



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 176316 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:** 86.00
Hospitalisation: Admitted to hospital **Age:** 76
Onset Date: 06/06/2002 **DOB:** 03/02/1926
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Patient was hospitalised.

Medicine Details:

DILTIAZEM HYDROCHLORIDE (Other drug) 360.0 Milligram Daily Reason: Essential benign hypertension Batch: Started: 27/04/2002 Stopped:
TRITACE (Other drug) 10.0 Milligram Daily Reason: Essential benign hypertension Batch: Started: 24/04/2002 Stopped:
ORAP (Other drug) 4.0 Milligram Daily Reason: Unspecified schizophrenia Batch: Started: 06/06/2002 Stopped:
RISPERIDONE (Other drug) 4.0 Milligram Daily Reason: Unspecified schizophrenia Batch: Started: 24/04/2002 Stopped: 12/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 176316	Seq: 1	Gender: F
Reported: 17/06/2002		Weight: 86.00
Hospitalisation: Admitted to hospital		Age: 76
Onset Date: 06/06/2002		DOB: 03/02/1926
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
400.0 Milligram	Daily
Batch:	Started: 09/05/2002
	Stopped: 06/06/2002

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 177631	Seq: 1	Gender: F
Reported: 02/08/2002		Weight:
Hospitalisation:		Age: 17
Onset Date: 12/07/2002		DOB: 01/01/1985
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast enlargement			
Breast pain			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason: Depression
Oral application	20.0 Milligram Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 12/07/2002 Stopped: 7D
ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 12/07/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred within 24 hours of the first dose of amisulpride, worse in the first 2-3 days. solian was initiated at 100mg for 7 days and then increased to 200mg/day. zyprexa was reduced from 15mg to 12.5mg to 10mg/mane.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 177866

Seq: 1

Gender: F

Reported: 08/08/2002

Weight: 50.00

Hospitalisation:

Onset Date: 25/07/2002

Age: 26

DOB: 06/08/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

AVANZA (Other drug)		Reason:	
	30.0 Milligram	Daily	
Batch:	Started: 04/07/2002	Stopped: 17/07/2002	
SERENACE (Other drug)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
COGENTIN (Other drug)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
PAXAM (Other drug)		Reason:	
Oral application	500.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient lives in hospital, pt has schizophrenia, asperger's syndrome and intellectual disability.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 177866 **Seq:** 1

Gender: F

Reported: 08/08/2002

Weight: 50.00

Hospitalisation:

Age: 26

Onset Date: 25/07/2002

DOB: 06/08/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SOLIAN (Suspected)	Reason: Othr&unspec metabolic diseases
1.0 Gram	Daily
Batch:	Started: 11/06/2002 Stopped: 25/07/2002
LAMICTAL (Suspected)	Reason:
300.0 Milligram	Daily
Batch:	Started: 15/03/2002 Stopped: 31/07/2002

Laboratory Investigations:

Additional Information:

Patient lives in hospital, pt has schizophrenia, asperger's syndrome and intellectual disability.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 178097 **Seq:** 1 **Gender:** F
Reported: 14/08/2002 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 25/07/2002 **DOB:** 06/08/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Crown of head.	

Medicine Details:

SERENACE (Other drug)	Reason: Depression		
10.0 Milligram	Daily		
Batch:	Started:	Stopped:	CONTIN
COGENTIN (Other drug)	Reason:		
1.0 Milligram	Daily		
Batch:	Started:	Stopped:	CONTIN
PAXAM (Other drug)	Reason: Depression		
0.5 Milligram	Daily		
Batch:	Started:	Stopped:	CONTIN
SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
1.0 Gram	Daily		
Batch:	Started: 11/06/2002	Stopped: 25/07/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patients history - intellectual disability, aspergers syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 178098

Seq: 1

Gender: M

Reported: 14/08/2002

Weight:

Hospitalisation:

Age: 39

Onset Date: 28/06/2002

DOB: 16/07/1962

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Headache Nausea Rash erythematous Vomiting			Date of recovery: 02/07/02.

Medicine Details:

LUVOX (Other drug) Oral application Batch:	150.0 Milligram Started: 11/02/2002	Reason: Depression Daily Stopped:	Oral
TEGRETOL (Other drug) Batch:	800.0 Milligram Started: 09/05/2001	Reason: Daily Stopped:	
SOLIAN (Suspected) Oral application Batch:	400.0 Milligram Started: 28/06/2002	Reason: Daily Stopped: 30/06/2002	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 178115	Seq: 1	Gender: M
Reported: 14/08/2002		Weight:
Hospitalisation:		Age: 45
Onset Date:		DOB: 27/05/1957
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations			

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified psychosis	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ecg normal when taken.



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Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 178529

Seq: 1

Gender: F

Reported: 28/08/2002

Weight:

Hospitalisation:

Age: 17

Onset Date: 27/07/2002

DOB: 01/07/1985

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic reaction affecting face & tongue.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 16/07/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Solian: 200mg bd increased to 600mg daily when reaction occurred. report 179558 is a duplicate of this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 178996	Seq: 1	Gender: F
Reported: 12/09/2002		Weight:
Hospitalisation:		Age: 30
Onset Date: 27/08/2002		DOB: 29/08/1971
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Chills Hyperhidrosis Insomnia			Patient recovered 28/8/02. ceased seroquel.

Medicine Details:

SEROQUEL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179322

Seq: 1

Gender: M

Reported: 23/09/2002

Weight: 71.00

Hospitalisation:

Onset Date: 14/08/2002

Age: 69

DOB: 02/07/1933

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Difficulty passing urine.	

Medicine Details:

CLOZAPINE (Other drug)		Reason: Unspecified schizophrenia
	400.0 Milligram	Daily
Batch:	Started:	Stopped:
	L TERM	
OMEPRAZOLE (Other drug)		Reason: Other diseases of esophagus
	20.0 Milligram	Daily
Batch:	Started:	Stopped:
	L TERM	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started: 07/08/2002	Stopped: 26/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prostate found to be marginally enlarged, small residual urine on ultrasound.



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Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179366	Seq: 1	Gender: F
Reported: 25/09/2002		Weight:
Hospitalisation:		Age:
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Somnolence			Was started on solian 100mg then increased to 200mg bd. dropped back to 100mg bd and increased weekly up to 600mg /day.

Medicine Details:

DIAZEPAM (Other drug)		Reason: Anxiety neurosis	
Oral application	5.0 Milligram	As necessary	Oral
Batch:	Started: 04/07/2002	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179410
Reported: 26/09/2002

Seq: 1

Gender: M
Weight: 80.00
Age: 26
DOB: 02/06/1976
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Took overdose.	Patient recovered 20/7/02.

Medicine Details:

AMISULPRIDE (Suspected)	Reason:		
Tablet	5.6 Gram	Total	Oral
Batch:	Started: 17/07/2002	Stopped:	
ZOPICLONE (Suspected)	Reason:		
Tablet	105.0 Milligram	Total	Oral
Batch:	Started: 17/07/2002	Stopped:	
CARBAMAZEPINE (Suspected)	Reason:		
Tablet	2.8 Gram	Total	Oral
Batch:	Started: 17/07/2002	Stopped:	
MIRTAZAPINE (Suspected)	Reason:		
Tablet	210.0 Milligram	Total	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179525 **Seq:** 1 **Gender:** M
Reported: 02/10/2002 **Weight:** 82.00
Hospitalisation: Hospitalisation prolonged **Age:** 59
Onset Date: 24/08/2002 **DOB:** 22/09/1942
Outcome: Recovered with sequelae **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Grand mal convulsion			Prolonged inpatient hospitalisation. date of recovery 29/08/02. amisulpride ceased.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: Stopped:
RISPERIDONE (Other drug)	Reason: Unspecified psychosis
4.0 Milligram Daily	
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Unspecified psychosis
Tablet 800.0 Milligram Daily Oral	
Batch:	Started: 23/08/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Close to status epilepticus - petit mals so frequent on 28/08/02 - more time fitting than otherwise. nb: fits occurred on re-challenged with amisulpride. no history of seizures otherwise. suspected drug is cert rechallenge. recovered with sequelae: due to interruption in his antipsychotic therapy, needed psychiatric hospitalisation 29/08/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179647	Seq: 1	Gender: F
Reported: 08/10/2002		Weight: 76.00
Hospitalisation:		Age: 32
Onset Date: 25/07/2002		DOB: 14/04/1970
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Generalised.	Date of recovery 29/10/02.

Medicine Details:

SOLIAN (Suspected)	Reason:
400.0 Milligram	Daily
Batch:	Started: 11/07/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Period of alcohol abuse; date stopped: 18/7/02. started solian 400mg increased to 600mg one week later.



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Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 179823	Seq: 1	Gender: F
Reported: 14/10/2002		Weight:
Hospitalisation: Admitted to hospital		Age: 52
Onset Date: 03/09/2002		DOB: 14/10/1949
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Hemiparesis Convulsion Dehydration Leukocytosis Respiratory disorder Tachycardia Urinary incontinence		39.1 - 40.5 degrees celsius. Left sided weakness.	Patient was hospitalised. date of recovery: 7/9/02. bromocriptine 5mg tds.

Medicine Details:

DIAMICRON (Other drug)	Reason: Diabetes mellitus
240.0 Milligram	Daily
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
1.5 Gram	Daily
Batch:	Started: Stopped:
QUILONUM SR (Suspected)	Reason: Unspecified psychosis
Tablet 13.5 Gram	Daily Oral
Batch:	Started: 09/08/2002 Stopped: 04/09/2002
SOLIAN (Suspected)	Reason:
Tablet 400.0 Milligram	Daily Oral
Batch:	Started: 30/08/2002 Stopped: 04/09/2002

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180172

Seq: 1

Gender: F

Reported: 28/10/2002

Weight: 51.00

Hospitalisation:

Age: 81

Onset Date: 24/09/2002

DOB: 31/03/1921

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Red rash over back and legs.	Treated with aristocort cream. recovered 17/10/02.

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 20/09/2002	Stopped: 24/09/2002	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180273	Seq: 1	Gender: F
Reported: 31/10/2002		Weight:
Hospitalisation:		Age: 28
Onset Date:		DOB: 01/09/1974
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Myopia		Visual acivity decreased.	Ceased solian.

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified psychosis	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped: 28/08/2002	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180376 **Seq:** 1 **Gender:** F
Reported: 06/11/2002 **Weight:** 58.00
Hospitalisation: **Age:** 58
Onset Date: 28/10/2002 **DOB:** 18/07/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Developed dyskinesic movements mouth & tongue.	Patient required a visit to doctor.

Medicine Details:

FLUANXOL (Other drug) Injection Batch:	60.0 Milligram Started: 07/02/2002	Reason: Unspecified schizophrenia Fortnightly L TERM	Intramuscular Stopped:
AKINETON (Other drug) Batch:	2.0 Milligram Started:	Reason: Daily L TERM	Stopped:
VIBRA-TABS 50 (Other drug) Batch:	50.0 Milligram Started:	Reason: Other acne of sebaceous glands Daily L TERM	Stopped:
TEMAZE (Other drug) Batch:	20.0 Milligram Started:	Reason: Specific disorders of sleep Daily L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had similar reaction to seroquel 6/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180376 **Seq:** 1

Gender: F

Reported: 06/11/2002

Weight: 58.00

Hospitalisation:

Age: 58

Onset Date: 28/10/2002

DOB: 18/07/1944

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CALTRATE (Other drug)	Reason: Menopausal symptoms
600.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 17/10/2002 Stopped: 28/10/2002

Laboratory Investigations:

Additional Information:

Had similar reaction to seroquel 6/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180391

Seq: 1

Gender: M

Reported: 06/11/2002

Weight:

Hospitalisation:

Age: 46

Onset Date: 20/10/2002

DOB: 03/07/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm	Severe		Date of recovery: 21/10/02.

Medicine Details:

SOLIAN (Suspected)	Reason:		
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Continued solian and no further problems. patient history of asthma. no attacks for months prior to taking solian.



