet -->spasms	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
0.2 Milligram	Daily
Batch:	Started: 18/02/1999 Stopped: 17/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking luxox. doctors comment: withdrawal syndrome to risperdal unusual.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153333

Seq: 1

Gender: F

Reported: 01/06/2000

Weight: 0.00

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pituitary tumour Diplopia Headache Hyperprolactinaemia	Severe Severe	Pituitary neoplasm	

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
0.0			
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
3.0 Milligram		Daily	Oral
Batch:	Started: 01/01/1996	Stopped: 28/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				Prolactin level of 50,000 miu/l. ct scan showed an enlarged pituitary.

Additional Information:

The dosage start date is not accurate but indicates that start occurred sometime during the year. The dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153461
Reported: 07/06/2000

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 16Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Ceased risperidone and reduced venlafaxine dose. commenced high dose cabergoline 0.5mg bd.
Hyperprolactinaemia			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Depression	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Depression	
Oral application	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Prolactinaemia diagnosed on 22/12/1999.
	Prolactin	66 - 490 MU/L	08/11/1999	1096	
	Prolactin	66 - 490 MU/L	30/11/1999	759	
	Prolactin	66 - 490 MU/L	10/01/2000	11MU/L	
	Prolactin	66 - 490 MU/L	17/04/2000	209MU/L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153543

Seq: 1

Gender: M

Reported: 09/06/2000

Weight: 85.00

Hospitalisation:

Age: 18Y

Onset Date: 25/05/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaphylactoid reaction			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153609

Seq: 1

Gender: M

Reported: 13/06/2000

Weight:

Hospitalisation:

Age: 60

Onset Date: 05/06/2000

DOB: 15/07/1939

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia		Temps of 35.4 and 34.8 degrees c.	
Blood creatine phosphokinase incr			

Medicine Details:

DIAZEPAM (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase				Ck was 1569, ck on the next 2 days was 635 and 359 respectively.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 153764

Seq: 1

Gender: M

Reported: 19/06/2000

Weight: 77.00

Hospitalisation:

Age: 29Y

Onset Date: 20/05/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Asthenia Blood creatine phosphokinase incr Chills Headache Hyperhidrosis Leukocytosis Malaise Neuroleptic malignant syndrome Pyrexia Visual disturbance		Rigidity in limbs	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
4.0 Milligram	Daily
Batch:	Started:
	Stopped: 20/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		20/05/2000	685	
	White blood cells		20/05/2000	13.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 154013

Seq: 1

Gender: M

Reported: 22/06/2000

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 06/06/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory disorder	Required Specialist Consultation	Restricted breathing.	
Dystonia		Very mild dystonia.	
Libido decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Oculomotor muscles neck, masseters, upper and lower trunk. chronic paranoid schizophrenia well controlled on risperdal 2mg/day. some treatment emergent dystonia (very mild), reduced libido and persistence of negative schizophrenic symptoms - affective blunting, disturbances in concentration.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 154038

Seq: 1

Gender: F

Reported: 23/06/2000

Weight:

Hospitalisation:

Age: 52Y

Onset Date: 16/03/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electroencephalogram abnormal			

Medicine Details:

RISPERDAL (Suspected)		Reason: Presenile dementia	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 09/03/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred within one week of starting risperdal therapy. medical history alzheimer's disease with a range of psychiatric symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 154039

Seq: 1

Gender: F

Reported: 23/06/2000

Weight:

Hospitalisation:

Age: 40Y

Onset Date: 31/05/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LIPEX (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
ASPIRIN (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
QUINAPRIL HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason:
6.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(30-40)IU/L	03/05/2000	121	
	Bilirubin	(3)UMOL/L	03/05/2000	12	
	GGT = SGGT =	(<40)IU/L	03/05/2000	112	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 154078

Seq: 1

Gender: M

Reported: 26/06/2000

Weight:

Hospitalisation:

Age: 25

Onset Date: 05/06/2000

DOB: 28/08/1974

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Clozaril and risperidone treatment ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 08/03/2000	Stopped: 10/06/2000	
RISPERIDONE (Suspected)		Reason:	
	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 154474

Seq: 1

Gender: M

Reported: 06/07/2000

Weight:

Hospitalisation:

Age: 13Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache Muscle twitching Dyskinesia Extrapyramidal disorder Extrapyramidal disorder Syncope Tardive dyskinesia Tremor		Bad headaches. Mouth twitching.	Cogentin.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tardive dyskinesia symptoms such as tremors, arm and leg jerkiness, rigidity of muscles, teeth chattering, body vibrations, eyes rolling in the head and mouth staying open. reactions occur throughout the day and the evening and have interfered with schooling and hygiene (such as showering).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155023

Seq: 1

Gender: F

Reported: 19/07/2000

Weight:

Hospitalisation:

Age: 40

Onset Date: 28/06/2000

DOB: 25/02/1960

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea Hyperprolactinaemia			Changed to olanzapine 7.5mg.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
1.5 Milligram	Daily
Batch:	Started: 18/12/1999 Stopped: 28/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Prolactin level 1621 (n:619).

Additional Information:

Date of recovery 12.7.00.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155243

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 81Y

Onset Date: 18/01/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 90/50	Risperidone ceased, commenced clozapine.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 12/01/2000 Stopped: 19/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking citalopram, oxazepam, paracetamol, aspirin, imdur, coloxyl with senna, duralax, vit b12. previous adr on haloperidol - delusions.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155271

Seq: 1

Gender: F

Reported: 20/07/2000

Weight: 50.00

Hospitalisation:

Age: 75Y

Onset Date: 16/12/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Widespread drug eruption	Diprosone oint, phenergan tds. omeprazole and perindopril ceased.

Medicine Details:

OMEPRAZOLE (Suspected)		Reason: Other diseases of esophagus	
Oral application	40.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1999	Stopped: 16/12/1999	
PERINDOPRIL (Suspected)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped: 16/12/1999	
CITALOPRAM HYDROBROMIDE (Suspected)		Reason: Depression	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1999	Stopped: 22/12/1999	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Oral application	0.5 Milligram	Daily	Oral
Batch:	Started: 30/11/1999	Stopped: 21/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of bulous pemphigoid. patient also taking panadol, oxazepam. previous adr to prednisolone, haloperidol, frusemide, flucloxacillin, ethasymic acid, olanzapine, diazepam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155271

Seq: 1

Gender: F

Reported: 20/07/2000

Weight: 50.00

Hospitalisation:

Age: 75Y

Onset Date: 16/12/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

FEFOL (Suspected)

Reason: Unspecified anemia

Oral application

1.0 Dose Unspecified Daily

Oral

Batch:

Started:

L TERM

Stopped: 22/12/1999

Laboratory Investigations:

Additional Information:

History of bulous pemphigoid. patient also taking panadol, oxazepam. previous adr to prednisolone, haloperidol, frusemide, flucloxacillin, ethasymic acid, olanzapine, diazepam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155823

Seq: 1

Gender: F

Reported: 04/08/2000

Weight:

Hospitalisation:

Age: 52

Onset Date: 14/06/2000

DOB: 10/10/1947

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Life threatening	Life threatening acute pancreatitis.	

Medicine Details:

RISPERDAL (Suspected)	Reason:
0.0	
Batch:	Started: 01/06/2000 Stopped: 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Risperdal given for behaviour changes. patient also taking gopten, norvasc and melleril. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 155898

Seq: 1

Gender: M

Reported: 07/08/2000

Weight:

Hospitalisation:

Age: AD

Onset Date: 31/07/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

LAMISIL (Interaction)		Reason: Cellulitis of finger and toe	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 01/06/2000	S TERM	Stopped:
RISPERIDONE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patients psychoses was not managed as well and this decrease in efficacy was noted 4 weeks after starting lamisil. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 156028 **Seq:** 1 **Gender:** F
Reported: 10/08/2000 **Weight:** 90.00
Hospitalisation: Admitted to hospital **Age:** 33
Onset Date: 23/07/2000 **DOB:** 13/11/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Blood creatine phosphokinase incr Myopathy		Altered conscious state.	Patient hospitalised. date of recovery 07/08/00. treatment ceased.

Medicine Details:

RISPERDAL (Suspected)	Reason:
4.0 Milligram	Daily
Batch:	Started: 04/07/2000 Stopped: 28/07/2000
QUININE (Suspected)	Reason: Pain in limb
300.0 Milligram	Daily
Batch:	Started: 20/07/2000 Stopped: 28/07/2000
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep
10.0 Milligram	Daily
Batch:	Started: 04/07/2000 Stopped: 28/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		28/07/2000	3072	
	Creatine		02/08/2000	134	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 156060 **Seq:** 1 **Gender:** M
Reported: 11/08/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 44Y
Onset Date: 04/08/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Hypertonia Neuroleptic malignant syndrome Pyrexia			Risperdal ceased. patient was hospitalised.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 01/05/2000	Stopped: 08/08/2000	
EPILIM (Suspected)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started: 02/08/2000	Stopped: 04/08/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lithium. long history of melleril use prior to risperdal. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157229

Seq: 1

Gender: F

Reported: 31/08/2000

Weight:

Hospitalisation:

Age: 18Y

Onset Date: 19/06/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	4.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2000	Stopped: 26/06/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157331

Seq: 1

Gender: U

Reported: 04/09/2000

Weight:

Hospitalisation:

Age:

Onset Date: 31/08/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Interstitial nephritis	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pre-existing renal impairment. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157738

Seq: 1

Gender: M

Reported: 15/09/2000

Weight: 110.00

Hospitalisation:

Age: 20Y

Onset Date: 09/09/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Weight increased			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	2.5 Milligram	Daily	
Batch:	Started: 10/02/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Ggt 77 (<51), alt 61 (<51).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157739

Seq: 1

Gender: M

Reported: 15/09/2000

Weight:

Hospitalisation:

Age: 88Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase incr Somnolence		Temp of 39.2 degrees	Date of recovery 11/09/00

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.5 Milligram	Daily	
Batch:	Started: 01/08/2000	Stopped: 09/09/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Cpk 1330.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157742

Seq: 1

Gender: M

Reported: 15/09/2000

Weight:

Hospitalisation:

Age: 45

Onset Date: 06/07/2000

DOB: 27/12/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Hypertonia Pyrexia			Bromocriptine then electroconvulsive therapy.

Medicine Details:

NORVIR (Suspected)	Reason: Hiv infection
800.0 Milligram Daily	
Batch:	Started: 01/01/2000 Stopped: 08/07/2000
FORTOVASE (Suspected)	Reason: Hiv infection
400.0 Milligram Daily	
Batch:	Started: 01/01/2000 Stopped: 08/07/2000
COMBIVIR (Suspected)	Reason: Hiv infection
2.0 Dose Unspecified Daily	
Batch:	Started: 01/01/2000 Stopped: 08/07/2000
RISPERDAL (Suspected)	Reason: Unspecified psychosis
4.0 Milligram Daily	
Batch:	Started: 01/03/2000 Stopped: 08/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine				Small rise in creatinine kinase levels

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 157742

Seq: 1

Gender: M

Reported: 15/09/2000

Weight:

Hospitalisation:

Age: 45

Onset Date: 06/07/2000

DOB: 27/12/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZIAGEN (Suspected)		Reason: Hiv infection
	2.0 Dose Unspecified Daily	
Batch:	Started: 01/01/2000	Stopped: 08/07/2000
VALIUM (Suspected)		Reason: Unspecified psychosis
	10.0 Milligram Daily	
Batch:	Started: 03/07/2000	Stopped: 08/07/2000

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 158671

Seq: 1

Gender: F

Reported: 18/10/2000

Weight:

Hospitalisation:

Age: 36

Onset Date: 13/10/2000

DOB: 24/04/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting			Pramin 1q6h prn, required a visit to doctor.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 11/10/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 158723

Seq: 1

Gender: F

Reported: 20/10/2000

Weight:

Hospitalisation:

Age: 25Y

Onset Date: 30/07/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Risperdal ceased

Medicine Details:

RISPERDAL (Suspected)		Reason: Manic depressive psycho, depre	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped: 21/09/2000	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Oral application	225.0 Milligram	Daily	Oral
Batch:	Started: 18/07/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes	1-4 X10E9/L	25/07/2000	1.0	
	Lymphocytes	1-4 X10E9/L	30/07/2000	0.9	
	Lymphocytes	1-4 X10E9/L	07/09/2000	0.9	
	Neutrophils	1.8-8 X10E9/L	25/07/2000	5.4	
	Neutrophils	1.8-8 X10E9/L	30/07/2000	2.0	
	Neutrophils	1.8-8 X10E9/L	07/09/2000	1.3	
	White blood cells	4-11 X10E9/L	25/07/2000	7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 158723

Seq: 1

Gender: F

Reported: 20/10/2000

Weight:

Hospitalisation:

Age: 25Y

Onset Date: 30/07/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Manic depressive psycho, depre	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped: 21/09/2000	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Oral application	225.0 Milligram	Daily	Oral
Batch:	Started: 18/07/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4-11 X10E9/L	30/07/2000	3.5	
	White blood cells	4-11 X10E9/L	07/09/2000	2.5	
	White blood cells	4-11 X10E9/L	25/09/2000	5.4	
	White blood cells	4-11 X10E9/L	29/09/2000	3.1	
	White blood cells	4-11 X10E9/L	06/10/2000	2.7	
	White blood cells	4-11 X10E9/L	13/10/2000	3.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 158867 **Seq:** 1 **Gender:** M
Reported: 27/10/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 36Y
Onset Date: 31/10/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Worsening of dystonia.	
Blood creatine phosphokinase incr			Patient hospitalised.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 11/10/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		11/10/2000	5000	Ck levels normalised to <200u/l.
	Creatine		12/10/2000	1000	Ck levels normalised to <200u/l.
	Creatine		23/10/2000	<200	Ck levels normalised to <200u/l.

Additional Information:

Patient also taking lithium carbonate. patient refuses treatment with any other antipsychotic. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 158896

Seq: 1

Gender: M

Reported: 31/10/2000

Weight:

Hospitalisation:

Age: 86Y

Onset Date: 31/08/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	Stopped:	4D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells				Slightly elevated wcc.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159301
Reported: 16/11/2000

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 04/10/2000

Age: 18Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Tongue was stiff & protruding, then curled up.	Given im benztropine

Medicine Details:

HALOPERIDOL (Suspected)		Reason:	
Injection	10.0 Milligram	1 time	Intramuscular
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 03/10/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking midazolam, diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159355
Reported: 16/11/2000

Seq: 1

Gender: F

Weight:

Hospitalisation:

Age: 22Y

Onset Date: 12/06/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Swollen tongue.	
Dyskinesia		Tongue darting.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 12/06/2000	Stopped: 13/06/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diane 35. no previous exposure but further exposure (one off dose) caused no further effects. this was the first exposure to antipsychotics - previously neuroleptic naive.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159674 **Seq:** 1 **Gender:** M
Reported: 01/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 76
Onset Date: 10/11/2000 **DOB:** 30/06/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia		Acute hypoglycaemia.	Patient was hospitalised. discharged 3 days later.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason: Otr spec symp psychopathol nec	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: 01/10/2000	Stopped:	CONTIN
RANITIDINE (Suspected)		Reason: Other diseases of esophagus	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Bsl prior to admission 1.3 mmol/l.

Additional Information:

No previous history of hypoglycaemia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159736

Seq: 1

Gender: M

Reported: 20/11/2000

Weight:

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Risperidone ceased

Medicine Details:

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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159796

Seq: 1

Gender: M

Reported: 07/12/2000

Weight:

Hospitalisation:

Age: 29Y

Onset Date: 09/11/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema Weight increased		Oedema hands, feet, face.	Patient already in hospital

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 06/11/2000	Stopped: 09/11/2000	
RISPERDAL (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 09/11/2000	Stopped: 13/11/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking clonazeapm, flupenthixol decanoate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159805

Seq: 1

Gender: M

Reported: 08/12/2000

Weight:

Hospitalisation:

Age: 38

Onset Date: 02/12/2000

DOB: 18/04/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		High temp 38.3 degrees.	
Blood creatine phosphokinase incr			
Neuroleptic malignant syndrome	Life threatening		Iv hydration, alkaline urine.
Renal failure acute	Life threatening		
Rhabdomyolysis	Severe		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1999	Stopped: 02/12/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		02/12/2000	240,000	

Additional Information:

Patient history of schizophrenia and intellectual retardation. sequelae: renal failure. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159814 **Seq:** 1 **Gender:** F
Reported: 08/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 48
Onset Date: 27/10/2000 **DOB:** 17/08/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Suicide attempt Tremor			Patient hospitalised

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2000	Stopped: 20/10/2000	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 20/10/2000	Stopped: 01/11/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking epilim, seroquel. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 159945

Seq: 1

Gender: F

Reported: 13/12/2000

Weight: 60.00

Hospitalisation:

Age: 26

Onset Date: 06/12/2000

DOB: 23/09/1974

Outcome: Not yet recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema		Swollen eyelid, puffy lips.	Respiridone ceased. required a visit to doctor.
Pruritus			
Urticaria			

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
1.0 Milligram	Daily
Batch:	Started: 05/12/2000 Stopped: 06/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same reaction occurred on rechallenge with risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160356

Seq: 1

Gender: M

Reported: 02/01/2001

Weight:

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharospasm Tardive dyskinesia		Uncontrollable eye shutting.	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	8.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Australian and new zealand journal of psychiatry 2000, 34 (5): 879-80.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160357
Reported: 02/01/2001

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 31/10/2000

Age: 25

DOB: 29/10/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Thrombocytopenia		Elevated prolactin level.	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Oral application	7.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1999	Stopped:	28/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		14/07/2000	169X10 ⁹ /L	
	Platelets		26/10/2000	123X10 ⁹ /L	
	Platelets		24/11/2000	102X10 ⁹ /L	
	Prolactin		26/10/2000	114.8MIU/L	
	Prolactin		24/11/2000	113.1MIU/L	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160468 **Seq:** 1 **Gender:** M
Reported: 09/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Renal impairment			Patient was admitted to hospital.

Medicine Details:

RISPERDAL (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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160773
Reported: 18/01/2001

Seq: 1

Gender: F
Weight: 89.00
Age: 37Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hearing voices and visual hallucinations.	
Psychotic disorder		Slashed wrists and breasts.	

Medicine Details:

ALDAZINE (Interaction)	Reason:
50.0 Milligram	As necessary
Batch:	Started: Stopped:
ZYBAN SR (Interaction)	Reason:
300.0 Milligram	Daily
Batch:	Started: 13/11/2000 Stopped: 04/01/2001
RISPERDAL (Interaction)	Reason:
4.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking adventan, akineton, aldazine, betnovate, depo-ralovera, diazepam, diffiam, efexor-xr, ergodryl mono, metoclopramide and panadeine forte. allergies to cephalixin, cortisone im, cotrimoxazole, doxycycline, erythromycin, gentamicin, lincomycin, neomycin, septrin, sodium, streptomycin and theophylline.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160797 **Seq:** 1 **Gender:** M
Reported: 22/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 04/01/2001 **DOB:** 25/05/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Patient hospitalised. patient diagnosed with hep c.

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
	4.0 Milligram	Daily
Batch:	Started: 27/12/2000	Stopped: 03/01/2001
LITHICARB (Suspected)		Reason: Unspecified schizophrenia
	1.2 Gram	Daily
Batch:	Started:	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		04/01/2000	689	
	ALT = SGPT		05/01/2001	540	
	ALT = SGPT		10/01/2001	555	
	ALT = SGPT		08/01/2001	562	
	ALT = SGPT		11/01/2001	595	
	AST = SGOT		04/01/2000	211	
	AST = SGOT		05/01/2001	181	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160797

Seq: 1

Gender: M

Reported: 22/01/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 35

Onset Date: 04/01/2001

DOB: 25/05/1965

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	
Batch:	Started: 27/12/2000	Stopped: 03/01/2001	
LITHICARB (Suspected)		Reason: Unspecified schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		08/01/2001	173	
	AST = SGOT		11/01/2001	177	
	AST = SGOT		10/01/2001	174	
	GGT = SGGT =		04/01/2000	84	
	GGT = SGGT =		10/01/2001	68	
	GGT = SGGT =		08/01/2001	61	
	GGT = SGGT =		05/01/2001	76	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160797

Seq: 1

Gender: M

Reported: 22/01/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 35

Onset Date: 04/01/2001

DOB: 25/05/1965

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	4.0 Milligram	Daily	
Batch:	Started: 27/12/2000	Stopped: 03/01/2001	
LITHICARB (Suspected)		Reason: Unspecified schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		11/01/2001	72	
	SAP = ALP		04/01/2000	146	
	SAP = ALP		05/01/2001	128	
	SAP = ALP		08/01/2001	117	
	SAP = ALP		10/01/2001	112	
	SAP = ALP		11/01/2001	117	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 160806
Reported: 22/01/2001
Hospitalisation:
Onset Date: 24/11/2000
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 77
DOB: 07/05/1923
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Tardive dyskinesia			Risperdal and cogentin ceased.

Medicine Details:

ZANTAC (Other drug)	Reason: 2.0 Dose Unspecified Daily
Batch:	Started: Stopped:
PANAMAX (Other drug)	Reason: 4.0 Dose Unspecified Daily
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: 5.0 Milligram Daily
Batch:	Started: 02/11/2000 Stopped: 05/12/2000
COGENTIN (Suspected)	Reason: 2.0 Milligram Daily
Batch:	Started: 14/11/2000 Stopped: 05/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 161118
Reported: 01/02/2001
Hospitalisation:
Onset Date: 24/01/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 23
DOB: 25/05/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Life threatening	Severe dystonia reaction	Given cogentin im.
Oculogyration			

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected)		Reason: Unspecified psychosis	
Injection	100.0 Milligram	1 time	Intramuscular
Batch:	Started: 22/01/2001	Stopped: 22/01/2001	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 22/01/2001	Stopped: 23/01/2001	
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 23/01/2001	Stopped: 24/01/2001	
DIAZEPAM (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started: 22/01/2001	Stopped: 22/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin. patient recovered 24/01/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 161533
Reported: 14/02/2001

Seq: 1

Gender: F
Weight: 50.00

Hospitalisation:

Onset Date: 20/02/2000
Outcome: Recovered

Age: 48Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema Hypoproteinaemia		Pedal oedema - moderately severe.	

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped:	CONTIN
TEMAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped:	
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Albumin				Albumin fell to 31.