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Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180397

Seq: 1

Gender: F

Reported: 06/11/2002

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Discharge from nipple.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: Stopped:
TEGRETOL (Suspected)	Reason:
Tablet	1.0 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180641 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block		Long pr interval.	

Medicine Details:

CLOPIXOL (Other drug)	Reason:
Injection 150.0 Milligram Daily Intramuscular	
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason:
Tablet 600.0 Milligram Daily Oral	
Batch:	Started: 01/09/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also has hypothyroidism and diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180655 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 55Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe	Severe tremor.	Patient hospitalised. solian ceased.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:		
0.0			
Batch:	Started:	Stopped:	
EPILIM (Other drug)	Reason:		
1.0 Gram	Daily		
Batch:	Started:	Stopped: CONTIN	
SEROQUEL (Other drug)	Reason:		
200.0 Milligram	Daily		
Batch:	Started:	Stopped: CONTIN	
SOLIAN (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Solian was first initiated at 200mg/daily and increased to 400mg/daily causing the reaction to occur. patient history - previous slight tremor noted.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180721	Seq: 1	Gender: M
Reported: 17/12/2002		Weight: 68.00
Hospitalisation:		Age: 22
Onset Date:		DOB: 30/05/1980
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue		tiredness and sleepiness, lack of concentration during the day waking up feeling extremely tired nightmares these side effects started gradually and have been getting worse	
Disturbance in attention			
Nightmare			
Somnolence			

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 12/09/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No other exposure to other antipsychotic medicines.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180810

Seq: 1

Gender: F

Reported: 18/12/2002

Weight: 0.00

Hospitalisation:

Age: 10

Onset Date: 19/09/2002

DOB: 31/03/1992

Outcome: Recovered

30/09/2002

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		urticarial rash - all body, erythema, not raised	Solian ceased.
Erythema			

Medicine Details:

SOLIAN (Suspected)	Reason:	
Tablet	Oral	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - Quetiapine, Aspirin and Daonil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180850	Seq: 1	Gender: U
Reported: 19/12/2002		Weight: 77.00
Hospitalisation:		Age: 22
Onset Date: 15/08/2002		DOB: 01/10/1979
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Laryngospasm		laryngeal dystonia	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Tablet	2.0 Gram
	Daily
	Oral
Batch:	Started:
	Stopped:
DIAZEPAM (Other drug)	Reason:
Tablet	5.0 Gram
	Daily
	Oral
Batch:	Started:
	Stopped:
SOLIAN (Suspected)	Reason:
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Benztropine and amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180898

Seq: 1

Gender: F

Reported: 20/12/2002

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date:

DOB: 29/01/1970

Outcome: Recovered

11/10/2002

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration Pain		Developed a oculogyric crisis and mild laryngeal discomfort.	Treated with IM Bzotropine.

Medicine Details:

ZOLOFT (Other drug)	Reason: Depression		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2002	Stopped:	
SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2002	Stopped: 11/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to Risperidone 2 years prior for 8 weeks and Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 180900

Seq: 1

Gender: F

Reported: 20/12/2002

Weight: 0.00

Hospitalisation:

Onset Date: 21/10/2002

Age: 29

DOB: 24/01/1973

Outcome: Recovered

23/10/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Orofacial dystonia and oculogyric crisis.	Admitted to hospital. Amisulpride discontinued. Given Cogentin IMI and oral Cogentin for days.
Oculogyration			

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 18/10/2002	Stopped: 22/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of EPSE. Had other side effects and various antipsychotics.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181278

Seq: 1

Gender: F

Reported: 09/01/2003

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia	

Medicine Details:

SOLIAN (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181380	Seq: 1	Gender: M
Reported: 10/01/2003		Weight: 0.00
Hospitalisation:		Age: 67
Onset Date: 07/10/2002		DOB: 23/04/1935
Outcome: Recovered	13/10/2002	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Treated in outpatient department only	Dizziness, headaches, unwell, bradycardia of 40.	Ceased Solian
Bradycardia	Treated in outpatient department only		
Headache	Treated in outpatient department only		

Medicine Details:

ASTRIX 100 (Other drug)		Reason: Other coagulation defects	
Capsule		Daily	Oral
Batch:	Started:	L TERM	Stopped:
LIPEX (Other drug)		Reason: Othr&unspec metabolic diseases	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 04/10/2002		Stopped: 12/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Minax, Talohexal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181380	Seq: 1	Gender: M
Reported: 10/01/2003		Weight: 0.00
Hospitalisation:		Age: 67
Onset Date: 07/10/2002		DOB: 23/04/1935
Outcome: Recovered	13/10/2002	Causality: Causality possible

Reaction Details:

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

Medicine Details:

ASTRIX 100 (Other drug)	Reason: Other coagulation defects
Capsule	Daily Oral
Batch:	Started: L TERM Stopped:
LIPEX (Other drug)	Reason: Othr&unspec metabolic diseases
Tablet	40.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 04/10/2002 Stopped: 12/10/2002

Laboratory Investigations:

Additional Information:

Patient was also taking Minax, Talohexal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181430
Reported: 13/01/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 07/12/2002
Outcome: Unknown

Age: 45
DOB: 18/12/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Nausea, extrapyramidal disorder, abdominal pain.	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 06/12/2002 Stopped: 07/12/2002

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181469	Seq: 1	Gender: F
Reported: 13/01/2003		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date:		DOB: 11/09/1962
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	Very severe tremor, akathisia, parkinsonism and extrapyramidal disorder.	
Akathisia	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recurred with trial 3 weeks later of 100mg nocte, ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181469
Reported: 13/01/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 40
DOB: 11/09/1962
Causality: Causality possible

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Additional Information:

Recurred with trial 3 weeks later of 100mg nocte, ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181475

Seq: 1

Gender: M

Reported: 13/01/2003

Weight: 0.00

Hospitalisation:

Onset Date: 20/11/2002

Age: 41

DOB: 13/12/1960

Outcome: Recovered

28/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Ataxia; slow movement, possible extrapyramidal syndrome.	

Medicine Details:

SOLIAN (Interaction)	Reason:		
200.0 Milligram	Daily		
Batch:	Started: 04/11/2002	Stopped:	
ZYPREXA (Interaction)	Reason:		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 20/08/2002	Stopped:	
KALMA (Other drug)	Reason:		
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Iron tablets.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181488

Seq: 1

Gender: F

Reported: 13/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 27/09/2002

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Hypersalivation	Cogentin

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 27/09/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At present patient is on 700mg/day Solian.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181697	Seq: 1	Gender: M
Reported: 15/01/2003		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism		Parkinsonism - blunted focus, tremor; shuffling gait.	Recovered 3 weeks after ceasing solian
Gait disturbance			
Tremor			

Medicine Details:

EFEXOR (Other drug)		Reason:	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181699
Reported: 15/01/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 60
DOB: 30/10/1942
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Severe EPS - marked motor and emotional restlessness, extrapyramidal disorder, unstable ataxia, insomnia; significant increase in pain	
Coordination abnormal			
Insomnia			
Restlessness			

Medicine Details:

SOLIAN (Suspected)	Reason: Depression
400.0 Milligram	Daily
Batch:	Started:
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History - not experienced on zyprexa or seroquel. Patient also taking cipramil, seroquel, oxynorm, stilnox, zocor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181703	Seq: 1	Gender: F
Reported: 15/01/2003		Weight: 0.00
Hospitalisation:		Age: 18
Onset Date:		DOB: 01/01/1985
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Irritability		Irritability, Disinhibition, Elation of Mood, No pressure of speech, Some increase in Energy	Currently reducing Solain dose in view of changing to Zyprexa.

Medicine Details:

ZYPREXA (Other drug)	Reason: Unspecified schizophrenia
15.0 Milligram	Daily
Batch:	Started: 11/06/2002 Stopped:
CITALOPRAM HYDROBROMIDE (Other drug)	Reason: Depression
20.0 Milligram	Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
400.0 Milligram	Reducing Oral
Batch:	Started: 01/08/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been treated for schizophrenia since June 1999 and never had manic features. Reaction occurred early October 2002. There was no evidence of substance misuse or akathisia. These features improved after halving the amisulpride to 200mg and re-introducing olanzapine 15mg. They fully remitted within days of stopping the amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181936

Seq: 1

Gender: F

Reported: 22/01/2003

Weight: 0.00

Hospitalisation:

Onset Date: 03/01/2003

Age: 29

DOB: 12/11/1973

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Required Visit to Doctor	Vomiting when dose of solian increased to 800mg/day. Some nausea on 600mg.	Reduced dose to 600mg.

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 12/12/2002	Stopped: 03/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been treated on clozaril, had just finished cross over.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181945	Seq: 1	Gender: F
Reported: 23/01/2003		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date:		DOB: 25/05/1963
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Hyperventilation, dysarthria	Solian ceased. IM serenace given
Hyperventilation			

Medicine Details:

COGENTIN (Other drug)	Reason:
Batch:	Started: Stopped:
EFEXOR (Other drug)	Reason:
Batch:	Started: Stopped:
HALDOL DECANOATE (Other drug)	Reason:
Batch:	Started: Stopped:
VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 181945

Seq: 1

Gender: F

Reported: 23/01/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 25/05/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

SOLIAN (Suspected)

Reason:

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182025 **Seq:** 1 **Gender:** F
Reported: 23/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 19/07/2002 **DOB:**
Outcome: Recovered 19/07/2002 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal seizures - 3 in one day	Taken to emergency dept and given iv phenytoin, then stabilized on this.

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 18/06/2002 Stopped: 19/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Background of intellectual disability following cardiac surgery at 4 years of age. Onset of schizophrenia at 17 yrs. At four yrs underwent cardiac surgery for congenital heart lesion with complication of surger leading to "brain damage" and required several EEGs but no know fit.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182035	Seq: 1	Gender: F
Reported: 24/01/2003		Weight: 0.00
Hospitalisation:		Age: 34
Onset Date: 25/10/2002		DOB: 19/04/1968
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Lactation - Non-Puerperal	

Medicine Details:

EPILIM (Suspected)	Reason: Unspecified schizophrenia
2.0 Gram	Daily
Batch:	Started: Stopped: Contin
SEROQUEL (Suspected)	Reason: Unspecified schizophrenia
Tablet 300.0 Milligram	Daily Oral
Batch:	Started: Stopped: Contin
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet 200.0 Milligram	Daily Oral
Batch:	Started: Stopped: Contin
LUVOX (Suspected)	Reason: Unspecified schizophrenia
Tablet 100.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182219

Seq: 1

Gender: F

Reported: 31/01/2003

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 13/11/2002

DOB: 12/05/1957

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Hypersalivation - dribbles from sides of mouth, occurs throughout day and night	

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis
300.0 Milligram	Daily
Batch:	Started: 06/11/2002
	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182498

Seq: 1

Gender: F

Reported: 07/02/2003

Weight: 110.00

Hospitalisation:

Age: 39

Onset Date: 12/01/2003

DOB: 30/07/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Required Visit to Doctor	Galactorrhoea	Reduced dose to 400mg nocte.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 07/01/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital at the time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182541	Seq: 1	Gender: M
Reported: 07/02/2003		Weight: 0.00
Hospitalisation:		Age: 85Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Life threatening	Suicidal ideation	

Medicine Details:

ZYPREXA (Other drug)	Reason: Unspecified schizophrenia
Tablet	10.0 Milligram Daily Oral
Batch:	Started: Stopped:
PROZAC (Other drug)	Reason: Depression
	20.0 Milligram Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking methylphenidate.
 Onset was 10/02.
 Solian was started and stopped sometime in October 2002



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182547 **Seq:** 1 **Gender:** M
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 20
Onset Date: 30/11/2002 **DOB:** 01/03/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Recurrent oculogyric crisis leading to falls	

Medicine Details:

CLOPIXOL (Other drug)	Reason: Unspecified psychosis		
Injection	100.0 Milligram	Fortnightly	Intramuscular
Batch:	Started: 19/08/2002	Stopped:	Stopped: 09/01/2003
COGENTIN (Other drug)	Reason:		
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 05/04/2000	Stopped:	Stopped:
SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 26/11/2002	Stopped:	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182570	Seq: 1	Gender: M
Reported: 10/02/2003		Weight: 0.00
Hospitalisation:		Age: 80
Onset Date: 23/09/2002		DOB: 19/12/1921
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Dehydration	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Delirium	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Hypertension	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)	Reason: Nausea and vomiting
Oral application	10.0 Milligram
1 time	
Batch:	Started: 22/09/2002
	Stopped:
HALOPERIDOL (Suspected)	Reason: Otr spec symp psychopathol nec
1.0 Milligram	As necessary
Batch:	Started: 22/09/2002
	Stopped: 24/09/2002
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
400.0 Milligram	Daily
Batch:	Started: 21/09/2002
	Stopped: 30/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2003	Creatine		02/10/2002	19	
10/02/2003	Creatine		03/10/2002	210	
10/02/2003	Creatine		04/10/2002	79	

Additional Information:

Patient als otaking gentamicin, quetiapine, ampicillin, augmentin duo forte, thyroxine, multivitamins, coloxyl with senna



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182570
Reported: 10/02/2003
Hospitalisation:
Onset Date: 23/09/2002
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 80
DOB: 19/12/1921
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given and GTN patch
Somnolence	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Urinary retention	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Vomiting	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)	Reason: Nausea and vomiting	
Oral application	10.0 Milligram	1 time
Batch:	Started: 22/09/2002	Stopped:
HALOPERIDOL (Suspected)	Reason: Otr spec symp psychopathol nec	
	1.0 Milligram	As necessary
Batch:	Started: 22/09/2002	Stopped: 24/09/2002
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia	
	400.0 Milligram	Daily
Batch:	Started: 21/09/2002	Stopped: 30/09/2002

Laboratory Investigations:

Additional Information:

Patient als otaking gentamicin, quetiapine, ampicillin, augmentin duo forte, thyroxine, multivitamins, coloxyl with senna



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182865

Seq: 1

Gender: F

Reported: 13/02/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 14/04/1952

Outcome: Recovered

06/02/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne	Required Visit to Doctor	Developed acneform rash on face and axillae - thickened inflammatory erythema without pustules.	

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis
600.0 Milligram	Daily
Batch:	Started: 21/10/2002
	Stopped: 01/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Started solian 100mg on 17/10/02 and increased to 600mg on 21/10/02. Patient also taking zyprexa, codeine, xanax, cafergot.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 182909
Reported: 14/02/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 27/11/2002
Outcome: Recovered

Age: 67
DOB: 21/08/1935
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Ventricular bigeminy	Withdrawal of Solian

Medicine Details:

SEROQUEL (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 25/11/2002	Stopped:	Contin
SOLIAN (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2002	Stopped:	28/11/2002

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 183617	Seq: 1	Gender: M
Reported: 03/03/2003		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 15/08/2002		DOB: 14/08/1977
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal side effects, Spasm of feet and severe restlessness.	Medication ceased
Muscle spasms			
Restlessness			

Medicine Details:

AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Amisulpride started and stopped 8/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 183642

Seq: 1

Gender: M

Reported: 03/03/2003

Weight: 70.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 02/03/1982

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Severe Extrapyramidal reaction, stiffness in neck and arms.	Benzotropine IMI, Amisulpride ceased.
Musculoskeletal stiffness			

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 08/02/2003	Stopped: 08/02/2003	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 183674

Seq: 1

Gender: F

Reported: 03/03/2003

Weight: 60.00

Hospitalisation:

Onset Date: 01/08/2002

Age: 99u

Outcome: Recovered

DOB:

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swelling		Swelling (fluid retention) in hands and feet.	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Amisulpride started and stopped Aug 02.
Patient was already in hospital.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 183682

Seq: 1

Gender: F

Reported: 04/03/2003

Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2002

Age: 54

DOB: 10/05/1948

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Tremor	Stopped medication.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Amisulpride started and stopped Aug 02.
Date of recovery Aug 02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184186	Seq: 1	Gender: F
Reported: 19/03/2003		Weight: 0.00
Hospitalisation:		Age: 34Y
Onset Date: 07/01/2002		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticarial rash	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)		Reason: Schizo-affective type psychos
Injection	200.0 Milligram	Fortnightly
Batch:	Started:	Stopped: Contin
CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason: Schizo-affective type psychos
Tablet	2.5 Milligram	Daily Oral
Batch:	Started:	Stopped: 07/01/2002
AMISULPRIDE (Suspected)		Reason: Schizo-affective type psychos
Tablet	400.0 Milligram	Daily Oral
Batch:	Started: 07/01/2002	Stopped: 08/01/2002

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184265

Seq: 1

Gender: F

Reported: 11/02/2003

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 17/01/2003

DOB: 07/07/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Galactorrhoea, induration around the right nipple with slight inversion.	Reduced dosage to 400mg initially and by hundreds to 0.
Nipple disorder			

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 04/01/2003	Stopped: 04/02/2003	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184497 **Seq:** 1 **Gender:** F
Reported: 28/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Intentional overdose Somnolence		Hypotension Nos, somnolence and non-accidental overdose.	Treated with activated charcoal

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient hospitalised for 6 hours.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184498	Seq: 1	Gender: M
Reported: 28/03/2003		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 99U
Onset Date: 02/03/2003		DOB:
Outcome: Recovered	16/03/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Complex partial seizures		Complex partial seizures exacerbated.	

Medicine Details:

CARBAMAZEPINE (Other drug)		Reason:	
Oral application	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient developed a total of 3 episodes of complex partial seizure activity on amisulpride while carbamazepine was within therapeutic levels. An episode recurred when the dose of amisulpride has been reduced at 400mg/d leading to complete cessation of amisulpride on 09/03/03. History: Chronic schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184759

Seq: 1

Gender: M

Reported: 08/04/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Itchy rash, nausea and vomiting.	Solian stopped because of vomiting.
Nausea			
Vomiting			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184760

Seq: 1

Gender: M

Reported: 08/04/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Itchy rash	

Medicine Details:

SOLIAN (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 184761	Seq: 1	Gender: F
Reported: 08/04/2003		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		Constipation	

Medicine Details:

SOLIAN (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 185100 **Seq:** 1 **Gender:** F
Reported: 14/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypercorticism		Patient experienced hypercortisolism and hyperprolactinemia.	Solian ceased.
Hyperprolactinaemia			

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: Stopped: 30/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lamictal, Dothiepin, Yasmin and Immoveane.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 185250	Seq: 1	Gender: M
Reported: 29/04/2003		Weight: 125.00
Hospitalisation:		Age: 24
Onset Date: 21/03/2003		DOB: 14/12/1978
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsive threshold lowered	Caused or prolonged inpatient hospitalisation	Convulsive threshold lowered	Diazepam administered. Daily dose of amisulpride reduced to 200mg and finally was changed to risperidone. Zuclopenthixol and sertraline were also reduced.

Medicine Details:

CLOPIXOL (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
SOLIAN (Suspected)	Reason:
Tablet	
Batch:	Started: 29/01/2003
Batch:	Stopped:
ZOLOFT (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/04/2003	Radiology				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 185348	Seq: 1	Gender: F
Reported: 02/05/2003		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date:		DOB: 02/08/1959
Outcome: Recovered		Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photophobia	Required Visit to Doctor	Photophobia	

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
2.0 Milligram	3 times
Batch:	Started: Stopped:
EPILIM (Other drug)	Reason:
Tablet 500.0 Milligram	2 times Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Unspecified psychosis
Tablet 600.0 Milligram	Daily Oral
Batch:	Started: 01/12/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Coded certain because of rechallenge. Patient also taking Epilim, clonazepam, fosinipril/hydrochlorothiazide and fluvoxamine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 185978	Seq: 1	Gender: F
Reported: 15/05/2003		Weight: 0.00
Hospitalisation:		Age: 46
Onset Date: 06/03/2003		DOB: 26/09/1956
Outcome: Recovered	11/03/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest discomfort		Hypersensitivity nos, rash pruritic, wheezing and chest tightness	
Hypersensitivity	Life threatening	Hypersensitivity nos, rash pruritic, wheezing and chest tightness	Patient has been switched to another Antipsychotic agent. Given an Antihistamine, Topical management of rash and Nebulised Salbutamol on a PRN basis for breathing difficulty.

Medicine Details:

EPILIM (Other drug)		Reason:	
Oral application	400.0 Milligram		Oral
Batch:	Started:	Stopped:	
EFEXOR-XR (Other drug)		Reason: Depression	
Capsule	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
	150.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason: Unspecified psychosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2003	Stopped: 08/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to "sulfa" drug, eggs, tomatoes, canteloupe and walnuts.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 185978

Seq: 1

Gender: F

Reported: 15/05/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/03/2003

Age: 46

Outcome: Recovered

11/03/2003

DOB: 26/09/1956

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic	Required Visit to Doctor	Hypersensitivity nos, rash pruritic, wheezing and chest tightness	Given antihistamine, ventolin neb, topical management of rash, antihistamine, salt baths and soothing lotions.
Wheezing		Hypersensitivity nos, rash pruritic, wheezing and chest tightness	

Medicine Details:

EPILIM (Other drug)	Reason:		
Oral application	400.0 Milligram	Oral	
Batch:	Started:	Stopped:	
EFEXOR-XR (Other drug)	Reason: Depression		
Capsule	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)	Reason:		
	150.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2003	Stopped: 08/03/2003	

Laboratory Investigations:

Additional Information:

Allergy to "sulfa" drug, eggs, tomatoes, canteloupe and walnuts.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186621 **Seq:** 1

Gender: M

Reported: 05/06/2003

Weight: 0.00

Hospitalisation:

Age: 52Y

Onset Date: 17/03/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186669 **Seq:** 1 **Gender:** F
Reported: 06/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: 15/01/2003 **DOB:** 25/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Loss of appetite, weight loss, depression/agitation, increase in paranoid ideation - symptoms started on switching from Olanzapine to Amisulpride .	
Anorexia		Loss of appetite, weight loss, depression/agitation, increase in paranoid ideation - symptoms started on switching from Olanzapine to Amisulpride .	

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:
AMARYL (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Schizophrenia
Oral application	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

recovery date: 05/03. Dose start and stop date: 01/03 - 04/03.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186669 **Seq:** 1 **Gender:** F
Reported: 06/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: 15/01/2003 **DOB:** 25/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression		Loss of appetite, weight loss, depression/agitation, increase in paranoid ideation - symptoms started on switching from Olanzapine to Amisulpride .	
Paranoia		Loss of appetite, weight loss, depression/agitation, increase in paranoid ideation - symptoms started on switching from Olanzapine to Amisulpride .	

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:
AMARYL (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Schizophrenia
Oral application	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

recovery date: 05/03. Dose start and stop date: 01/03 - 04/03.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186669 **Seq:** 1 **Gender:** F
Reported: 06/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: 15/01/2003 **DOB:** 25/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight decreased		Loss of appetite, weight loss, depression/agitation, increase in paranoid ideation - symptoms started on switching from Olanzapine to Amisulpride .	

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:
AMARYL (Other drug)	Reason: Diabetes mellitus
Tablet	Dose Unspecified Daily Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Schizophrenia
Oral application	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

recovery date: 05/03. Dose start and stop date: 01/03 - 04/03.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186777	Seq: 1	Gender: M
Reported: 10/06/2003		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 08/04/2003		DOB: 30/04/1980
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Coordination abnormal		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Hyperhidrosis		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Hypertonia		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 07/04/2003	Stopped: 08/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2003	Creatine		09/04/2003	2261	
10/06/2003	Creatine		09/04/2003	473	

Additional Information:

Patient was also taking Cipramil and Valium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186777
Reported: 10/06/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 08/04/2003
Outcome: Recovered

Age: 22
DOB: 30/04/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Muscle spasms		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	Ceased Solian, given diazepam, Cogentin.
Tremor		Neuroleptic malignant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 07/04/2003 Stopped: 08/04/2003

Laboratory Investigations:

Additional Information:

Patient was also taking Cipramil and Valium.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186798

Seq: 1

Gender: M

Reported: 11/06/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 30/05/2003

DOB: 06/07/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Observed fit	Admitted to ICU, Valium stat and Dilantin

Medicine Details:

SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 03/07/1994	Stopped: 30/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

189532 is a duplicate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186881	Seq: 1	Gender: M
Reported: 13/06/2003		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 99u
Onset Date: 30/05/2003		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions nos	Admitted to Intensive Care unit.