Additional Information:

Patient also taking lithium and thioridazine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 161558

Seq: 1

Gender: M

Reported: 10/02/2001

Weight: 100.00

Hospitalisation:

Age: 84

Onset Date: 23/01/2001

DOB: 17/05/1916

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Thought disorder	Required a visit to doctor.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 25/12/2000	Stopped: 25/01/2001	
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 24/10/2000	Stopped: 25/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aldactone, astrix, lanoxin, lasix. patient recovered 28/1/01.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 161582 **Seq:** 1 **Gender:** F
Reported: 16/02/2001 **Weight:** 85.00
Hospitalisation: Admitted to hospital **Age:** 74
Onset Date: 15/01/2001 **DOB:** 29/07/1926
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Irrational behaviour, aggressive.	Cessation of drugs, patient hospitalised
Thinking abnormal		Thought disorder	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 12/02/2000	Stopped: 20/01/2001	
ZOLOFT (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
Batch:	Started: 19/10/2000	Stopped: 20/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fosamax, augmentin forte, astrix.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 161616 **Seq:** 1 **Gender:** M
Reported: 16/02/2001 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: 10/11/2000 **DOB:** 30/06/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia			Glucose infusion. patient hospitalised

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
SODIUM VALPROATE (Suspected)	Reason: Otr spec symp psychopathol nec
200.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
RANITIDINE (Suspected)	Reason:
300.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Bsl - 1.3mmol/l

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162004

Seq: 1

Gender: M

Reported: 28/02/2001

Weight: 110.00

Hospitalisation:

Age: 16

Onset Date: 08/02/2001

DOB: 26/08/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Drug withdrawal syndrome Dyskinesia		Weight gain 25kg.	Required a visit to doctor.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
6.0 Milligram	Daily
Batch:	Started: 01/10/1999 Stopped: 04/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fluvoxamine, quetiopine. reaction occurred 4 days after the cessation of risperidone and 4 days into quetiopine therapy. patient has asperger's and mildly intellectually impaired. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162258

Seq: 1

Gender: M

Reported: 07/03/2001

Weight:

Hospitalisation:

Age: 19Y

Onset Date: 02/01/2001

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash	Required Specialist Consultation	Itchy all over. Rash on face	Ceased phenytoin.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 13/12/1999	Stopped: 21/12/2000	
PHENYTOIN SODIUM (Suspected)		Reason: Prophylaxis	
Capsule	400.0 Milligram	Daily	Oral
Batch:	Started: 13/02/2000	Stopped: 21/12/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking lacrilube, rhinocort. patient recovered 22/12/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162375

Seq: 1

Gender: F

Reported: 08/03/2001

Weight: 60.00

Hospitalisation:

Age: 44Y

Onset Date: 14/12/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Cease risperidone on 14/12/2000. restarted on 20/12/2000.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	0.5 Milligram	As necessary	Oral
Batch:	Started: 12/11/2000	Stopped: 14/12/2000	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant medical history - alzheimer's disease - agitated. patient also taking - donepezil and sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162384

Seq: 1

Gender: F

Reported: 08/03/2001

Weight: 38.00

Hospitalisation:

Onset Date: 11/01/2001

Age:

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Anorexia Confusional state Dry mouth Fatigue Hypertension Neuropathy peripheral		Involuntary jerking movements.	

Medicine Details:

BACLOFEN (Suspected)		Reason: Abnormal involuntary movement	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started: 07/01/2001	Stopped: 12/01/2001	
QUININE (Suspected)		Reason: Pain in limb	
Oral application	300.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2001	Stopped: 11/01/2001	
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason: Pain	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 07/01/2001	Stopped: 10/01/2001	
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason: Pain	
Oral application	50.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2001	Stopped: 11/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking trimethoprim, digesic, heparin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162384

Seq: 1

Gender: F

Reported: 08/03/2001

Weight: 38.00

Hospitalisation:

Age:

Onset Date: 11/01/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PERSANTIN SR (Suspected)		Reason:	
Capsule	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 11/01/2001	
RISPERIDONE (Suspected)		Reason: Abdominal pain	
	1.0 Milligram	Daily	
Batch:	Started: 10/01/2001	Stopped: 11/01/2001	

Laboratory Investigations:

Additional Information:

Patient was also taking trimethoprim, digesic, heparin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162385 **Seq:** 1 **Gender:** F
Reported: 08/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: 22/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Treated with antibiotics, ceased quetiapine. was admitted to hospital.
Somnolence			

Medicine Details:

CIPRAMIL (Suspected)	Reason:
20.0 Milligram	Daily
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
2.0 Milligram	Daily
Batch:	Started: Stopped:
QUETIAPINE (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started: Stopped: 22/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 28/2/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162499

Seq: 1

Gender: F

Reported: 13/03/2001

Weight: 30.00

Hospitalisation:

Age: 9

Onset Date: 01/12/2000

DOB: 29/09/1991

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			Required a visit to doctor. date of recovery 22/01/01

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application	250.0 Microgram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		01/12/2000	131	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162682
Reported: 16/03/2001

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 05/01/2001

Age: 41

DOB: 16/02/1959

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Risperdal ceased. date of recovery 16.1.01.

Medicine Details:

RISPERDAL (Suspected)	Reason: Otr spec symp psychopathol nec		
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 03/01/2001	Stopped: 12/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		30/12/2000	6.14	
	Neutrophils		05/01/2001	5.14	
	Neutrophils		08/01/2001	1.65	
	Neutrophils		11/01/2001	1.47	
	Neutrophils		12/01/2001	1.44	
	Neutrophils		13/01/2001	2	
	Neutrophils		15/01/2001	1.65	

Additional Information:

Patient also taking dilantin, coloxyl with senna, nilstat and heparin. patient history: 3.12.00 pushbike accident, multiple fractures, chi (multi focal haemorrhage with oedema), small intraventricular sub-dural bleed, splenic lacerations and post traumatic amnesia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 162682
Reported: 16/03/2001

Seq: 1

Gender: M

Weight:

Hospitalisation:

Age: 41

Onset Date: 05/01/2001

DOB: 16/02/1959

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 03/01/2001	Stopped: 12/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		16/01/2001	4.78	
	Neutrophils		18/01/2001	2.17	
	Neutrophils		29/01/2001	3.55	

Additional Information:

Patient also taking dilantin, coloxyl with senna, nilstat and heparin. patient history: 3.12.00 pushbike accident, multiple fractures, chi (multi focal haemorrhage with oedema), small intraventricular sub-dural bleed, splenic lacerations and post traumatic amnesia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163013
Reported: 22/03/2001

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 20/03/2001

Age: 78

DOB: 09/07/1922

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Blistering lower lip.	
Face oedema		Swelling of lower lip.	Required a visit to doctor.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	0.5 Dose Unspecified Daily Oral
Batch:	Started: 19/02/2001 Stopped: 17/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No other recent change in treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163278

Seq: 1

Gender: F

Reported: 02/04/2001

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 01/03/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Paranoia	
	1.0 Milligram	Daily	
Batch:	Started: 01/05/1997	Stopped: 28/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking diazepam, aspirin, thyroxine, hrt. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163344

Seq: 1

Gender: M

Reported: 28/03/2001

Weight:

Hospitalisation:

Age: 20

Onset Date:

DOB: 29/03/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast enlargement Hyperprolactinaemia Neutropenia			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 22/09/2000	Stopped: 28/02/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		08/09/2000	3.7	
	Neutrophils		08/02/2001	1.4	
	Neutrophils		15/02/2001	1.9	
	Neutrophils		01/03/2001	1.3	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163504

Seq: 1

Gender: F

Reported: 06/04/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence Choking Coma Constipation Salivary hypersecretion Vomiting		Bedwetting	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	
AROPAX (Suspected)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	6.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163762

Seq: 1

Gender: F

Reported: 17/04/2001

Weight:

Hospitalisation:

Age: 57

Onset Date: 03/04/2001

DOB: 23/10/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome			Dantrolene, cogentin, bromocriptine, sinemet.

Medicine Details:

CEFTRIAXONE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: 30/03/2001
GENTAMICIN SULPHATE (Other drug)	Reason:
0.0	
Batch:	Started: 27/03/2001 Stopped:
AMOXYCILLIN SODIUM (Other drug)	Reason:
0.0	
Batch:	Started: Stopped: 04/04/2001
PROTAPHANE (Other drug)	Reason:
44.0 Unit Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		26/03/2001	52	
	Creatine		03/04/2001	333	
	Creatine		04/04/2001	316	
	Creatine		05/04/2001	252	
	Creatine		06/04/2001	1347	
	Creatine		06/04/2001	1623	
	Creatine		07/04/2001	1367	

Additional Information:

Previous nms secondary to haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163762

Seq: 1

Gender: F

Reported: 17/04/2001

Weight:

Hospitalisation:

Age: 57

Onset Date: 03/04/2001

DOB: 23/10/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Other drug)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started: 26/03/2001	Stopped:	
CLONAZEPAM (Other drug)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started: 26/03/2001	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
Injection	0.5 Milligram	1 time	Intramuscular
Batch:	Started: 28/03/2001	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 30/03/2001	Stopped: 04/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		09/04/2001	403	

Additional Information:

Previous nms secondary to haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163762

Seq: 1

Gender: F

Reported: 17/04/2001

Weight:

Hospitalisation:

Age: 57

Onset Date: 03/04/2001

DOB: 23/10/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspected)

Reason: Diabetes mellitus

2.0 Gram

Daily

Batch:

Started: 29/03/2001

Stopped: 04/04/2001

Laboratory Investigations:

Additional Information:

Previous nms secondary to haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 163982

Seq: 1

Gender: M

Reported: 26/04/2001

Weight:

Hospitalisation:

Age: 52

Onset Date:

DOB: 03/03/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choking			
Dysphagia			
Tongue oedema			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164332 **Seq:** 1 **Gender:** F
Reported: 07/05/2001 **Weight:** 81.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 06/11/2000 **DOB:** 20/03/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucinations of spiders on my back.	Symptoms settled by decreasing risperidal to 2mg daily, patient was hospitalised.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Otr disord amino-acid transprt
150.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 05/03/2001
RISPERDAL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
LITHIUM CARBONATE (Suspected)	Reason: Schizophrenia
1.2 Gram Daily	
Batch:	Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333 **Seq:** 1 **Gender:** F
Reported: 07/05/2001 **Weight:** 81.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 04/01/2001 **DOB:** 20/03/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Extremely sleepy.	Required a visit to doctor, was hospitalised. dose of riperidone was increased to 3mg.
Catatonia			
Hyponatraemia			
Red blood cell sedimentation rate i			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Schizophrenia
150.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 05/03/2001
RISPERIDONE (Suspected)	Reason:
2.0 Milligram Daily	
Batch:	Started: Stopped:
LITHIUM CARBONATE (Suspected)	Reason: Schizophrenia
1.2 Gram Daily	
Batch:	Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		24/10/2000	74	
	ALT = SGPT		05/03/2001	94	
	AST = SGOT		24/10/2000	40	
	AST = SGOT		05/03/2001	34	
	Creatinine		05/03/2001	0.321	
	Creatinine		19/03/2001	0.134	
	Creatinine		27/03/2001	0.147	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333

Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 81.00

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 04/01/2001

DOB: 20/03/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		03/04/2001	0.159	
	Creatinine		01/05/2001	0.146	
	Creatinine		19/04/2001	0.122	
	Creatinine		10/04/2001	0.143	
	Erythrocyte		05/03/2001	96	
	Erythrocyte		19/03/2001	91	
	Erythrocyte		27/03/2001	84	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333

Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 81.00

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 04/01/2001

DOB: 20/03/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Erythrocyte		03/04/2001	81	
	Erythrocyte		10/04/2001	74	
	Erythrocyte		19/04/2001	60	
	Erythrocyte		01/05/2001	45	
	GGT = SGGT =		24/10/2000	50	
	GGT = SGGT =		05/03/2001	131	
	Haemoglobin		19/03/2001	10.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333

Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 81.00

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 04/01/2001

DOB: 20/03/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		27/03/2001	10.1	
	Haemoglobin		03/04/2001	10.0	
	Prolactin		03/04/2001	5467	
	Prolactin		10/04/2001	1058	
	Prolactin		01/05/2001	488	
	Prolactin		19/04/2001	627	
	SAP = ALP		24/10/2000	104	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333

Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 81.00

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 04/01/2001

DOB: 20/03/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	LITHIUM	05/03/2001	113	
	Serum drug level		05/03/2001	1.40	
	Serum glucose		05/03/2001	10.0	
	Serum glucose		19/03/2001	8.0	
	Serum glucose		03/04/2001	4.9	
	Serum glucose		27/03/2001	5.7	
	Sodium		05/03/2001	124	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333

Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 81.00

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 04/01/2001

DOB: 20/03/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urate		05/03/2001	0.85	
	Urate		03/04/2001	0.34	
	Urate		27/03/2001	0.33	
	Urate		19/03/2001	0.37	
	Urea		05/03/2001	2.7	
	Urea		19/03/2001	10.2	
	Urea		27/03/2001	7.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164333 **Seq:** 1

Reported: 07/05/2001

Hospitalisation: Admitted to hospital

Onset Date: 04/01/2001

Outcome: Recovered

Gender: F

Weight: 81.00

Age: 52

DOB: 20/03/1948

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Schizophrenia	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:		Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Schizophrenia	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urea		03/04/2001	6.2	
	Urea		10/04/2001	5.2	
	Urea		19/04/2001	3.5	
	Urea		01/05/2001	6.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164334
Reported: 07/05/2001
Hospitalisation:
Onset Date: 19/03/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 81.00
Age: 52
DOB: 20/03/1948
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia Thirst Hyperprolactinaemia Thinking abnormal Anaemia Diabetes mellitus Drug level increased Polydipsia Renal failure acute		Can not sleep. Drinking litres of water, dry mouth, very thirsty. Prolactin extremely high. Weird thoughts etc.	Ceased risperidone.

Medicine Details:

LITHIUM CARBONATE (Interaction)		Reason:	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped: 05/03/2001
RISPERIDONE (Interaction)		Reason: Schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 06/11/2000		Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164502

Seq: 1

Gender: M

Reported: 14/05/2001

Weight:

Hospitalisation:

Age: 50Y

Onset Date: 28/09/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Nothing comes out.	

Medicine Details:

SEREPAX (Other drug)		Reason:	
	7.5 Milligram	As necessary	
Batch:	Started:	L TERM	Stopped: CONTIN
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	0.0 Milligram	6 times	
Batch:	Started: 01/08/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month. patient had been on modecate for 30 years before switching to risperdal. weaned off it over 3/12.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164601

Seq: 1

Gender: U

Reported: 18/05/2001

Weight:

Hospitalisation:

Age: 21Y

Onset Date: 28/12/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

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:

The date of onset is not necessarily accurate but indicates onset sometime in the month. 2 years of use of risperdal. pt developed tarditive dyskinesia. dystonia cease d with reduction in dose but psychotic relapse necessitated reinstitution of risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164602

Seq: 1

Gender: M

Reported: 18/05/2001

Weight:

Hospitalisation:

Age:

Onset Date: 15/05/2001

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 25/04/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 164913

Seq: 1

Gender: M

Reported: 28/05/2001

Weight: 75.00

Hospitalisation:

Age: 36

Onset Date: 17/03/2001

DOB: 02/08/1964

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria	Severe	Rash on face, arms, trunk, legs, feet, ears, scalp	
Face oedema			
Oedema genital			
Oedema peripheral			
Periorbital oedema			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 16/02/2001	Stopped: 17/02/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165069 **Seq:** 1 **Gender:** F
Reported: 01/06/2001 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: 28/05/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder			

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	500.0 Microgram	Daily	Oral
Batch:	Started:	Stopped: 28/05/2001	
RISPERDAL (Suspected)		Reason:	
	1.5 Milligram	Daily	
Batch:	Started: 01/05/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. The dose start and stop dates are not accurate but indicates risperidal was started and stopped sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165276 **Seq:** 1 **Gender:** M
Reported: 12/06/2001 **Weight:** 76.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 19/02/2001 **DOB:** 24/11/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Aphasia Arrhythmia Neuroleptic malignant syndrome Bradycardia Hypertonia	Severe	Bp 70-90. Mutism. Pulse very slow and irregular. Severe neuroleptic malignant syndrome.	Patient was hospitalised. required a visit to doctor. reaction was life threatening. treated with baclofen 1 bd. melleril ceased.

Medicine Details:

GINKGO BILOBA (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
VITAMINS (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
TENORMIN (Other drug)	Reason:
25.0 Milligram Daily	
Batch:	Started: Stopped:
CARTIA (Other drug)	Reason:
100.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165276

Seq: 1

Gender: M

Reported: 12/06/2001

Weight: 76.00

Hospitalisation: Admitted to hospital

Age: 79

Onset Date: 19/02/2001

DOB: 24/11/1921

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ARICEPT (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FOLIC ACID (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
	0.5 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped: 22/02/2001	

Laboratory Investigations:

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165391
Reported: 13/06/2001
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 44
DOB: 06/03/1957
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Psychosis aggravated.	Zyban ceased. date of recovery 3/2001.

Medicine Details:

JEZIL (Other drug)	Reason: Othr&unspec metabolic diseases
2.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped:
ASPIRIN (Other drug)	Reason:
0.5 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped:
ZYBAN SR (Suspected)	Reason: Smoker
2.0 Dose Unspecified Daily	
Batch:	Started: 01/03/2001 Stopped: 28/03/2001
RISPERIDONE (Suspected)	Reason:
6.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The start and stop dates for zyban are not necessarily accurate but indicates the drug was started and stopped sometime in the month. increased "voices" schizophrenic symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165405

Seq: 1

Gender: F

Reported: 14/06/2001

Weight: 70.00

Hospitalisation:

Age: 20

Onset Date: 08/06/2001

DOB: 12/04/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Required visit to doctor, stopped risperdone, treated with cogentin

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 15/05/2001 Stopped: 10/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime of the month



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 165936

Seq: 1

Gender: M

Reported: 29/06/2001

Weight: 100.00

Hospitalisation:

Age: 34

Onset Date: 28/06/2000

DOB: 05/03/1966

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			No medication given. risperidone ceased. date of recovery 06/2001
Salivary hypersecretion			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
2.0 Gram	Daily
Batch:	Started:
Stopped:	
RISPERIDONE (Suspected)	Reason: Unspecifid affective psychosis
4.0 Milligram	Daily
Batch:	Started: 01/06/2000
Stopped:	01/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 166064
Reported: 04/07/2001
Hospitalisation:
Onset Date: 20/06/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 40.00
Age: 15
DOB: 10/07/1985
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction affecting r extensors of hand	Cogentin given and stopped risperdal.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
1.0 Milligram Daily	
Batch:	Started: 14/05/2001 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
2.0 Milligram Daily	
Batch:	Started: 24/05/2001 Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
3.0 Milligram Daily	
Batch:	Started: 11/06/2001 Stopped: 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 166153

Seq: 1

Gender: F

Reported: 05/07/2001

Weight:

Hospitalisation:

Age: 36

Onset Date: 15/06/2001

DOB: 03/04/1965

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	
Oral application	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date of risperdal is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 166344
Reported: 11/07/2001

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 28/02/2001

Age: 30Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Patient has not menstruated for the past year.	Plans to cease zoloft if event do not resolve
Hyperprolactinaemia			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2001	Stopped: 15/06/2001	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Prolactin level of 3000 plus.
	Radiology				Mri scan was performed which revealed a microadenoma.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in' the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 166613

Seq: 1

Gender: F

Reported: 18/07/2001

Weight: 84.00

Hospitalisation:

Age: 45

Onset Date: 04/06/2001

DOB: 19/01/1956

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Migraine			Patient required visit to doctor, risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified psychosis
2.0 Milligram	Daily
Batch:	Started: 04/06/2001 Stopped: 25/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered on the 27/6/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 166866

Seq: 1

Gender: F

Reported: 24/07/2001

Weight:

Hospitalisation:

Age: 42

Onset Date: 16/05/2001

DOB: 20/03/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breath odour Gingivitis			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Obsessive compulsive neurosis	
	1.5 Gram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 24/01/2001	Stopped: 12/06/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Gingivitis diagnosed when teeth became loose, front tooth moved. patient will require orthodontic treatment and cosmetic dentistry.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167034

Seq: 1

Gender: M

Reported: 31/07/2001

Weight:

Hospitalisation:

Age: AD

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vitamin B12 deficiency Pancytopenia Pyrexia		B12 and folic acid deficiency	B12 and folate replacement

Medicine Details:

RISPERDAL (Suspected)	Reason:
0.0	
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167091

Seq: 1

Gender: M

Reported: 01/08/2001

Weight: 102.00

Hospitalisation:

Age: 84

Onset Date: 25/07/2001

DOB: 02/02/1917

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Life threatening		
Consciousness fluctuating	Life threatening		
Convulsion	Life threatening		
Hypertonia	Life threatening		Haloperidol and risperdone ceased. treated with diazepam im 5mg tds and fluid therapy.
Neuroleptic malignant syndrome	Life threatening		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase				Raised cpk (1364 rr<256) and creatinine (186). after treatment cpk level decreased to 699.

Additional Information:

Patient deteriorated and died on 29/07/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167091

Seq: 1

Gender: M

Reported: 01/08/2001

Weight: 102.00

Hospitalisation:

Age: 84

Onset Date: 25/07/2001

DOB: 02/02/1917

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment	Life threatening		

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Patient deteriorated and died on 29/07/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167239

Seq: 1

Gender: F

Reported: 06/08/2001

Weight:

Hospitalisation:

Age:

Onset Date: 28/06/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
NARDIL (Suspected)		Reason:	
Tablet	90.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but onset was sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167375 **Seq:** 1 **Gender:** M
Reported: 09/08/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 26/06/2001 **DOB:** 10/11/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Confusional state Consciousness fluctuating Delirium Hyponatraemia			Patient admitted to hospital. treated with iv haloperidol, iv diazepam, im accuphase.

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 24/06/2001	Stopped: 03/07/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	137 -	04/07/2001	132MMOL/L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167591

Seq: 1

Gender: F

Reported: 16/08/2001

Weight:

Hospitalisation:

Age: 88

Onset Date: 08/08/2001

DOB: 15/05/1913

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Tardive dyskinesia			

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	10/08/2001 6W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Known chronic renal failure. (cr = 350).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167812

Seq: 1

Gender: F

Reported: 23/08/2001

Weight:

Hospitalisation:

Age: 20

Onset Date: 28/05/2001

DOB: 14/10/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.5			Neutrophil count of 1.4

Additional Information:

Relevant medical history - patient has schizophrenia, with good prognosis - has had two psychotic episodes. the patient is not taking any other medicines with the possible exception of the oral contraceptive pill. probable viral illness not long before this initial test. the onset date is not necessarily accurate but indicates the onset sometime in may 2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167821 **Seq:** 1 **Gender:** M
Reported: 23/08/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 30Y
Onset Date: 06/08/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia Hypertonia Neuroleptic malignant syndrome			Admitted to hospital 17/07/2001.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2001	Stopped: 06/08/2001	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		06/08/2001	362U/L	
	Creatine		08/08/2001	417	
	Creatine		09/08/2001	348	
	Creatine		10/08/2001	292	
	Creatine		11/08/2001	191	
	Serum drug level		06/08/2001	1.0	
	Serum drug level		08/08/2001	-	

Additional Information:

Relevant medical history - bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167821

Seq: 1

Gender: M

Reported: 23/08/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 30Y

Onset Date: 06/08/2001

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2001	Stopped: 06/08/2001	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		09/08/2001	-	
	Serum drug level		10/08/2001	-	
	Serum drug level		11/08/2001	-	

Additional Information:

Relevant medical history - bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 168403

Seq: 1

Gender: F

Reported: 14/09/2001

Weight: 49.00

Hospitalisation:

Age: 23

Onset Date: 08/08/2001

DOB: 23/03/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Date of recovery 11.8.01.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started: 07/08/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 168626 **Seq:** 1 **Gender:** F
Reported: 24/09/2001 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 28/12/2000 **DOB:** 28/01/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Caused or prolonged inpatient hospitalisation		Mastectomy, risperidone withdrawn

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	0.0		Oral
Batch:	Started:	Stopped:	06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 168658

Seq: 1

Gender: F

Reported: 24/09/2001

Weight: 80.00

Hospitalisation:

Age: 35Y

Onset Date: 28/08/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped: 20/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not accurate but indicates the drug was started sometime early in the year. reaction has occurred previously while on risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169052 **Seq:** 1 **Gender:** F
Reported: 11/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Hypotension Syncope			Patient hospitalised. risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 04/09/2001 Stopped: 06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: patient fell and fractured her face.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169118 **Seq:** 1 **Gender:** M
Reported: 11/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection			Patient hospitalised. given bactrim.
Neutropenia			

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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169144
Reported: 15/10/2001
Hospitalisation:
Onset Date: 26/09/2001
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 26
DOB: 03/09/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonia.	Given imi cogentin. date of recovery 26/09/2001. required a visit to doctor.