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: without history of seizure.
Patient has been on Clozapine since 1994.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 186970	Seq: 1	Gender: M
Reported: 16/06/2003		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date: 10/06/2003		DOB:
Outcome: Recovered	10/06/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Salivation, dystonia, torticollis and movements of tongue.	Cogentin 2mg/IM given.
Dystonia			
Tongue paralysis			
Torticollis			

Medicine Details:

SEROQUEL (Suspected)		Reason: Schizophrenia
Tablet	100.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
SOLIAN (Suspected)		Reason: Schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started: 01/06/2003	Stopped: 10/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Poor compliance and medications.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 187133

Seq: 1

Gender: M

Reported: 20/06/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 02/06/2003

DOB: 01/08/1963

Outcome: Recovered

04/06/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Sweaty, muscle twitching, headaches worsened , agitation.	
Headache		Sweaty, muscle twitching, headaches worsened , agitation.	
Hyperhidrosis		Sweaty, muscle twitching, headaches worsened , agitation.	Ceased Solian
Muscle twitching		Sweaty, muscle twitching, headaches worsened , agitation.	Ceased Solian

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis
200.0 Milligram	Daily
Batch:	Started: 02/06/2003
	Stopped: 04/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Nexium, Panadeine Forte, Efexor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 187143	Seq: 1	Gender: F
Reported: 20/06/2003		Weight: 86.00
Hospitalisation:		Age: 39
Onset Date: 01/06/2003		DOB: 26/10/1963
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus generalised	Required Visit to Doctor	Generalised itching, amenorrhoea	
Amenorrhoea	Required Visit to Doctor		

Medicine Details:

CLOZARIL (Other drug)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 21/02/1995	L TERM	Stopped: Contin
AMISULPRIDE (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/01/2003		Stopped: 02/07/2003

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 187800

Seq: 1

Gender: F

Reported: 27/06/2003

Weight: 0.00

Hospitalisation:

Age: 64Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		ERECTILE DYSFUNCTION	Solian was stopped.

Medicine Details:

SOLIAN (Suspected)	Reason:
	200.0 Milligram Daily
Batch:	Started: 18/02/2003 Stopped: 03/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking warfarin.
History of hyperthyroidism (inactive), Atrial fibrillation.
According to the reporter, it is possible that the onset of impotence was psychological, as he continued to have occasional morning erections.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 187958

Seq: 1

Gender: M

Reported: 30/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 19/01/2003

Age: 39

DOB: 05/02/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Limb stiffness shuffling gait.	Cogentin x 3mg.

Medicine Details:

MIRTAZAPINE (Other drug)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: Stopped:
AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
Tablet	600.0 Milligram Daily Oral
Batch:	Started: Stopped: 19/01/2003

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188041	Seq: 1	Gender: M
Reported: 03/07/2003		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Inability to articulate	It was recommended to stop amisulpride and valproate.
Gait disturbance		Inability to walk unaided.	
Jaundice		Jaundice, sweating increased, muscle spasm.	
Muscle spasms	Severe	Severe muscle spasm	
Aphasia	Severe		
Hyperhidrosis			

Medicine Details:

EPILIM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	1000.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Hepatitis B



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188245 **Seq:** 1 **Gender:** F
Reported: 09/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 07/05/2003 **DOB:** 09/04/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Acutely psychotic with manic features	Patient hospitalised for four weeks, treated with valproate and haloperidol

Medicine Details:

SOLIAN (Suspected)	Reason: Schizophrenia
800.0 Milligram	Daily
Batch:	Started: 22/01/2003 Stopped: 07/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Schizophrenia with predominantly negative symptoms, Chronic low grade depression. Patient also taking olanzapine, citalopram



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188530	Seq: 1	Gender: M
Reported: 17/07/2003		Weight: 63.00
Hospitalisation:		Age: 25
Onset Date: 09/07/2003		DOB: 03/08/1977
Outcome: Recovered	13/07/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep disorder	Required Visit to Doctor	Insomnia (sleep disturbance)	Changed to Zyprexa

Medicine Details:

SOLIAN (Suspected)		Reason: Schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 08/07/2003	Stopped: 11/07/2003	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188664

Seq: 1

Gender: F

Reported: 21/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 13/11/2002

Age: 26

Outcome: Unknown

DOB: 16/04/1976

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2002	Stopped: 08/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2003	Other data				

Additional Information:

Galactorrhoea two months throughout use of Amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188705	Seq: 1	Gender: U
Reported: 22/07/2003		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date: 28/05/2003		DOB: 20/07/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Autonomic nervous system imbalance Delirium Hyperhidrosis Muscle rigidity Pyrexia Neuroleptic malignant syndrome		neuroleptic malignant syndrome, autonomic lability, diaphoresis, rigidity, fever.	Bromocriptine, also started s/c heparin/ iv fluids.

Medicine Details:

AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 28/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/07/2003	Creatine				

Additional Information:

Patient was also taking Temazepam, Diageoam, Clonazepam, Depo clopioxol.
Dose was doubled 3 days prior to presentation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 188706	Seq: 1	Gender: M
Reported: 22/07/2003		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date: 14/07/2003		DOB: 04/07/1973
Outcome: Recovered	14/07/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Clonus Extrapyramidal disorder Hyperhidrosis Hyperreflexia Pain in jaw Tachycardia		Cogwheel rigidity, jaw pain, sweating, tachycardia, hyper-reflexia, clonus	Benztropine and Midazolam.

Medicine Details:

LUVOX (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/07/2003	Stopped: 14/07/2003	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 189120
Reported: 05/08/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 51
DOB: 23/07/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular extrasystoles		Asymptomatic (corrected QT not reported)	
Electrocardiogram QT prolonged		QT Prolonged, Supraventricular extrasystoles, ventricular extrasystoles	Solian and Quilonum were ceased.
Sinoatrial block		apparent sinoatrial block with junctional escape	
Supraventricular extrasystoles			

Medicine Details:

QUILONUM SR (Suspected)	Reason:		
450.0 Milligram/24 hour	Oral		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	1200.0 Milligram	Daily	Oral
Batch:	Started: 24/07/2002	Stopped: 02/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2003	Electrocardiograph				
05/08/2003	QT interval			458 ms	

Additional Information:

Patient was also taking Olanzapine, Dilantin, Quilonum, i.e.:
Amisulpride 1,200 mg/day, olanzapine 40 mg/day, phenytoin 260 mg/day, lithium 450 mg/day. Dechallenge of amisulpride and lithium reduced the prolongation of the QT interval but prolongation and extrasystoles persisted



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 189460

Seq: 1

Gender: F

Reported: 13/08/2003

Weight: 0.00

Hospitalisation:

Onset Date: 01/07/2003

Age: 29

DOB: 15/09/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Hyperprolactinaemia-Galactorrhoea	Daily dose of Solian was reduced to 700mg.
Galactorrhoea			

Medicine Details:

SOLIAN (Suspected)	Reason:
	800.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Thin discharge from breast 15 years before.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 189732	Seq: 1	Gender: M
Reported: 20/08/2003		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date:		DOB: 04/12/1972
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block left		Left anterior fascicular block.	
Electrocardiogram abnormal		Left anterior fascicular block.	
QRS axis abnormal		Left anterior fascicular block.	

Medicine Details:

EPILIM (Suspected)	Reason:
Batch:	Started: Stopped:
SERZONE (Suspected)	Reason:
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/08/2003	Electrocardiograph				

Additional Information:

Onset date:2001



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 189778

Seq: 1

Gender: U

Reported: 22/08/2003

Weight: 85.00

Hospitalisation:

Age: 48

Onset Date: 15/03/2003

DOB: 10/12/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parotid gland enlargement	Required Visit to Doctor	Parotid enlargement.	

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 05/11/2002	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 189976

Seq: 1

Gender: M

Reported: 29/08/2003

Weight: 0.00

Hospitalisation:

Age: 20Y

Onset Date: 28/06/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions	Solian stopped

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	Oral
Batch:	Started:
	Stopped: 30/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2003	Other data				

Additional Information:

Previously treated with olanzapine



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190309

Seq: 1

Gender: F

Reported: 08/09/2003

Weight: 0.00

Hospitalisation:

Onset Date: 27/02/2003

Age: 75Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Headache Malaise Tardive dyskinesia Condition aggravated		Increased tardive dyskinesia, confusion and agitation, headache and feeling unwell	Olanzapine 5mg nocte and Lorazepam prn. Therapy ceased

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
Tablet 50.0 Milligram	Daily Oral
Batch:	Started: Stopped: 27/02/2003
AMISULPRIDE (Suspected)	Reason:
Tablet 100.0 Milligram	Daily Oral
Batch:	Started: Stopped: 27/02/2003
COGENTIN (Suspected)	Reason:
Tablet 2.0 Milligram	Daily Oral
Batch:	Started: Stopped: 27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of tardive dyskinesia (chewing, biting) resulted from Stelazine 30years ago. Patient prone to agitation and depression. Other drugs used: Lorazepam, Olanzapine, Mirtazapine, Aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190319	Seq: 1	Gender: M
Reported: 08/09/2003		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date:		DOB: 10/12/1954
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parotid gland enlargement		Bilateral painless parotid gland enlargement.	

Medicine Details:

SOLIAN (Suspected)		Reason: Schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 05/11/2002	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190660	Seq: 1	Gender: F
Reported: 19/09/2003		Weight: 59.00
Hospitalisation:		
Onset Date: 25/07/2003		Age: 18
Outcome: Recovered	02/09/2003	DOB: 30/11/1984
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Required Visit to Doctor	Akathisia, tiredness, hunger, breast tenderness	Cessation of all medications
Breast tenderness	Required Visit to Doctor		
Fatigue	Required Visit to Doctor		
Galactorrhoea	Required Visit to Doctor		
Hunger	Required Visit to Doctor		
Metrorrhagia	Required Visit to Doctor		

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
100.0 Milligram	Daily Oral
Batch:	Started: 15/06/2003 Stopped: 01/07/2003
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet 200.0 Milligram	Daily Oral
Batch:	Started: 01/07/2003 Stopped: 05/08/2003

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190712	Seq: 1	Gender: F
Reported: 22/09/2003		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date:		DOB: 27/02/1977
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Caused or prolonged inpatient hospitalisation	Peripheral oedema, oedema of face and eyelids progressing to exfoliative dermatitis.	Withdrawal of carbamazepine then Solian. Prednisolone 50mg, promethazine and derssings used.
Dermatitis exfoliative	Caused or prolonged inpatient hospitalisation		
Eyelid oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	2.0 Milligram	As necessary	Oral
Batch:	Started: 01/07/2003	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	100.0 Milligram	As necessary	Oral
Batch:	Started: 01/07/2003	Stopped:	
CARBAMAZEPINE (Suspected)		Reason:	
Tablet	200.0 Milligram	2 times	Oral
Batch:	Started: 01/07/2003	Stopped: 15/08/2003	
SOLIAN (Suspected)		Reason:	
	400.0 Milligram	2 times	Oral
Batch:	Started: 01/07/2003	Stopped: 30/08/2003	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190712
Reported: 22/09/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 26
DOB: 27/02/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
Tablet 2.0 Milligram	As necessary Oral
Batch:	Started: 01/07/2003 Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
Tablet 100.0 Milligram	As necessary Oral
Batch:	Started: 01/07/2003 Stopped:
CARBAMAZEPINE (Suspected)	Reason:
Tablet 200.0 Milligram	2 times Oral
Batch:	Started: 01/07/2003 Stopped: 15/08/2003
SOLIAN (Suspected)	Reason:
400.0 Milligram	2 times Oral
Batch:	Started: 01/07/2003 Stopped: 30/08/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 190993

Seq: 1

Gender: M

Reported: 30/09/2003

Weight: 0.00

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	Akathisia, constant pacing, moving, sleep problems and behavioral problems.	Diazepam 5 mg/day.
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		
Sleep disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/05/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Catatonic for seven months. Neuroleptic malignant syndrome on quetiapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 191040

Seq: 1

Gender: U

Reported: 02/10/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history incomplete.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 191634

Seq: 1

Gender: M

Reported: 27/10/2003

Weight: 70.00

Hospitalisation:

Onset Date: 23/08/2003

Age: 18

Outcome: Recovered

02/09/2003

DOB: 09/07/1985

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Muscle twitching		Motor agitation and increase in motor rics.	

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 21/08/2003 Stopped: 29/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Could not tolerate these and took self off medication.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 191998	Seq: 1	Gender: F
Reported: 10/11/2003		Weight: 0.00
Hospitalisation:		Age: 47
Onset Date: 22/09/2003		DOB: 21/01/1956
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy	Required Visit to Doctor	Lethargic, unwell and blood pressure 100/60 Sodium prior to Solian was about 139 to 144mmol/L after Solian Na decreased from 139 to 129mmol/L in 4 weeks.	
Hyponatraemia	Required Visit to Doctor		
Hypotension	Required Visit to Doctor		
Malaise	Required Visit to Doctor		

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 02/09/2003
	Stopped: 04/09/2003
SOLIAN (Suspected)	Reason: Unspecified psychosis
	400.0 Milligram
	Daily
Batch:	Started: 04/09/2003
	Stopped: 07/09/2003
SOLIAN (Suspected)	Reason: Unspecified psychosis
	600.0 Milligram
	Daily
Batch:	Started: 07/09/2003
	Stopped: 15/09/2003
SOLIAN (Suspected)	Reason: Unspecified psychosis
	1.5 Gram
	Daily
Batch:	Started: 15/09/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/11/2003	Other data				

Additional Information:

Other drugs used: Naprosyn, Epilim, Oxycontin and panadol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 192208

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 02/11/2003

Age: 48

DOB: 05/11/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Faintness/syncope	
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		Sotalol and intravenous digoxin, intravenous amlodarone. Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Oral application	12.5 Milligram Daily Oral
Batch:	Started: 28/11/2000 Stopped: 04/11/2003
SOLIAN (Suspected)	Reason:
	100.0 Milligram Daily
Batch:	Started: Stopped:
SODIUM VALPROATE (Suspected)	Reason:
	1.0 Dose Unspecified Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 192237

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 16/09/2003

Age: 24

DOB: 06/11/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypocalcaemia	Caused or prolonged inpatient hospitalisation	Hypocalcaemia	Treated with iv Calcium.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	37.5 Milligram	Daily	Oral
Batch:	Started: 02/06/1999	Stopped:	Contin
SOLIAN (Suspected)	Reason:		
Tablet	200.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 192462

Seq: 1

Gender: M

Reported: 24/11/2003

Weight: 0.00

Hospitalisation:

Age: 27Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation	Urinary incontinence.	

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason: Depression
Batch:	Started:	Stopped:
SOLIAN (Suspected)		Reason: Unspecified psychosis
Tablet	200.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Amisulpride was discontinued after ten days of treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 193092

Seq: 1

Gender: U

Reported: 12/12/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 193475
Reported: 22/12/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 24/10/2003
Outcome: Recovered

Age: 44
DOB: 03/12/1958
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Amenorrhoea Galactorrhoea Loss of libido		Patient experienced galactorrhoea and amenorrhoea with hyperprolactinaemia, loss of libido.	

Medicine Details:

AROPAX (Other drug)	Reason: Unspecified schizophrenia		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 28/03/2002	Stopped:	Contin
SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2002	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/12/2003	Prolactin		24/10/2003	About one year	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 193897
Reported: 09/01/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia Depression Tremor		Tardive dyskinesia, chronic depression, tremor	Was unsuccessfully treated with a number antidepressant trials. Solian was ceased, propranolol and tetrabenazine 12.5mg were given.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 194470
Reported: 10/02/2004

Seq: 1

Gender: U
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia Hyperprolactinaemia		Tardive dyskinesia, hyperprolactinaemia.	

Medicine Details:

SOLIAN (Suspected)	Reason: Schizophrenia
400.0 Milligram	Daily
Batch:	Started:
	Stopped: 15/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2004	Prolactin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 194471
Reported: 10/02/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 40Y
DOB:
Causality: Causality possible

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Dose Unspecified
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Venlafaxine, Morphine, Valproate, Voltaren.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 194695
Reported: 17/02/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania Insomnia		Mania and insomnia.	Solian was ceased

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia Oral	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had no previous history of bipolar disorder. The diagnosis was schizoaffective disorder and so with that mood component, the physician thought this probably the cause of the mania.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 194696	Seq: 1	Gender: F
Reported: 17/02/2004		Weight: 0.00
Hospitalisation:		Age: 32
Onset Date:		DOB: 09/01/1972
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Electrocardiogram QT corrected interval prolonged, ventricular extrasystoles.	Ceased Solian
Ventricular extrasystoles			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	1000.0 Milligram	Daily	Oral
Batch:	Started: 26/06/2002	Stopped:	Contin
SOLIAN (Suspected)		Reason:	
Tablet	1200.0 Milligram	Daily	Oral
Batch:	Started: 05/12/2002	Stopped:	21/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2004	Electrocardiograph				ECG showed ATc prolonged and ventricular premature beats (values not stated)

Additional Information:

ECG picture QTc prolonged and ventricular premature beats (values not stated).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 194859
Reported: 24/02/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia - involuntary tongue movements.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	400.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 195074

Seq: 1

Gender: F

Reported: 03/03/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female		Breast cancer, mastectomy.	A mastectomy was performed.

Medicine Details:

PARACETAMOL (Other drug)	Reason: Pain	
Batch:	Started:	Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Solian was stopped sometime in Jan 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 195919

Seq: 1

Gender: M

Reported: 24/03/2004

Weight: 0.00

Hospitalisation:

Age: 27Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures.	
Drug level increased			

Medicine Details:

SOLIAN (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)	Reason:		
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/03/2004	Other data				

Additional Information:

Patient known to be a fast metaboliser of Clozapine experienced seizures while he was treated in monotherapy.
Reaction onset date: Oct 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196052 **Seq:** 1 **Gender:** F
Reported: 29/03/2004 **Weight:** 90.00
Hospitalisation: **Age:** 63
Onset Date: 08/09/2003 **DOB:** 15/12/1939
Outcome: Death, maybe drug 08/09/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspiration Dysgeusia Cardiac arrest Tremor		Gastric contents. Patient complained of bitter taste, lots of shaking, looked terrible.	

Medicine Details:

SOLIAN (Suspected)	Reason: Depression
800.0 Milligram	Daily
Oral	
Batch:	Started: 04/04/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long history of major depression. Many other drugs in past documented. Patient supposed to on Epilem as a mood stabiliser not found in system at autopsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196124	Seq: 1	Gender: F
Reported: 31/03/2004		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date:		DOB: 08/09/1955
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myasthenia gravis	Required Visit to Doctor	Myasthenia Gravis.	Patient given 60mg Mestinon. Efexor-XR dose reduced to 375mg daily. However, reaction did not abate after dose reduction.

Medicine Details:

EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	450.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2003	L TERM	Stopped:
BUSPAR (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:
SOLIAN (Suspected)		Reason: Depression	
	200.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has emphysema secondary to chronic chest infection from childhood.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196231
Reported: 05/04/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 01/04/2004
Outcome: Recovered

02/04/2004

Age: 44
DOB: 20/05/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonic reaction, generalised muscle stiffness, neck tightness, difficulty breathing, tachycardia.	Benzotropine given.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Obsessive compulsive neurosis		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 31/03/2004	Stopped: 01/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Thyroxine, Calcium supplement, Clomipramine, Olanzapine. History: OCD and depression. No previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196231 **Seq:** 1 **Gender:** M
Reported: 05/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 01/04/2004 **DOB:** 20/05/1959
Outcome: Recovered 02/04/2004 **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Obsessive compulsive neurosis
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 31/03/2004 Stopped: 01/04/2004

Laboratory Investigations:

Additional Information:

Other drugs: Thyroxine, Calcium supplement, Clomipramine, Olanzapine. History: OCD and depression. No previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196561 **Seq:** 1 **Gender:** U
Reported: 19/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: 14/04/2004 **DOB:** 24/07/1979
Outcome: Recovered 15/04/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema	Life threatening	Patient experienced angio-oedema.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Depression
40.0 Milligram	Daily
Batch:	Started: 11/04/2004 Stopped:
AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
200.0 Milligram	Daily
Batch:	Started: 03/04/2004 Stopped: 14/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had angioedema to chlorpromazine and metoclopramide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196618

Seq: 1

Gender: M

Reported: 19/04/2004

Weight: 70.00

Hospitalisation:

Onset Date: 01/01/2004

Age: 55Y

Outcome: Recovered

09/01/2004

DOB:

Causality: Causality probable

Reaction Details:

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

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
300.0 Milligram	Daily
Batch:	Started:
	Stopped: 01/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Olanzapine, Paroxetine, Atenol, Trandolapril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196702	Seq: 1	Gender: M
Reported: 22/04/2004		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 01/07/2003		DOB: 04/06/1955
Outcome: Recovered	04/08/2003	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Required Visit to Doctor	Parkinson's Syndrome	ceased solian

Medicine Details:

EPILIM (Other drug)	Reason: Epilepsy
2.0 Gram	Daily
Batch:	Started:
	Stopped: contin
SOLIAN (Suspected)	Reason: Schizophrenia
800.0 Milligram	Daily
Batch:	Started: 25/06/2003
	Stopped: 21/07/2003

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196833

Seq: 1

Gender: M

Reported: 27/04/2004

Weight: 90.00

Hospitalisation:

Age: 40

Onset Date: 16/04/2004

DOB: 10/11/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Required Visit to Doctor	Raised troponin level.	

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
1.0 Gram	Daily
Batch:	Started: 15/02/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/04/2004	Troponin		16/04/2004	0.14	
27/04/2004	Troponin		09/04/2004	0.66	

Additional Information:

Patient also taking Venlafaxine, Clopixol and Cisinopril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196948

Seq: 1

Gender: F

Reported: 13/04/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 16/12/2003

DOB: 18/10/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Symptoms progressing.	Amisulpride ceased.

Medicine Details:

AMISULPRIDE (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 196965 **Seq:** 1

Gender: U

Reported: 03/05/2004

Weight: 0.00

Hospitalisation:

Age: 77

Onset Date:

DOB: 02/06/1926

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life threatening	Hyponatraemia leading to cerebral oedema and fitting.	Intubation and given Mannitol.
Brain oedema	Life threatening		
Convulsion	Life threatening		

Medicine Details:

MIRTAZAPINE (Suspected)	Reason: Depression		
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started: 01/12/2003	Stopped: 22/04/2004	
AMISULPRIDE (Suspected)	Reason:		
	300.0 Milligram	Daily	
Batch:	Started: 01/03/2004	Stopped:	
THIAMINE (Suspected)	Reason:		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2004	Stopped:	Continuing
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep		
	10.0 Milligram	Daily	Oral
Batch:	Started: 01/12/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2004	Sodium				

Additional Information:

Patient also taking Betoptic and Xalatan.
Had been on Mirtazapine since December 03, was increased February 04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197153
Reported: 10/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/01/2004
Outcome: Unknown

Age: 47
DOB: 15/10/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Urinary retention	

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	
COGENTIN (Suspected)	Reason:		
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/05/2004	Other data				

Additional Information:

Patient was also taking Thiordazine and Cephalexin.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197546

Seq: 1

Gender: M

Reported: 21/05/2004

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date:

DOB: 24/10/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Sexual impotence	Stopped Amisulpride

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking OPV - batch: S3359A5A and MMR - batch: 632A44A.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197704

Seq: 1

Gender: F

Reported: 28/05/2004

Weight: 126.00

Hospitalisation:

Age: 44

Onset Date: 21/05/2004

DOB: 03/01/1960

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		The patient weighed 126 kg with a body mass index (BMI) of 45, considered morbidly obese.	
Sudden death			

Medicine Details:

SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 11/01/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 21/05/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197788

Seq: 1

Gender: M

Reported: 04/03/2004

Weight: 89.50

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		December 2003 Neuroleptic malignant syndrome.	Amisulpride ceased

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenged twice with amisulpride and same reaction occurred.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197825 **Seq:** 1 **Gender:** F
Reported: 03/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31
Onset Date: **DOB:** 13/07/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Life threatening	Increase lithium levels resulting in vomiting, diarrhoea, acute renal failure and coma.	
Coma	Life threatening		
Diarrhoea	Life threatening		
Drug interaction	Life threatening		
Renal failure acute	Life threatening		

Medicine Details:

AMISULPRIDE (Interaction)	Reason:
Batch:	Started: Stopped:
LITHIUM CARBONATE (Interaction)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Serquel, Clopixal depot.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197825 **Seq:** 1 **Gender:** F
Reported: 03/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31
Onset Date: **DOB:** 13/07/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Life threatening		

Medicine Details:

AMISULPRIDE (Interaction)	Reason:	
Batch:	Started:	Stopped:
LITHIUM CARBONATE (Interaction)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Patient was also taking Serquel, Clopixal depot.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197974	Seq: 1	Gender: U
Reported: 08/06/2004		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 09/03/2004		DOB: 03/04/1963
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Reflux oesophagitis	Caused or prolonged inpatient hospitalisation	Reflux and dysphagia, chronically dry mouth and chronic oesophageal thrush.	Fungilin lozenges, hdration with eating.
Dry mouth	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IMIPRAMINE HYDROCHLORIDE (Suspected)		Reason: Toxic diffuse goiter	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
AMISULPRIDE (Suspected)		Reason: Depression	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
THYROXINE SODIUM (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	L TERM	Stopped:
LITHIUM CARBONATE (Suspected)		Reason: Unspecified psychosis	
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 197974

Seq: 1

Gender: U

Reported: 08/06/2004

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 09/03/2004

DOB: 03/04/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oesophageal candidiasis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OMEPRAZOLE (Suspected)	Reason:
40.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
BENZTROPINE MESYLATE (Suspected)	Reason:
Tablet	2.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198037

Seq: 1

Gender: M

Reported: 10/06/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 10/08/1975

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Gross tremors.	Solian was ceased.

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 13/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tremor appeared when the daily dose of amisulpride was increased from 200mg to 400mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198055	Seq: 1	Gender: F
Reported: 11/06/2004		Weight: 70.00
Hospitalisation:		
Onset Date: 27/05/2004		Age: 26
Outcome: Recovered	02/06/2004	DOB: 02/11/1977
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic	Required Visit to Doctor	Pruritic rash - generalised which developed into non-palpable purpura.	Antihistamine
Purpura	Required Visit to Doctor		

Medicine Details:

EFEXOR-XR (Other drug)	Reason: Unspecified psychosis
300.0 Milligram	Daily
Batch:	Started:
Batch:	Stopped:
SOLIAN (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 24/05/2004
	Stopped: 27/05/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198123	Seq: 1	Gender: F
Reported: 15/06/2004		Weight: 60.00
Hospitalisation:		Age: 40Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne	Required Visit to Doctor	Pimples, breast milk, prolonged period, extreme dizziness when walking (nearly passed out).	
Dizziness	Required Visit to Doctor		
Galactorrhoea	Required Visit to Doctor		
Menorrhagia	Required Visit to Doctor		

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	800.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198404 **Seq:** 1 **Gender:** F
Reported: 23/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: **DOB:** 22/05/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	increased suicidal ideation.	Amisulpride ceased.

Medicine Details:

SOLIAN (Suspected)	Reason:
1.2 Gram	Daily
Oral	
Batch:	Started: 23/02/2003
	Stopped: 06/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking various concomitant medications.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198406	Seq: 1	Gender: F
Reported: 23/06/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 37
Onset Date: 01/06/2004		DOB: 09/04/1967
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Weight increased		Lack of efficacy and weight gain	

Medicine Details:

SOLIAN (Suspected)	Reason:
Batch:	Dose Unspecified Oral
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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198513
Reported: 25/06/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Patient experienced chronic depersonalisation.	

Medicine Details:

SOLIAN (Suspected)	Reason:
100.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped: 9 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms lasted 11 months while the patient had been medication free.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 198527

Seq: 1

Gender: M

Reported: 28/06/2004

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date:

DOB: 30/01/1988

Outcome: Recovered

18/06/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Trismus	Required Visit to Doctor	Trismus and opisthotonos.	
Opisthotonus	Required Visit to Doctor		

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 17/06/2004	Stopped:	18/06/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199181
Reported: 19/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 30
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue	Life threatening	Swollen tongue, dyspnoea.	Oxygen
Dyspnoea	Life threatening		

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	100.0 Milligram 1 time Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199263
Reported: 21/07/2004

Seq: 1

Gender: M
Weight: 92.00

Hospitalisation:

Onset Date: 15/04/2004
Outcome: Recovered

Age: 44
DOB: 24/01/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment	Required Visit to Doctor	Renal impairment.	Dose of Luvox reduced to 100mg daily and Solian reduced to 100mg daily.

Medicine Details:

LUVOX (Suspected)	Reason: Depression		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 26/03/2003	Stopped:	
SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/03/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2004	Creatinine				
21/07/2004	Creatinine				
21/07/2004	Urea				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199302

Seq: 1

Gender: M

Reported: 22/07/2004

Weight: 0.00

Hospitalisation:

Age: 64

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Depressive symptom Paranoia Parkinsonism		Patient developed extrapyramidal symptoms, parkinsonism symptoms along with depressive symptoms and worsening of paranoia.	Amisulpride discontinued and Quetiapine commenced 25mg/daily.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	1 week

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Chronic paranoid schizophrenia of about 15 years duration, 10 year history of poorly treated diabetes mellitus. After 3 weeks of Amisulpride 200mg/daily dose was increased to 400mg/daily. Amisulpride was later reduced back to 200mg/daily before being discontinued. This report is a seq to 199462.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199534 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 07/07/2004 **DOB:** 19/10/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose		Overdose.	

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:		
40.0 Milligram	Oral		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 24/12/2002	Stopped: 07/07/2004	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199544 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31Y
Onset Date: 25/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Serious dystonias on 3 out of 6 clients.	Diazepam, observation and change to other antipsychotic.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199545 **Seq:** 1 **Gender:** F
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 25/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Serious dystonias.	Diazepam, observation and change to other antipsychotic.

Medicine Details:

SOLIAN (Suspected)	Reason:	
Tablet	200.0 Milligram	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199546 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22Y
Onset Date: 25/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Serious dystonias.	diazepam, observation and changed to other antipsycotic

Medicine Details:

SOLIAN (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199760	Seq: 1	Gender: M
Reported: 06/08/2004		Weight: 0.00
Hospitalisation:		Age: 51
Onset Date: 07/07/2004		DOB: 01/10/1952
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced neuroleptic malignant syndrome.	Amisulpride ceased. Paracetamol for raised temperature, 0.9% Sodium Chloride infusion for dehydration, Clonazepam .5mg IM PRN for agitation.
Blood creatine phosphokinase incr			
Circulatory collapse			
Contusion			
Dehydration			
Hearing impaired			
Leukocytosis			

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Injection	0.5 Milligram	1 time	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
	0.3 Milligram	As necessary	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2004	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/08/2004	Creatine		07/07/2004	733	
06/08/2004	Creatine		09/07/2004	4238	
06/08/2004	Creatine		13/07/2004	now dropping	
06/08/2004	White blood cells		07/07/2004	15.1	With neutrophilia

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199760
Reported: 06/08/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 07/07/2004
Outcome: Recovered

Age: 51
DOB: 01/10/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity Psychotic disorder Pyrexia Tremor			

Medicine Details:

CLONAZEPAM (Other drug) Injection Batch:	0.5 Milligram Started:	Reason: 1 time Stopped:
DIAZEPAM (Other drug) Batch:	0.3 Milligram Started:	Reason: As necessary Stopped:
DIAZEPAM (Other drug) Batch:	0.5 Milligram Started:	Reason: Daily Stopped:
AMISULPRIDE (Suspected) Tablet Batch:	400.0 Milligram Started: 31/05/2004	Reason: Unspecified schizophrenia Daily Oral Stopped: 07/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199839 **Seq:** 1 **Gender:** M
Reported: 10/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: 26/07/2004 **DOB:** 08/11/1975
Outcome: Recovered 03/08/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Facial rash	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
Tablet 1.0 Gram Daily	
Batch:	Started: 23/07/2004 Stopped:
SOLIAN (Suspected)	Reason: Unspecified psychosis
Tablet 800.0 Milligram Daily Oral	
Batch:	Started: 23/07/2004 Stopped: 28/07/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 199898 **Seq:** 1 **Gender:** F
Reported: 11/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 05/08/2004 **DOB:** 31/12/1954
Outcome: Recovered 06/08/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia		Patient experienced numbness all over body.	

Medicine Details:

ZANTAC (Other drug)	Reason: Gastroenteritis and colitis	
1.0 Dose Unspecified As necessary		
Batch:	Started:	Stopped:
ZYPREXA (Other drug)	Reason: Unspecified schizophrenia	
20.0 Milligram Daily		
Batch:	Started:	Stopped:
PREMIA 5 (Other drug)	Reason: Menopausal symptoms	
Tablet 1.0 Dose Unspecified Daily Oral		
Batch:	Started:	Stopped:
SOLIAN (Suspected)	Reason:	
Tablet 100.0 Milligram Oral		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200025	Seq: 1	Gender: M
Reported: 16/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 51
Onset Date: 15/06/2004		DOB: 01/10/1952
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuromalignant syndrome, high temperature, generalised muscle aches and pains, creatine kinase at 9,000-10,000, renal compromise, agitated and anxious.	Solian ceased. Intensive care and rehydration with fluid.
Anxiety	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2004	Creatine				Creatinine kinase at 9,000-10,000.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200025 **Seq:** 1 **Gender:** M
Reported: 16/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: 15/06/2004 **DOB:** 01/10/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200034	Seq: 1	Gender: F
Reported: 23/06/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 37
Onset Date: 03/06/2004		DOB: 09/04/1967
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting Constipation Nausea Rash		Vomiting, nausea, rash and constipation.	

Medicine Details:

LANSOPRAZOLE (Other drug)	Reason:	
30.0 Milligram		
Batch:	Started:	Stopped:
MOCLOBEMIDE (Other drug)	Reason:	
300.0 Milligram		
Batch:	Started:	Stopped:
ARTANE (Other drug)	Reason:	
2.0 Milligram		
Batch:	Started:	Stopped:
TEMAZEPAM (Other drug)	Reason:	
10.0 Milligram		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Since 1995, the patient had been previously hospitalised several times for psychosis, generally related to medication non-compliance. She was suffering from elevated blood pressure, type II diabetes and borderline personality with mild intellectual disability.
 One week prior to admission the patient was using phentermine resin and herbalife for weight loss and the patient said phentermine resin "makes me feel good".



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200034	Seq: 1	Gender: F
Reported: 23/06/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 37
Onset Date: 03/06/2004		DOB: 09/04/1967
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Medicine Details:

DUROMINE (Other drug)	Reason: Obesity othr than endoc origin	
Batch:	Started:	Stopped:
DIAFORMIN (Other drug)	Reason: Diabetes mellitus	
	1.0 Gram	Daily
Batch:	Started:	Stopped:
SOLIAN (Suspected)	Reason:	
	400.0 Milligram	Daily
Batch:	Started: 01/06/2004	Stopped: 09/06/2004

Laboratory Investigations:

Additional Information:

Since 1995, the patient had been previously hospitalised several times for psychosis, generally related to medication non-compliance. She was suffering from elevated blood pressure, type II diabetes and borderline personality with mild intellectual disability.
One week prior to admission the patient was using phentermine resin and herbalife for weight loss and the patient said phentermine resin " makes me feel good".



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200046

Seq: 1

Gender: F

Reported: 17/08/2004

Weight: 110.00

Hospitalisation:

Age: 39

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Profuse breast discharge-milky drenched at night-few drop during the day., menstration ceased 4 months ago.	
Amenorrhoea			

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 15/02/2002	Stopped:	
EDRONAX (Other drug)		Reason: Depression	
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started: 31/10/2002	Stopped:	
SOLIAN (Suspected)		Reason: Hallucinations	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 06/04/2004	Stopped: 10/08/2004	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200106	Seq: 1	Gender: M
Reported: 18/08/2004		Weight: 139.50
Hospitalisation:		Age: 40
Onset Date: 15/07/2004		DOB: 10/12/1963
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Required Visit to Doctor	Dystonia.	Ceased Solian.

Medicine Details:

CLOZAPINE (Other drug)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 01/10/1998 L TERM Stopped: 0
EPILIM E.C. 200 (Other drug)	Reason:
Tablet	1.0 Gram Daily Oral
Batch:	Started: L TERM Stopped: 0
NEXIUM (Other drug)	Reason: Other diseases of esophagus
Tablet	20.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
PANAMAX (Other drug)	Reason: Pain
Tablet	4.0 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Attempt to switch to Solain from Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200106

Seq: 1

Gender: M

Reported: 18/08/2004

Weight: 139.50

Hospitalisation:

Age: 40

Onset Date: 15/07/2004

DOB: 10/12/1963

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Additional Information:

Attempt to switch to Solain from Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200124
Reported: 18/08/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased Galactorrhoea Pituitary tumour benign Prolactinoma		Prolactinoma-Blood prolactin increased.	

Medicine Details:

Lexapro (Other drug)	Reason:
10.0 Milligram	
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Anxiety neurosis
50.0 Milligram	Daily
Batch:	Started: 01/03/2004 Stopped: 31/08/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/08/2004	Other data				MRI scan showed micro-prolactinoma.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200188	Seq: 1	Gender: M
Reported: 20/08/2004		Weight: 100.00
Hospitalisation:		Age: 26
Onset Date: 15/06/2004		DOB: 11/10/1977
Outcome: Recovered	11/08/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue	Life threatening	Seroquel making patient very tired and weak, only able to walk a few minutes before exhausted and unable to lift weights he previously could lift.	Seroquel dose reduced.
Asthenia	Life threatening		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram		
Batch:	Started:	Stopped:	
SEROQUEL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 08/10/2003	Stopped: 06/08/2004 0	
SOLIAN (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 08/10/2003	Stopped: 06/08/2004	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200414

Seq: 1

Gender: F

Reported: 30/08/2004

Weight: 114.00

Hospitalisation:

Age: 62

Onset Date: 03/07/2004

DOB: 03/04/1942

Outcome: Death, maybe drug

03/07/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Probable fatal cardiac arrythmia.	

Medicine Details:

TEMAZEPAM (Other drug)	Reason:	
10.0 Milligram	Daily	
Batch:	Started:	Stopped:
ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis	
Batch:	Started:	Stopped: 30/06/2004
SOLIAN (Suspected)	Reason: Unspecifid affective psychosis	
400.0 Milligram	Daily	
Batch:	Started: 03/02/2004	Stopped: 03/07/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200429	Seq: 1	Gender: F
Reported: 30/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 21
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Experienced hypotension which caused her to fall.	
Fall	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome, sweating, headache, stiff joints, atrial flutter, fever, fine tremor, rash.	Ceased Clozaril.
Atrial flutter	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/09/2004	Creatine	0-195	27/07/2004	655	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200605	Seq: 1	Gender: M
Reported: 07/09/2004		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 25/07/2004		DOB: 30/01/1965
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed shortness of breath, neuroleptic malignant syndrome and myocarditis. Electrocardiogram abnormal - not specified.	Antihypertensive drug nos.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
SEROQUEL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/09/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200605	Seq: 1	Gender: M
Reported: 07/09/2004		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 25/07/2004		DOB: 30/01/1965
Outcome: Unknown		Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Other drug)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: Stopped: 0
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
	800.0 Milligram Daily Oral
Batch:	Started: Stopped: 0
SEROQUEL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 200713
Reported: 10/09/2004

Seq: 1

Gender: U
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Patient experienced a gastrointestinal haemorrhage.	

Medicine Details:

SOLIAN (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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201358

Seq: 1

Gender: M

Reported: 29/09/2004

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 15/08/2004

DOB: 22/07/1955

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyuria Diabetes mellitus Drug ineffective Hyperglycaemia Polydipsia		Patient experienced polyuria, polydipsia, hyperglycaemia, drug ineffective and diabetes mellitus type 2.	Treated with Metformin and Gliclazide.

Medicine Details:

SOLIAN (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 15/09/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/09/2004	Serum glucose				BSL - 31.

Additional Information:

Patient stopped taking Solian 2/12 ago.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201407	Seq: 1	Gender: M
Reported: 01/10/2004		Weight: 105.00
Hospitalisation:		Age: 25
Onset Date: 25/09/2004		DOB: 22/07/1979
Outcome: Recovered	25/09/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration	Required Visit to Doctor	Oculogyric crisis with ongoing extra-pyramidal symptoms, cramps in feet, stiff muscles.	IM benztropine
Extrapyramidal disorder	Required Visit to Doctor		
Muscle spasms	Required Visit to Doctor		
Musculoskeletal stiffness	Required Visit to Doctor		

Medicine Details:

TEMAZEPAM (Other drug)	10.0 Milligram	Daily	Reason: Schizophrenia
Batch:	Started: 24/09/2004	Stopped:	
SOLIAN (Suspected)	800.0 Milligram	Daily	Reason: Schizophrenia
Batch:	Started: 24/09/2004	Stopped: 0	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201436	Seq: 1	Gender: F
Reported: 05/10/2004		Weight: 0.00
Hospitalisation:		Age: 69
Onset Date:		DOB: 28/06/1935
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema		Angioneurotic oedema, swollen tongue, dyspnoea, rash, headache, insomnia.	
Dyspnoea			
Headache			
Insomnia			
Rash			
Swollen tongue			

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201565	Seq: 1	Gender: F
Reported: 08/10/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 20Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonia, complete deviation of her face to the left with a locked jaw, respiratory rate increased, anxiety, intentional overdose, swollen tongue. Patients bowels had not opened for 1-2 days and he was also very clumsy with walking and he was unable to stand or sit.	Benzatropine 2mg.
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	8.0 Gram	Total	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/10/2004	Magnetic Resonance				<p>MRI BRAIN Report: The ventricles, cisterns and sulci are within normal limits. No focal cerebral, brain stem or cerebellar white matter lesions are demonstrated. Conclusion: No abnormality is demonstrated on MRI of the brain.</p> <p>MRI SPINE Report: There is moderate expansion of the cervical cord with moderate hyperintensity on T2 weighted sequences in the central two thirds of the cervical cord and also slight hyperintensity in the central thoracic cord ...</p>

Additional Information:

The 20-year-old female patient consumed alcohol, possibly smoked cannabis and tried to suicide by taking 20 x 400 mg tablets, ie 8 g of Amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201565	Seq: 1	Gender: F
Reported: 08/10/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 20Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation		
Respiratory rate increased	Caused or prolonged inpatient hospitalisation		
Swollen tongue	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	8.0 Gram	Total	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/10/2004	Other data				<p>... extending to the level of T9. The above findings are in keeping with extensive cervical cord. In view of the history this probably represent ADEM of the cord post vaccination.</p> <p>Patient had normal tone and power in his upper limbs with brisk reflexes bilaterally and a normal sensory level. His lower limbs showed equivocal tone and reduced power in all groups bilaterally. his reflexes were brisk and he had no clonus. He had bilateral up going plantar reflexes.</p>

Additional Information:

The 20-year-old female patient consumed alcohol, possibly smoked cannabis and tried to suicide by taking 20 x 400 mg tablets, ie 8 g of Amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201638	Seq: 1	Gender: M
Reported: 11/10/2004		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 15/08/2004		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient developed involuntary leg movements for the past few months which gradually worsened. Patient also experienced convulsion and episode of sweating in the chest area.	Amisulpride ceased.
Dyskinesia			
Hyperhidrosis			

Medicine Details:

CLOPIXOL (Interaction)	Reason: Unspecified psychosis
Batch:	Started:
Stopped:	
STELAZINE (Interaction)	Reason:
	Oral
Batch:	Started:
Stopped:	
SOLIAN (Interaction)	Reason: Depression
Tablet	Daily
	Oral
Batch:	Started:
Stopped:	25/09/2004 0
PARACETAMOL (Other drug)	Reason:
	Oral
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201895	Seq: 1	Gender: M
Reported: 21/10/2004		Weight: 72.00
Hospitalisation:		Age: 75
Onset Date: 27/09/2004		DOB: 19/02/1929
Outcome: Recovered	06/10/2004	Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 201895

Seq: 1

Gender: M

Reported: 21/10/2004

Weight: 72.00

Hospitalisation:

Age: 75

Onset Date: 27/09/2004

DOB: 19/02/1929

Outcome: Recovered

06/10/2004

Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 202017	Seq: 1	Gender: F
Reported: 26/10/2004		Weight: 0.00
Hospitalisation:		Age: 17
Onset Date: 10/09/2004		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydactyly		On 10 September 2004 the mother vaginally delivered a full term infant at approximately 40 weeks gestation. The infant was born with an extra digit. There is no corrective treatment planned and the infant is otherwise healthy. The mother is healthy and had no delivery complications.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Batch:	Oral
Started:	Stopped:
CANNABIS PREPARATION (Suspected)	Reason:
Batch:	
Started:	Stopped:
AMISULPRIDE (Suspected)	Reason:
Batch:	Oral
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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 202038

Seq: 1

Gender: M

Reported: 26/10/2004

Weight: 115.00

Hospitalisation:

Age: 41

Onset Date: 08/10/2004

DOB: 16/03/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Required Visit to Doctor	Patient experienced a acute dystonic reaction.	Cogentin given.

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	Milligram	Daily	Oral
Batch:	Started: 05/10/2004	Stopped: 08/10/2004	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 202207 **Seq:** 1 **Gender:** F
Reported: 01/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 15/06/2004 **DOB:** 18/05/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Patient experienced hair loss.	No treatment given.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 0
SODIUM VALPROATE (Other drug)	Reason: Unspecified schizophrenia
Tablet	1.0 Gram Daily Oral
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
	200.0 Milligram Daily Oral
Batch:	Started: 30/04/2004 Stopped: Ongoing

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 202390

Seq: 1

Gender: F

Reported: 09/11/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Patient experienced QT prolonged.	

Medicine Details:

SOLIAN (Suspected)	Reason:		
Batch:	Started:	Stopped:	0
		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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 202418

Seq: 1

Gender: M

Reported: 09/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Overdose.	

Medicine Details:

SOLIAN (Suspected)	Reason:
800.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Serum drug level				Amisulpride blood level at 5.6mg/l.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203049

Seq: 1

Gender: M

Reported: 25/11/2004

Weight: 80.00

Hospitalisation:

Age: 30

Onset Date: 07/09/2004

DOB: 10/09/1973

Outcome: Recovered

15/10/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Oro-facial involuntary dyskinesic movements.	
Dyskinesia			

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 24/06/2004	Stopped: 07/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

movements occurred when dose increased and stopped when dose decreased to 800mg/daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203119

Seq: 1

Gender: F

Reported: 29/11/2004

Weight: 51.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 07/05/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Patient experienced amenorrhea and galactorrhea.	Switched to Olanzapine and then Abilify.
Galactorrhea			

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started: 01/05/2004 Stopped: 08/07/2004 0
HALOPERIDOL (Other drug)	Reason:
Batch:	Started: 01/08/2004 Stopped: 0
ALPRAZOLAM (Other drug)	Reason:
Batch:	Started: 01/05/2004 Stopped: 15/05/2004 0
AMISULPRIDE (Suspected)	Reason:
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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203119 **Seq:** 1

Gender: F

Reported: 29/11/2004

Weight: 51.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 07/05/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

EFEXOR-XR (Suspected)	Reason: Depression
Capsule, modified release	75.0 Milligram Daily Oral
Batch:	Started: 07/01/2004 Stopped: Contin

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203160 **Seq:** 1 **Gender:** F
Reported: 01/12/2004 **Weight:**
Hospitalisation: **Age:** 67
Onset Date: 12/11/2004 **DOB:** 16/09/1937
Outcome: Recovered 16/11/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Diagnosed as NMS	Clopine ceased.
Cellulitis		The patient developed cellulitis and associated elevated temperatures.	Clopine ceased.
Pyrexia			

Medicine Details:

CLOPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 25/10/2004	Stopped: 12/11/2004	
AMISULPRIDE (Suspected)		Reason: Unspecified psychosis	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 27/08/2004	Stopped: 12/11/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2004	Creatine				2879
01/12/2004	Neutrophils		08/11/2004	4.6	
01/12/2004	Other data				Serum myoglobin: 1146
01/12/2004	Other data				Temperature: 40
01/12/2004	White blood cells		08/11/2004	6.14	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203166	Seq: 1	Gender: M
Reported: 01/12/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 41
Onset Date: 09/11/2004		DOB: 03/06/1963
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient experienced delirium, exacerbation of psychotic symptoms, tachycardia, hypertension, raised CK levels, leucocytosis and neutrophilia.	Clozaril ceased.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
SOMAC (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 16/12/1994 Stopped: 14/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2004	Creatine	<200	09/11/2004	665	
01/12/2004	Creatine	<200	10/11/2004	1920	
01/12/2004	White blood cells		16/02/1994	11.2	
01/12/2004	White blood cells		09/11/2004	18.40	

Additional Information:



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203166 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 09/11/2004 **DOB:** 03/06/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Batch:	600.0 Milligram Daily
Started: 01/09/2004	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203187	Seq: 1	Gender: F
Reported: 01/12/2004		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vasculitic rash		Patient experienced a vasculitis-type rash and an ankle oedema.	Referred to a dermatologist.
Oedema peripheral			

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 203866	Seq: 1	Gender: F
Reported: 04/01/2005		Weight: 0.00
Hospitalisation:		Age: 49
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient developed tardive dyskinesia.	Solian discontinued.

Medicine Details:

SOLIAN (Suspected)	Reason: Schizo-affective type psychos
1.0 Gram	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204112 **Seq:** 1 **Gender:** M
Reported: 11/01/2005 **Weight:** 90.00
Hospitalisation: **Age:** 41
Onset Date: 08/12/2004 **DOB:**
Outcome: Recovered 15/12/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations	Required Visit to Doctor	The patient had palpitations, was sweaty and confused after being changed from Solian to Abilify, therefore some co-administration and could be a drug-drug interaction.	
Confusional state	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		

Medicine Details:

Abilify (Interaction)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 10/12/2004	
SOLIAN (Interaction)		Reason:	
	400.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2004	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204194
Reported: 13/01/2005
Hospitalisation:
Onset Date: 22/12/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 19
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nuchal rigidity Extrapyramidal disorder Neck pain Salivary hypersecretion		The patient experienced neck rigidity and pain, hypersalivation and spasm of T-M joint - extrapyramidal disorder.	Benzotropine 2mg IM.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
600.0 Milligram	Daily Oral
Batch:	Started: 21/12/2004 Stopped: 22/12/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204253	Seq: 1	Gender: M
Reported: 14/01/2005		Weight: 80.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date:		DOB: 11/09/1975
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	The patient experienced cardiomyopathy requiring heart transplant urgently. Ejection fraction about 20%	ICU admission, Solian ceased. Antibiotics and possible heart transplant. Perindopril and carvedilol on discharge
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Cardiac failure	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)		Reason: Depression	
Capsule	300.0 Milligram	Oral	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	400.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
OLANZAPINE (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Creatine				peaked at 343
14/01/2005	Other data	cardiac			dilated left ventricle of 78mm (normal 56mm)with severely depressed systolic function, estimated ejection fraction of <20% and mild mitral regurgitation.
14/01/2005	White blood cells				23.3 on day 3

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulias V, banna E, Cohen P, gary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204253 **Seq:** 1 **Gender:** M
Reported: 14/01/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 11/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)	Reason: Depression
Capsule 300.0 Milligram Oral	
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
400.0 Milligram Daily Oral	
Batch:	Started: S TERM Stopped: 0
OLANZAPINE (Suspected)	Reason:
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 0

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulias V, banna E, Cohen P, gary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204253 **Seq:** 1 **Gender:** M
Reported: 14/01/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 11/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

EFEXOR-XR (Other drug)	Reason: Depression
Capsule 300.0 Milligram Oral	
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
400.0 Milligram Daily Oral	
Batch:	Started: S TERM Stopped: 0
OLANZAPINE (Suspected)	Reason:
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 0

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulias V, banna E, Cohen P, gary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204323 **Seq:** 1 **Gender:** M
Reported: 18/01/2005 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 16
Onset Date: 24/01/2004 **DOB:** 23/07/1987
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonic reaction, oculogyric crisis and spasms of the leg, back and facial muscles.	Benztropine 2mg IM then oral 2mg bd.
Muscle spasms	Caused or prolonged inpatient hospitalisation		
Oculogyration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected)	Reason: Depression		
Batch:	Started:	Stopped:	Oral
SOLIAN (Suspected)	Reason: Depression		
Batch:	Started:	Stopped:	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/01/2005	Electrocardiograph				ECG: QTC borderline 0.42, otherwise normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 204818	Seq: 1	Gender: M
Reported: 02/02/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 53
Onset Date: 12/08/2004		DOB: 18/11/1950
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus bradycardia	Caused or prolonged inpatient hospitalisation	Sinus bradycardia and intermittant sinus arrest.	Cessation of suspected offending agents.
Sinus arrest	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZE (Other drug)	Reason:
10.0 Milligram	
Batch:	Started: 29/07/2004 Stopped:
DIAZEPAM (Other drug)	Reason:
	Oral
Batch:	Started: 29/07/2004 Stopped:
ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	20.0 Milligram Daily Oral
Batch:	Started: 28/07/2004 Stopped: 11/08/2004
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 20/08/2004

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 205195
Reported: 11/02/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 16
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred		The patient experienced blurred vision for 2-3 months while taking Amisulpride.	

Medicine Details:

DIAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 205392 **Seq:** 1 **Gender:** M
Reported: 17/02/2005 **Weight:** 57.00
Hospitalisation: Admitted to hospital **Age:** 58
Onset Date: **DOB:** 29/08/1946
Outcome: Recovered 13/01/2005 **Causality:** Causality probable

Reaction Details:

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

Medicine Details:

NORVASC (Other drug)	Reason: Essential benign hypertension
10.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
DUCENE (Other drug)	Reason: Anxiety neurosis
4.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARTIA (Other drug)	Reason: Acute, ill-def cerebrovascular disease w/o hyperten
100.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
Mirtazon (Other drug)	Reason: Depression
60.0 Milligram Daily	
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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 205392 **Seq:** 1 **Gender:** M
Reported: 17/02/2005 **Weight:** 57.00
Hospitalisation: Admitted to hospital **Age:** 58
Onset Date: **DOB:** 29/08/1946
Outcome: Recovered 13/01/2005 **Causality:** Causality probable

Reaction Details:

Medicine Details:

QUITX STEP 2 NICOTINE PATCHES 14MG (Other drug)	Reason: Smoker
14.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral	
Batch:	Started: L TERM Stopped: 09/01/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 205432

Seq: 1

Gender: U

Reported: 22/02/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient developed a tardive dyskinesia.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 205918	Seq: 1	Gender: M
Reported: 10/03/2005		Weight: 120.00
Hospitalisation: Required a visit to the doctor		Age: 50
Onset Date:		DOB: 21/09/1954
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	When the patient switched from Olanzapine to Amisulpride he had a hypomanic episode.	Ceased Solian and resumed Zyprexa.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason:	
	600.0 Milligram	Daily	Oral
Batch:	Started: 15/09/2004		Stopped: 15/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has schizoaffective illness with residual symptoms of chronic condition.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206113

Seq: 1

Gender: M

Reported: 16/03/2005

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 12/03/2005

DOB: 07/12/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting			Ceased medication

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 11/03/2005 Stopped: 15/03/2005

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206273

Seq: 1

Gender: F

Reported: 24/03/2005

Weight: 0.00

Hospitalisation:

Age: 12

Onset Date: 15/02/2005

DOB: 17/08/1992

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		ECG showed QTc prolongation. Refer to CIOMS report attached as supporting document.	

Medicine Details:

SOLIAN (Suspected)	Reason:
50.0 Milligram	Oral
Batch:	Started: 15/02/2005
	Stopped: 22/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A rechallenge was performed about 1 month later and reaction did not occur



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206365 **Seq:** 1 **Gender:** U
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	The patient recently 'decided to jump off a friend's balcony' in a suicide attempt.	Recovering in hospital.

Medicine Details:

EDRONAX (Suspected)	Reason: Unspecified schizophrenia
Tablet 16.0 Milligram Daily Oral	
Batch:	Started: Stopped:
SODIUM VALPROATE (Suspected)	Reason:
Tablet 2.0 Gram Daily Oral	
Batch:	Started: Stopped:
AMISULPRIDE (Suspected)	Reason:
Tablet 800.0 Milligram Daily Oral	
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Suspected)	Reason:
Tablet 2.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206378 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: 07/03/2005 **DOB:** 06/11/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Subarachnoid haemorrhage	Life threatening	The patient experienced subarachnoid haemorrhage during therapy with Amisulpride.	

Medicine Details:

CLOZAPINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason:		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/03/2005	Radiology				aneurysm of right anterior cerebral artery

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206904
Reported: 11/04/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2003
Outcome: Unknown

Age: 24
DOB: 22/02/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Amenorrhoea Dysmenorrhoea Hyperprolactinaemia Oligomenorrhoea		Patient experienced galactorrhoea in 03/2003, oligomenorrhoea in 12/2003, amenorrhoea in 2004 and hyperprolactinaemia in 12/2004.	

Medicine Details:

CLOZARIL (Interaction) Tablet Batch:	Reason: Unspecified schizophrenia Oral Started: 23/01/2003 Stopped:
SOLIAN (Interaction) 800.0 Milligram Batch:	Reason: Oral Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2005	Prolactin				(Mar 2005) Prolactin: >3000 (units not specified).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 206911

Seq: 1

Gender: U

Reported: 12/04/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pituitary tumour			Cabergoline - but no response

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 207062 **Seq:** 1 **Gender:** M
Reported: 14/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 15/10/2004 **DOB:** 27/01/1965
Outcome: Death, maybe drug 02/04/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Diffuse large cell lymphoma. The patient died from lymphoma whilst on Clopine treatment.	
Angiocentric lymphoma	Death		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 30/04/2004 Stopped: 02/04/2005 0
FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
	20.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 0
AMISULPRIDE (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 30/10/2002 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 207958

Seq: 1

Gender: M

Reported: 18/05/2005

Weight