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)		Reason: Dependence on unspecifid drugs
	70.0 Milligram	Daily
Batch:	Started:	Stopped: CONTIN
RISPERIDONE (Suspected)		Reason: Dependence on unspecifid drugs
	2.0 Milligram	Daily
Batch:	Started: 26/09/2001	Stopped: 26/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169145

Seq: 1

Gender: F

Reported: 15/10/2001

Weight:

Hospitalisation:

Age: 26

Onset Date: 26/09/2001

DOB: 29/08/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis		Acute torticollis.	Given cogentin imi. 26/09/2001. required a visit to doctor.

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)		Reason: Dependence on unspecifid drugs	
60.0 Milligram		Daily	
Batch:	Started:	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason: Dependence on unspecifid drugs	
2.0 Milligram		Daily	
Batch:	Started: 26/09/2001	Stopped:	26/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169325 **Seq:** 1 **Gender:** F
Reported: 22/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 73Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Rehydrated with nasogastric feeding. patient hospitalised.

Medicine Details:

BENZTROPINE MESYLATE (Other drug)	Reason:
2.0 Milligram	Daily
Batch:	Started: Stopped:
MIANSERIN HYDROCHLORIDE (Other drug)	Reason:
40.0 Milligram	Daily
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
750.0 Milligram	Daily
Batch:	Started: Stopped:
ALPRAZOLAM (Other drug)	Reason:
0.5 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.5			Neutrophil - 9.6
	White blood cells	4.0 - 11.0			Wbc - 13.3

Additional Information:

History of schizoaffective disorder, depression and had had a stroke in 1997.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169325

Seq: 1

Gender: F

Reported: 22/10/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 73Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

History of schizoaffective disorder, depression and had had a stroke in 1997.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169779

Seq: 1

Gender: F

Reported: 07/11/2001

Weight: 0.00

Hospitalisation:

Age: 13

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Synostosis		Worsening of synostosis	Required a visit to doctor, treated with artane 2mg bd.

Medicine Details:

TOFRANIL (Other drug)		Reason: Explosive personality disorder	
	35.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Explosive personality disorder	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is not a neonatal report. Patient was born with problematic fusion between ulna-radias bones. At 7 months she experienced seizures. After this time, changes in behaviour & development led her to be diagnosed with 'global intellectual disability with global delay in language' (possibly a result of seizures?) - problems included: self mutilation, anger and aggression. At 5 years, slight changes in gait, bone changes in foot were picked up - slight twisting of foot. This was not too bad and patient could walk without problems. Since beginning Risperdal, especially in last 2 years, the foot twisting has worsened dramatically - it looks like a turned in foot when it was only subtle previously and patient has a lot more trouble walking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169845

Seq: 1

Gender: M

Reported: 08/11/2001

Weight:

Hospitalisation:

Age: 82

Onset Date: 23/10/2001

DOB: 28/03/1919

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Ceased risperdal.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 16/11/2000	Stopped:	23/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	<250 U/L	20/10/2001	569	
	Creatine	<250 U/L	26/10/2001	487	
	Creatine	<250 U/L	29/10/2001	409	
	Neutrophils	(1.5-7.5)	20/10/2001	11.2	
	Neutrophils	(1.5-7.5)	26/10/2001	7.6	
	Neutrophils	(1.5-7.5)	29/10/2001	7.6	

Additional Information:

Patient rechallenged on risperal and experienced same symptoms. patient recovered 2/11/01. see original for other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169864 **Seq:** 1 **Gender:** M
Reported: 09/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 43Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis			Risperdal ceased. admitted to hospital. given an injection of droperidol.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History - autism, developmental disability, pigeon chest, family history of motor neuron disease. risperdal was rechallenged causing the same reaction to occur.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169865 **Seq:** 1 **Gender:** M
Reported: 09/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 43Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Patient admitted to hospital. treated with cogentin, benzodiazepine and an anti-inflammatory agent.

Medicine Details:

RISPERDAL (Suspected)	Reason:
Tablet	0.0
Batch:	Started: Stopped: Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169995
Reported: 19/11/2001

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 23/10/2001

Age: 22

DOB: 29/07/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			

Medicine Details:

PHOSPHATE-SANDOZ (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started: 04/10/2001	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
Capsule	10.0 Milligram	Daily	Oral
Batch:	Started: 04/10/2001	Stopped:	CONTIN
THIAMINE (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 04/10/2001	Stopped:	CONTIN
METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 04/10/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		02/11/2001	86	Baseline haemoglobin level was 140g/l.
	Haemoglobin		04/11/2001	87	Baseline haemoglobin level was 140g/l.
	Haemoglobin		08/11/2001	92	Baseline haemoglobin level was 140g/l.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169995

Seq: 1

Gender: F

Reported: 19/11/2001

Weight:

Hospitalisation:

Age: 22

Onset Date: 23/10/2001

DOB: 29/07/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

PARACETAMOL (Other drug)		Reason:	
Tablet	3.0 Gram	Daily	Oral
Batch:	Started: 04/10/2001	Stopped:	
RISPERIDONE (Suspected)		Reason: Paranoia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 22/10/2001	Stopped: 07/11/2001	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170038 **Seq:** 1 **Gender:** M
Reported: 19/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 01/11/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			Risperidone discontinued. admitted to hospital. date of recovery 02/11/2001.

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started: 24/10/2001	Stopped:	
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 27/10/2001	Stopped: 01/11/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant medical history - drug abuse, thc (tetrahydrocannabinol) abuse, schizoaffective disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170135 **Seq:** 1 **Gender:** F
Reported: 20/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 73Y
Onset Date: 30/06/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Tachycardia Speech disorder Coordination abnormal Faecal incontinence Hypertonia Hypokinesia Leukocytosis Neuroleptic malignant syndrome		38.5 Hr 120 bpm. Mutism	Patient was hospitalised. tolvon, risperidone, benztropine, lithium carbonate were ceased.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
750.0 Milligram	Daily
Batch:	Started: 31/12/1999 Stopped: 06/07/2000
ALPRAZOLAM (Other drug)	Reason:
500.0 Microgram	Daily
Batch:	Started: 31/12/1999 Stopped:
ASPIRIN (Other drug)	Reason:
150.0 Milligram	Daily
Batch:	Started: 31/12/1999 Stopped:
TOLVON (Suspected)	Reason:
40.0 Milligram	Daily
Batch:	Started: 31/12/1999 Stopped: 06/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mja vol 174, 4 june 2001, page 593



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170135 **Seq:** 1 **Gender:** F
Reported: 20/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 73Y
Onset Date: 30/06/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started: 31/12/1999	Stopped: 06/07/2001	
BENZTROPINE MESYLATE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 31/12/1999	Stopped: 06/07/2000	

Laboratory Investigations:

Additional Information:

Mja vol 174, 4 june 2001, page 593



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170198
Reported: 23/11/2001
Hospitalisation:
Onset Date: 30/05/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 83.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia		Rate 35	Propranolol ceased. admitted to cardiac ward.

Medicine Details:

CELECOXIB (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
ALPRAZOLAM (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 31/05/2001	
SALBUTAMOL (Other drug)		Reason: Asthma	
	400.0 Microgram	Daily	
Batch:	Started:	Stopped:	CONTIN
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170198
Reported: 23/11/2001
Hospitalisation:
Onset Date: 30/05/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 83.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

OESTROGENS CONJUGATED (Other drug)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started:	Stopped:	CONTIN
DOXEPIN HYDROCHLORIDE (Other drug)		Reason: Migraine	
Capsule	150.0 Milligram Daily	Oral	
Batch:	Started:	Stopped:	CONTIN
PROPRANOLOL HYDROCHLORIDE (Suspected)		Reason: Migraine	
Tablet	40.0 Milligram Daily	Oral	
Batch:	Started: 01/01/1994	Stopped:	30/05/2001
RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram Daily	Oral	
Batch:	Started:	Stopped:	31/05/2001

Laboratory Investigations:

Additional Information:

P/h of allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170201
Reported: 23/11/2001
Hospitalisation:
Onset Date: 17/05/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 84Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium Hyponatraemia Orthostatic hypotension			Ceased monoplus, diltiazem, risperidone.

Medicine Details:

FOLIC ACID (Other drug)		Reason:	
Tablet	0.5 Milligram	Weekly	Oral
Batch:	Started:	Stopped:	CONTIN
METHOTREXATE (Other drug)		Reason:	
Tablet	7.5 Milligram	Weekly	Oral
Batch:	Started:	Stopped:	CONTIN
OMEPRAZOLE (Other drug)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
PREDNISONE (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Sodium decreased to 108.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170201
Reported: 23/11/2001
Hospitalisation:
Onset Date: 17/05/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 84Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

MONOPLUS NOS (Suspected)		Reason: Essential benign hypertension	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped: 17/05/2001	
FOSINOPRIL (Suspected)		Reason: Essential benign hypertension	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 17/05/2001	
DILTIAZEM HYDROCHLORIDE (Suspected)		Reason: Essential benign hypertension	
Tablet	180.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 17/05/2001	
RISPERIDONE (Suspected)		Reason: Depression	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170304 **Seq:** 1 **Gender:** M
Reported: 27/11/2001 **Weight:** 115.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 23/09/2001 **DOB:** 07/05/1958
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Blood creatine phosphokinase incr Hypertonia		Clouding of consciousness.	Patient was hospitalised.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 01/03/2000	Stopped:	2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had similar reaction 1 year ago, also soon after starting low dose risperidone. the dose start date for risperidone is not necessarily accurate but indicates risperidone was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170538 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 47Y
Onset Date: 17/03/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Patient was hospitalised. treated with cogentin.

Medicine Details:

VENTOLIN (Other drug)		Reason: Asthma	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
ATROVENT (Other drug)		Reason: Asthma	
	1.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
FLIXOTIDE (Other drug)		Reason: Asthma	
	750.0 Microgram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
SEREVENT (Other drug)		Reason: Asthma	
Inhalation	4.0 Dose Unspecified	Daily	Inhalation
Batch:	Started:	L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperdal is not necessarily accurate but indicates the drug was started sometime in the month. has had tremors previously. parkinsonian symptoms: mild tremor of the left hand, generalised hyper-reflexia, shuffling gait, decreased balance and drowsiness.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170538

Seq: 1

Gender: F

Reported: 29/11/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 47Y

Onset Date: 17/03/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

EPILIM (Other drug)		Reason: Other&unspecified epilepsy	
Tablet	1.5 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped: CONTIN
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

The dose start date for risperdal is not necessarily accurate but indicates the drug was started sometime in the month. has had tremors previously. parkinsonian symptoms: mild tremor of the left hand, generalised hyper-reflexia, shuffling gait, decreased balance and drowsiness.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170971

Seq: 1

Gender: F

Reported: 10/12/2001

Weight:

Hospitalisation:

Age: 28

Onset Date: 06/09/2001

DOB: 25/08/1973

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Patient was hospitalised. date of recovery 9.9.01. risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/03/2001	Stopped: 07/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171082

Seq: 1

Gender: F

Reported: 11/12/2001

Weight:

Hospitalisation:

Age:

Onset Date: 05/09/2001

DOB:

Outcome: Recovered with sequelae

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Dizziness Fall Orthostatic hypotension			Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 04/09/2001	Stopped:	06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: sustained fractured zygoma secondary to her fall.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171392

Seq: 1

Gender: U

Reported: 13/12/2001

Weight: 71.00

Hospitalisation:

Onset Date: 29/10/2001

Age: 45

DOB: 04/03/1956

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia			

Medicine Details:

TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
	10.0 Milligram	As necessary	
Batch:	Started:	Stopped:	CONTIN
FLUOXETINE HYDROCHLORIDE (Other drug)		Reason: Depression	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	0.5 Milligram	Daily	
Batch:	Started: 01/06/1998	Stopped:	30/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171619

Seq: 1

Gender: M

Reported: 02/01/2002

Weight: 59.00

Hospitalisation:

Onset Date: 23/10/2001

Age: 63Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			Ceased carbamazepine and risperidone.
Neutropenia			

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason: Constipation	
Tablet	2.0 Dose Unspecified	As necessary	Oral
Batch:	Started:	Stopped:	
PROPRANOLOL HYDROCHLORIDE (Other drug)		Reason: Acute myocard infarc,no hypert	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
PERINDOPRIL (Other drug)		Reason: Acute myocard infarc,no hypert	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CARBAMAZEPINE (Suspected)		Reason: Paralysis agitans	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin	(130-180)-(2-7.5)	18/10/2001	116	
	Haemoglobin	(130-180)-(2-7.5)	23/10/2001	0.98	
	Haemoglobin	(130-180)-(2-7.5)	25/10/2001	89	
	Platelets		18/10/2001	103	
	White blood cells		18/10/2001	478 -2.37	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171619

Seq: 1

Gender: M

Reported: 02/01/2002

Weight: 59.00

Hospitalisation:

Age: 63Y

Onset Date: 23/10/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Paralysis agitans	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ASPIRIN (Suspected)		Reason: Acute myocard infarc,no hypert	
Oral application	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171664

Seq: 1

Gender: M

Reported: 07/11/2001

Weight:

Hospitalisation:

Age: 40

Onset Date:

DOB: 26/07/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Confusional state Malaise Neuroleptic malignant syndrome Pyrexia		Decrease in conscious state	

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
0.0	
Batch:	Started: 04/10/2001 Stopped: 06/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171721

Seq: 1

Gender: M

Reported: 04/01/2002

Weight: 0.00

Hospitalisation:

Onset Date: 28/03/2001

Age: 16

DOB: 02/07/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Testicular disorder			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	
DEXAMPHETAMINE SULPHATE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				In march 01, he developed a benign 'pearl' lesion in his right testicle with small hydroceles. scrotal ultrasound 17.5.01 revealed palpable lump in right hemiscrotum, representing a calcified scrotal pearl, maximal diameter 7mm. scrotal ultrasound on 21.11.01 demonstrated small bilateral hydroceles and right scrotal pearl.
17/12/2002	Other data				Comparison with the previous ultrasound of 17.5.01 indicates the size of the calcified right scrotal lesion is unaltered.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171809
Reported: 11/01/2002

Seq: 1

Gender: F
Weight: 68.00
Age: 40
DOB: 17/01/1961
Causality: Causality possible

Hospitalisation:

Onset Date: 03/01/2002
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block Electrocardiogram QT prolonged		Early heart block.	Change to small dose sertraline 50mg.

Medicine Details:

HALOPERIDOL (Other drug)	Reason:
3.7 Milligram	Daily
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
0.5 Milligram	Daily
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
20.0 Milligram	Daily
Batch:	Started: Stopped:
CITALOPRAM HYDROBROMIDE (Suspected)	Reason: Depression
80.0 Milligram	Daily
Batch:	Started: 27/11/2001 Stopped: 03/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171809

Seq: 1

Gender: F

Reported: 11/01/2002

Weight: 68.00

Hospitalisation:

Age: 40

Onset Date: 03/01/2002

DOB: 17/01/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

1.5 Milligram

Daily

Batch:

Started: 01/01/2000

Stopped:

Laboratory Investigations:

Additional Information:

The dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171891
Reported: 08/01/2002

Seq: 1

Gender: M
Weight: 103.00

Hospitalisation:

Onset Date: 28/06/2001
Outcome: Recovered

Age: 19
DOB: 31/10/1981
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Pallor Pharyngitis Vomiting Weight increased			Required a visit to doctor.

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	
	225.5 Microgram	Daily	
Batch:	Started:	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason: Other atyp forms schizophrenia	
	500.0 Microgram	Daily	
Batch:	Started: 01/08/1999	Stopped:	28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates risperidone was started sometime in the month. patient recovered 28/12/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171949

Seq: 1

Gender: M

Reported: 06/12/2001

Weight:

Hospitalisation:

Age: 83

Onset Date: 13/11/2001

DOB: 08/11/1918

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Haloperidol ceased.

Medicine Details:

DIAZEPAM (Other drug)	Reason: Neuroses
Oral application	0.0 Oral
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
Tablet	0.0 Oral
Batch:	Started: Stopped:
PERHEXILINE MALEATE (Other drug)	Reason:
Tablet	0.0 Oral
Batch:	Started: Stopped:
HALDOL DECANOATE (Suspected)	Reason:
Injection	1.0 Dose Unspecified 4 times Intravenous
Batch:	Started: 05/11/2001 Stopped: 09/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171949

Seq: 1

Gender: M

Reported: 06/12/2001

Weight:

Hospitalisation:

Age: 83

Onset Date: 13/11/2001

DOB: 08/11/1918

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		Reason:	
Injection	2.0 Milligram	1 time	Intramuscular
Batch:	Started: 05/11/2001	Stopped: 09/11/2001	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 05/11/2001	Stopped: 12/11/2001	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172027 **Seq:** 1 **Gender:** F
Reported: 21/01/2002 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 49Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Experienced a cerebral seizure whilst in casualty.	
Hyponatraemia			
Neuroleptic malignant syndrome			

Medicine Details:

EFEXOR (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Oral application	3.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was hospitalised with dystonia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172161
Reported: 24/01/2002
Hospitalisation:
Onset Date: 04/01/2002
Outcome: Recovered

Seq: 1

Gender: F
Weight: 40.00
Age: 95
DOB: 17/05/1906
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema Angioedema Dysarthria Dysphagia		Within 1-2 hours of taking risperidone.	Date of recovery 17.1.02. patient was already in hospital. risperidone ceased.

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)	Reason: Cellul&absc otr,mult&nos sites
2.0 Gram Daily	
Batch:	Started: S TERM Stopped:
ASPIRIN (Other drug)	Reason: Otr&nos disord of heart rhythm
150.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
DIGOXIN (Other drug)	Reason: Otr&nos disord of heart rhythm
125.0 Microgram Daily	
Batch:	Started: L TERM Stopped: CONTIN
LASIX (Other drug)	Reason: Congestive heart failure
80.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172161
Reported: 24/01/2002
Hospitalisation:
Onset Date: 04/01/2002
Outcome: Recovered

Seq: 1

Gender: F
Weight: 40.00
Age: 95
DOB: 17/05/1906
Causality: Causality probable

Reaction Details:

Medicine Details:

SLOW-K (Other drug)		Reason: Congestive heart failure	
	2.0 Dose Unspecified Daily		
Batch:	Started: L TERM	Stopped:	CONTIN
OROXINE (Other drug)		Reason: Myxedema	
	25.0 Microgram Daily		
Batch:	Started: L TERM	Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172435

Seq: 1

Gender: M

Reported: 06/02/2002

Weight: 68.00

Hospitalisation:

Age: 17

Onset Date: 04/12/2001

DOB: 30/05/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness over past few days when stands up.	
Dysphagia			Required a visit to doctor. cogentin.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 29/11/2001	Stopped:
RISPERIDONE (Suspected)		Reason: Depression
	0.5 Milligram	Daily
Batch:	Started: 29/11/2001	Stopped: 04/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172482 **Seq:** 1 **Gender:** M
Reported: 04/01/2002 **Weight:** 77.00
Hospitalisation: Admitted to hospital **Age:** 83
Onset Date: 13/11/2001 **DOB:** 08/11/1918
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Neuroleptic malignant syndrome Weight decreased			Midazolam. patient hospitalised.

Medicine Details:

WARFARIN SODIUM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
Injection	4.0 Dose Unspecified Total	Intravenous	
Batch:	Started: 05/11/2001	Stopped: 09/11/2001	
GALANTAMINE HYDROBROMIDE (Suspected)		Reason:	
Tablet	24.0 Milligram Daily	Oral	
Batch:	Started: 08/12/2000	Stopped: 10/11/2001	
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram Daily	Oral	
Batch:	Started: 05/11/2001	Stopped: 12/11/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172505

Seq: 1

Gender: F

Reported: 06/02/2002

Weight: 65.00

Hospitalisation:

Age: 25

Onset Date: 28/08/2001

DOB: 17/05/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			Required a visit to doctor. reduction of dose to 1.5mg has not produced reaction as yet.

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172611

Seq: 1

Gender: U

Reported: 11/02/2002

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia	Required Specialist Consultation	Mild anaemia.	
Leukopenia			
Thrombocytopenia			

Medicine Details:

RISPERDAL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172782

Seq: 1

Gender: U

Reported: 18/02/2002

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

RISPERIDONE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172980
Reported: 20/02/2002

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 19/11/2001

Age: 79Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonism.	

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other drug)		Reason: Incontinence of urine	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 15/10/2001	
RAMIPRIL (Other drug)		Reason: Essential benign hypertension	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started:	Stopped: 18/10/2001	
ASPIRIN (Other drug)		Reason: Acute, ill-def cerebrovascular disease w/o hyperten	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ATENOLOL (Other drug)		Reason: Essential benign hypertension	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not necessarily accurate but indicates the drug was started sometime in the month. patient history: advanced alzheimers, cva 1990(l). risperidone ceased. sequelae: fractured pelvis. multifactoral gait disorder and history of falls.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172980

Seq: 1

Gender: M

Reported: 20/02/2002

Weight:

Hospitalisation:

Age: 79Y

Onset Date: 19/11/2001

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason:

Tablet

1.0 Milligram

Daily

Oral

Batch:

Started: 01/08/2000

Stopped: 24/10/2001

Laboratory Investigations:

Additional Information:

The dose start date for risperidone is not necessarily accurate but indicates the drug was started sometime in the month. patient history: advanced alzheimers, cva 1990(l). risperidone ceased. sequelae: fractured pelvis. multifactoral gait disorder and history of falls.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173009

Seq: 1

Gender: M

Reported: 21/02/2002

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression	Life threatening		Reaction was life threatening. patient already in hospital.

Medicine Details:

CLONAZEPAM (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173235

Seq: 1

Gender: F

Reported: 28/02/2002

Weight:

Hospitalisation:

Age: 39Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast engorgement Hyperprolactinaemia Tardive dyskinesia Therapeutic response decreased			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	>500			Prolactin 6400 iu/l whilst taking risperdal 4mg daily dose.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173407 **Seq:** 1 **Gender:** F
Reported: 06/03/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: 07/02/2002 **DOB:** 21/05/1928
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation Dizziness Hyperglycaemia			Pateint was hospitalised. treated with stemetil

Medicine Details:

CALCIUM NOS (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
SOLPRIN (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MODURETIC (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 01/07/2000	Stopped:	
VIOXX (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173407

Seq: 1

Gender: F

Reported: 06/03/2002

Weight:

Hospitalisation: Admitted to hospital

Age: 73

Onset Date: 07/02/2002

DOB: 21/05/1928

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Schizophrenia

Tablet

4.0 Milligram

Daily

Oral

Batch:

Started: 30/04/1999

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173525

Seq: 1

Gender: F

Reported: 11/03/2002

Weight: 90.00

Hospitalisation:

Age: 34

Onset Date: 28/05/2001

DOB: 04/10/1966

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Development of gestational diabetes on risperidone	Required a visit to doctor. insulin therapy.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
3.0 Milligram	Daily
Batch:	Started: 01/01/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for risperidone is not accurate but indicates risperidone was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173574

Seq: 1

Gender: F

Reported: 13/03/2002

Weight: 58.00

Hospitalisation:

Age: 17

Onset Date: 18/12/2001

DOB: 06/01/1984

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema Dyspnoea Tongue oedema		Swollen throat	Required a visit of a doctor.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified psychosis
2.0 Milligram	Daily
Batch:	Started: 17/12/2001 Stopped: 22/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173827

Seq: 1

Gender: F

Reported: 19/03/2002

Weight: 55.00

Hospitalisation:

Age: 29

Onset Date: 28/02/2002

DOB: 31/07/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw clenching.	Required a visit to doctor. decrease risperidone then cease. start olanzapine, start benztropine 1mg bd for symptoms.
Dizziness			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecified schizophrenia
1.2 Gram	Daily
Batch:	Started:
Stopped:	
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram	Daily
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recent dose increase from 5mg daily to 6mg daily on 27/2/2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 174390

Seq: 1

Gender: U

Reported: 10/04/2002

Weight:

Hospitalisation:

Age: 73

Onset Date:

DOB: 14/07/1928

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

LOSEC (Other drug)	Reason: Other diseases of esophagus
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
50.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
RISPERIDONE (Suspected)	Reason: Otr spec symp psychopathol nec
2.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 06/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175000 **Seq:** 1 **Gender:** M
Reported: 01/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 16/04/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		White cells, red cells & platelets all decreased.	Patient was hospitalised. discontinued both moclobemide and risperidone.

Medicine Details:

VITAMINORUM B.P.C. (Other drug)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started:	Stopped:	
ASCORBIC ACID (Other drug)		Reason:	
	500.0 Milligram Daily		
Batch:	Started:	Stopped:	
PRAZOSIN HYDROCHLORIDE (Other drug)		Reason:	
	2.0 Milligram Daily		
Batch:	Started:	Stopped:	
NILSTAT (Other drug)		Reason:	
	4.0 Millilitre Daily		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175000

Seq: 1

Gender: M

Reported: 01/05/2002

Weight:

Hospitalisation: Admitted to hospital

Age:

Onset Date: 16/04/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

THIAMINE (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MOCLOBEMIDE (Suspected)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 16/04/2002	Stopped: 19/04/2002	

Laboratory Investigations:

Additional Information:

No previous history of allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175257 **Seq:** 1 **Gender:** F
Reported: 08/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aphasia Cerebrovascular disorder Confusional state Coordination abnormal Hallucination Hypertonia Neuroleptic malignant syndrome			Patient hospitalised. treated with dantrolene 25mg bd, bromocriptine. also required intensive nursing, including catheterisation, iv therapy and ng-tube.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
6.0 Milligram	Daily
Batch:	Started: Stopped: 4Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		26/04/2002	856	Two weeks after risperdal was discontinued.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175257 **Seq:** 1 **Gender:** F
Reported: 08/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	4Y

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175339

Seq: 1

Gender: F

Reported: 09/05/2002

Weight: 90.00

Hospitalisation:

Age: 43

Onset Date: 12/12/2001

DOB: 08/09/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Affect lability Hyperproteinaemia			Required a visit to doctor. continue on meds with rpt, blood prolactin level & mri.

Medicine Details:

EPILIM (Other drug)	Reason: Unspecified schizophrenia
1.5 Gram Daily	
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason: Unspecified schizophrenia
2.0 Milligram Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
2.0 Milligram Daily	
Batch:	Started: 01/01/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175346

Seq: 1

Gender: F

Reported: 09/05/2002

Weight: 50.00

Hospitalisation:

Age: 19

Onset Date: 29/01/2002

DOB: 20/04/1982

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Risperidone ceased. required a visit to doctor.
Hyperprolactinaemia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 16/01/2002	Stopped: 29/01/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175626 **Seq:** 1 **Gender:** M
Reported: 22/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 13/05/2002 **DOB:** 26/03/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis			Patient hospitalised. withdrew all medications; increased hydration.

Medicine Details:

HOMEOPATHIC MEDICINE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
BENZYDAMINE HYDROCHLORIDE (Other drug)	Reason:
2.0 Milligram	As necessary
Batch:	Started: Stopped:
ZOPICLONE (Other drug)	Reason: Specific disorders of sleep
15.0 Milligram	Daily
Batch:	Started: Stopped:
SODIUM VALPROATE (Suspected)	Reason:
1.4 Gram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bili=146, alt=821, alk phos=384. bili=27, alt=62, alk phos=94.

Additional Information:

History of heavy etoh use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175626

Seq: 1

Gender: M

Reported: 22/05/2002

Weight:

Hospitalisation: Admitted to hospital

Age: 52

Onset Date: 13/05/2002

DOB: 26/03/1950

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Unspecified psychosis

2.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

History of heavy etoh use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175638
Reported: 22/05/2002

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 03/03/2002

Age: 21

DOB: 04/03/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight decreased		Lost 13kg on topiramate.	Trated with mirtazapine.
Agitation			
Depression			Treated with mirtazapine.
Psychotic disorder			

Medicine Details:

SOMAC (Other drug)	Reason: Other diseases of esophagus
40.0 Milligram Daily	
Batch:	Started: Stopped:
VENTOLIN (Other drug)	Reason: Asthma
Inhalation 4.0 Dose Unspecified Daily Inhalation	
Batch:	Started: Stopped:
TOPIRAMATE (Suspected)	Reason: Obesity othr than endoc origin
200.0 Milligram Daily	
Batch:	Started: 12/11/2001 Stopped: 14/03/2002
RISPERIDONE (Suspected)	Reason: Other diseases of esophagus
4.0 Milligram Daily	
Batch:	Started: 01/12/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Still appears to have low grade psychosis started on mirtazapine depression improved. the dose start date for risperidone is not accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175827

Seq: 1

Gender: F

Reported: 03/06/2002

Weight: 50.00

Hospitalisation:

Age: 25

Onset Date: 20/05/2002

DOB: 28/08/1976

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain Galactorrhoea		Breast tenderness.	Required a visit to doctor. date of recovery 15.5.02. risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
3.0 Milligram	Daily
Batch:	Started: 14/03/2002 Stopped: 10/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of eczema.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 176460

Seq: 1

Gender: F

Reported: 20/06/2002

Weight:

Hospitalisation:

Age: 76

Onset Date:

DOB: 27/02/1926

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Parkinsonian tremor: coarse tremor	Ceased nefazodone and commenced mianerin.

Medicine Details:

OLANZAPINE (Other drug)		Reason: Otr spec symp psychopathol nec
	2.5 Milligram	Daily
Batch:	Started: 24/01/2002	Stopped: 07/02/2002
MIANSERIN HYDROCHLORIDE (Other drug)		Reason: Depression
	20.0 Milligram	Daily
Batch:	Started: 01/02/2002	Stopped: CONTIN
LITHIUM CARBONATE (Other drug)		Reason: Depression
	250.0 Milligram	Daily
Batch:	Started: 28/12/2001	Stopped: CONTIN
TEGRETOL CR (Other drug)		Reason: Depression
	400.0 Milligram	Daily
Batch:	Started: 13/02/2002	Stopped: 15/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking metamucil, lipitor, raloxifene. patient recovered 4/2/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 176460
Reported: 20/06/2002
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 76
DOB: 27/02/1926
Causality: Causality possible

Reaction Details:

Medicine Details:

OXAZEPAM (Other drug)		Reason: Anxiety neurosis	
	22.5 Milligram	Daily	
Batch:	Started: 07/02/2002	Stopped:	CONTIN
DIAZEPAM (Other drug)		Reason: Anxiety neurosis	
	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	07/02/2002
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	500.0 Milligram	1 time	
Batch:	Started: 23/12/2001	Stopped:	
RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
	1.5 Milligram	Daily	
Batch:	Started: 24/12/2001	Stopped:	27/12/2001

Laboratory Investigations:

Additional Information:

Patient was also taking metamucil, lipitor, raloxifene. patient recovered 4/2/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 176460

Seq: 1

Gender: F

Reported: 20/06/2002

Weight:

Hospitalisation:

Age: 76

Onset Date:

DOB: 27/02/1926

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CITALOPRAM HYDROBROMIDE (Suspected)		Reason: Depression
	20.0 Milligram	Daily
Batch:	Started: 25/12/2001	Stopped: 04/01/2002
NEFAZODONE HYDROCHLORIDE (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 07/01/2002	Stopped: 29/01/2002

Laboratory Investigations:

Additional Information:

Patient was also taking metamucil, lipitor, raloxifene. patient recovered 4/2/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177232 **Seq:** 1 **Gender:** F
Reported: 18/07/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 54Y
Onset Date: 30/03/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cranial nerve disorder		Developed bell's palsy.	Patient was hospitalised, prescribed valium and increased risperdal to 2mg.
Herpes zoster			

Medicine Details:

DEPTRAN (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	CONTIN
LIPEX (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Depression	
Tablet	1.0 Milligram	Daily	Oral
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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177426 **Seq:** 1 **Gender:** M
Reported: 24/07/2002 **Weight:** 40.00
Hospitalisation: Admitted to hospital **Age:** 12Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria Dyspnoea Dystonia Extrapyramidal disorder Hypertonia Muscle twitching		Difficulty in talking	Benztropine 0.02mg/kg

Medicine Details:

MORPHINE SULPHATE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
KETOROLAC (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
TROPISETRON HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
METHYLPHENIDATE HYDROCHLORIDE (Suspected)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Difficulty in talking, shortness of breath and difficulty moving because of stiffness. his speech was slurred and he was unable to close his mouth. the patient then began experiencing a twitching in his hands, shoulders, neck and head, which progressed to jerking movements of his jaw and arms. j.pediatr. child health (2002) 38, 95-97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177426

Seq: 1

Gender: M

Reported: 24/07/2002

Weight: 40.00

Hospitalisation: Admitted to hospital

Age: 12Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Difficulty in talking, shortness of breath and difficulty moving because of stiffness. his speech was slurred and he was unable to close his mouth. the patient then began experiencing a twitching in his hands, shoulders, neck and head, which progressed to jerking movements of his jaw and arms. j.pediatr. child health (2002) 38, 95-97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177691 **Seq:** 1 **Gender:** F
Reported: 05/08/2002 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 72Y
Onset Date: 29/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Parkinson's	Patient was hospitalised.

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason: Constipation	
2.0 Dose Unspecified As necessary			
Batch:	Started:	Stopped:	CONTIN
PANADEINE (Other drug)		Reason:	
0.0 As necessary			
Batch:	Started:	Stopped:	
PANADEINE FORTE (Other drug)		Reason:	
0.0 As necessary			
Batch:	Started:	Stopped:	
LACTULOSE (Other drug)		Reason:	
20.0 Millilitre Daily			
Batch:	Started:	Stopped:	15/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177691

Seq: 1

Gender: F

Reported: 05/08/2002

Weight: 105.00

Hospitalisation: Admitted to hospital

Age: 72Y

Onset Date: 29/06/2002

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	
	150.0 Microgram	Daily	
Batch:	Started:	Stopped:	CONTIN
KEFLEX (Other drug)		Reason:	
	2.0 Gram	Daily	
Batch:	Started:	Stopped:	12/07/2002
METFORMIN HYDROCHLORIDE (Other drug)		Reason: Diabetes mellitus	
	1.6 Gram	Daily	
Batch:	Started:	Stopped:	CONTIN
WARFARIN SODIUM (Other drug)		Reason: Phleb&thrombophleb lowr extrem	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177691

Seq: 1

Gender: F

Reported: 05/08/2002

Weight: 105.00

Hospitalisation: Admitted to hospital

Age: 72Y

Onset Date: 29/06/2002

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)

Reason: Schizophrenia

2.0 Milligram

Daily

Batch:

Started:

Stopped: 03/07/2002

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177918

Seq: 1

Gender: M

Reported: 12/08/2002

Weight:

Hospitalisation:

Age: 25

Onset Date: 10/06/2002

DOB: 05/08/1976

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Date of recovery: 23/6/02. risperidone ceased. required a visit to doctor.

Medicine Details:

RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Tablet	2.0 Milligram
	Daily
	Oral
Batch:	Started: 09/06/2002
	Stopped: 16/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient changed to olanzapine and symptoms resolved within a week.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177921

Seq: 1

Gender: M

Reported: 12/08/2002

Weight: 80.00

Hospitalisation:

Onset Date: 07/08/2002

Age:

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Dry mouth			Sertraline ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 06/08/2002	Stopped: 09/08/2002	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 06/08/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 178383

Seq: 1

Gender: M

Reported: 28/08/2002

Weight:

Hospitalisation:

Age: 35

Onset Date:

DOB: 02/02/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Widespread rash - crusting-photographed.	Patient required a visit to doctor. treated with steroid cream.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 08/07/2002	Stopped: 06/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 178557 **Seq:** 1 **Gender:** M
Reported: 29/08/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 20Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion Drug ineffective Extrapyramidal disorder Hallucination			The patient was admitted into psychiatric unit of hospital, whilst in hospital patient was treated with olanzapine and amphetamine abuse ceased. risperidone was stopped.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of amphetamine substance abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 178719

Seq: 1

Gender: M

Reported: 04/09/2002

Weight:

Hospitalisation:

Age: 29Y

Onset Date: 20/08/2002

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased risperidone.

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason: Unspecified psychosis	
Injection	20.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 31/07/2002	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 29/07/2002	Stopped: 21/08/2002	
DIAZEPAM (Suspected)		Reason: Specific disorders of sleep	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 29/07/2002	Stopped: 19/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 178803

Seq: 1

Gender: F

Reported: 09/09/2002

Weight:

Hospitalisation:

Age:

Onset Date: 08/06/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eye pain	Severe	Severe pain behind one eye.	
Muscle twitching		Twitching eye.	

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 08/03/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179064

Seq: 1

Gender: F

Reported: 16/09/2002

Weight:

Hospitalisation:

Age: 6Y

Onset Date: 28/08/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

CARBAMAZEPINE (Other drug)		Reason:	
Oral Liquid	0.0	Oral	
Batch:	Started:	Stopped:	
DEXAMPHETAMINE SULPHATE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started: 26/08/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant history - mental retardation, behavioural problems and no epilepsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179113 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Dyspnoea Malaise Myocarditis			Admitted to hospitalised (icu).

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)		Reason:	
Injection	25.0 Milligram	Weekly	Intramuscular
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:

Relevant history - schizophrenia 5 years ago.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179196

Seq: 1

Gender: M

Reported: 23/09/2002

Weight:

Hospitalisation:

Age: 18Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Risperidone ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Cpk value of greater than 2000.

Additional Information:

Long history of different antipsychotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179257

Seq: 1

Gender: M

Reported: 08/10/2002

Weight:

Hospitalisation:

Age: 89Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome			Ceased risperidone.

Medicine Details:

DIGOXIN (Other drug)		Reason:	
Tablet	125.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
WARFARIN SODIUM (Other drug)		Reason: Otr&nos disord of heart rhythm	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 30/07/2002	Stopped: 20/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck elevated mildly

Additional Information:

This report is a seq of 179256.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179555

Seq: 1

Gender: F

Reported: 03/10/2002

Weight:

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2001	Stopped: 01/01/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Over a number months (date unspecified), sodium dropped from an unspecified level to 126.

Additional Information:

The dose start and stop dates for risperidone are not accurate but indicates the drug was start and stopped sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179613

Seq: 1

Gender: U

Reported: 02/10/2002

Weight: 88.00

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Required a visit to doctor.
Urticaria			

Medicine Details:

MONOFEME 28 (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
INDERAL (Other drug)	Reason:
80.0 Milligram Daily	
Batch:	Started: Stopped:
CLONIDINE HYDROCHLORIDE (Other drug)	Reason:
300.0 Milligram Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
Tablet 2.0 Milligram Daily Oral	
Batch:	Started: 01/01/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179738

Seq: 1

Gender: M

Reported: 08/10/2002

Weight: 74.00

Hospitalisation:

Age: 22

Onset Date: 30/09/2002

DOB: 27/02/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonia	Cougentin 2mg imi. patient recovered 30/9/02.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 24/09/2002	Stopped: 30/09/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose increased from 1mg to 3mg the day before reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179741

Seq: 1

Gender: M

Reported: 08/10/2002

Weight: 28.00

Hospitalisation:

Age: 7

Onset Date: 26/09/2002

DOB: 16/05/1995

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epistaxis		2 episodes of epistaxis.	

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug)		Reason: Behavior disorders of childhood	
	10.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
RISPERIDONE (Suspected)		Reason: Explosive personality disorder	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has cousin with schizophrenia on risperidone, was on a while then ceased due to nose bleeds.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179860 **Seq:** 1 **Gender:** F
Reported: 16/10/2002 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 80
Onset Date: 08/10/2002 **DOB:** 16/12/1921
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating			Ceased risperidone. patient hospitalised. date of recovery 09/10/02.

Medicine Details:

ATENOLOL (Other drug)	Reason: Essential benign hypertension
25.0 Milligram Daily	
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason: Acute, ill-def cerebrovascular disease w/o hyperten
100.0 Milligram Daily	
Batch:	Started: Stopped:
ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
10.0 Milligram Daily	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason:
Tablet 1.5 Milligram Daily Oral	
Batch:	Started: Stopped: 2D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180321

Seq: 1

Gender: F

Reported: 01/11/2002

Weight: 0.00

Hospitalisation:

Age: 13

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

TRILEPTAL (Suspected)		Reason:	
	0.0		Oral
Batch:	Started:	Stopped:	
RISPERIDONE (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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180341

Seq: 1

Gender: F

Reported: 04/11/2002

Weight: 50.00

Hospitalisation:

Age: 16

Onset Date: 28/09/2002

DOB: 10/05/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Orobuccal	Required a visit to doctor. patient being weaned off risperidone from 24/10/02.

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 01/06/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start is not necessarily accurate but indicates risperidone was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180477 **Seq:** 1 **Gender:** F
Reported: 11/11/2002 **Weight:** 55.00
Hospitalisation: Admitted to hospital **Age:** 76Y
Onset Date: 28/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia Fatigue Stupor Thinking abnormal Tongue paralysis			Patient hospitalised. risperdal ceased. date of recovery 03/1999.

Medicine Details:

DIGOXIN (Other drug)	Reason:
1.2 Milligram Daily	
Batch:	Started: L TERM Stopped:
SPAN-K (Other drug)	Reason:
120.0 Gram Daily	
Batch:	Started: L TERM Stopped:
LASIX (Other drug)	Reason:
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
OROXINE (Other drug)	Reason:
150.0 Microgram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Description: cognitive and moter impairment/fall and consequent hip fracture. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug resperdal is not necessarily accurate but indicates the drug was started sometime in month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180477

Seq: 1

Gender: F

Reported: 11/11/2002

Weight: 55.00

Hospitalisation: Admitted to hospital

Age: 76Y

Onset Date: 28/01/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 15/11/1998	Stopped: 18/02/2001	

Laboratory Investigations:

Additional Information:

Description: cognitive and moter impairment/fall and consequent hip fracture. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug resperdal is not necessarily accurate but indicates the drug was started sometime in month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180801

Seq: 1

Gender: F

Reported: 18/12/2002

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date:

DOB: 14/05/1986

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Movement in the bottom lip, involuntary chewing movement and tongue movements experienced at night - psychiatrist confirmed tardive dyskinesia	Patient being weaned off Risperidone and weaned onto Quetiapine Fumarate.

Medicine Details:

RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
Tablet	2.0 Milligram Oral
Batch:	Started: L TERM Stopped: 15/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's history - Schizophrenia for 2 years. Dose of Risperidone was increased to 3mg/daily on the 16/05/02. Patient recovered 3-4 weeks from the date risperidone was ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180856

Seq: 1

Gender: F

Reported: 19/12/2002

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 09/10/2002

DOB: 09/07/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia and was persistent on repeated blood tests.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2002	Neutrophils	2 - 8	09/10/2002	1.6	
19/12/2002	Neutrophils	2 - 8	11/02/2003	1.5	
19/12/2002	White blood cells	4 - 11.0	09/10/2002	3.1	
19/12/2002	White blood cells	4 - 11.0	11/02/2003	2.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180880

Seq: 1

Gender: M

Reported: 19/12/2002

Weight: 90.00

Hospitalisation:

Age: 75

Onset Date: 20/11/2002

DOB: 23/05/1927

Outcome: Recovered

22/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer haemorrhage	Life threatening	massive GI bleed - of duodenal ulcer	Over sewing of duodenal ulcer. Indomethacin dose reduced to 50mg bd.

Medicine Details:

ALLOPURINOL (Other drug)		Reason: Gout	
Tablet	100.0 Milligram	Oral	
Batch:	Started:	Stopped:	CONTIN
METOPROLOL TARTRATE (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
KETOROLAC (Suspected)		Reason: Pain	
	60.0 Milligram	1 time	
Batch:	Started: 08/11/2002	Stopped:	
KETOROLAC (Suspected)		Reason: Pain	
	30.0 Milligram	1 time	
Batch:	Started: 09/11/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient is an alcoholic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180880

Seq: 1

Gender: M

Reported: 19/12/2002

Weight: 90.00

Hospitalisation:

Age: 75

Onset Date: 20/11/2002

DOB: 23/05/1927

Outcome: Recovered

22/11/2002

Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Suspected)		Reason: Other coagulation defects	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/11/2002	
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 19/11/2002	
TRAMADOL HYDROCHLORIDE (Suspected)		Reason: Pain	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/11/2002	Stopped:	
DIAZEPAM (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 04/11/2002	Stopped: 09/11/2002	

Laboratory Investigations:

Additional Information:

patient is an alcoholic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180880

Seq: 1

Gender: M

Reported: 19/12/2002

Weight: 90.00

Hospitalisation:

Age: 75

Onset Date: 20/11/2002

DOB: 23/05/1927

Outcome: Recovered

22/11/2002

Causality: Causality possible

Reaction Details:

Medicine Details:

INDOMETHACIN (Suspected)

Reason:

200.0 Milligram

Daily

Batch:

Started: 07/11/2002

Stopped:

Laboratory Investigations:

Additional Information:

patient is an alcoholic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 183078

Seq: 1

Gender: F

Reported: 17/12/2002

Weight: 0.00

Hospitalisation:

Age: 95Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Amnesia Circulatory collapse Speech disorder		Patient presented with loss of memory, an inability to speak, dystonia and collapse.	Reisperdal ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 183079
Reported: 17/12/2002

Seq: 1

Gender: M
Weight: 0.00
Age: 85

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia		Patient presented with loss of memory, an inability to speak, confusion and collapse.	Risperdal ceased.
Circulatory collapse		Patient presented with loss of memory, an inability to speak, confusion and collapse.	Risperdal ceased.
Confusional state		Patient presented with loss of memory, an inability to speak, confusion and collapse.	Risperdal ceased.
Speech disorder		Patient presented with loss of memory, an inability to speak, confusion and collapse.	Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Tablet	1.0 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 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames:
RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 183080

Seq: 1

Gender: U

Reported: 17/12/2002

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia Circulatory collapse Somnolence Speech disorder		Patient presented with loss of memory, an inability to speak, drowsiness and collapse.	Risperal ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: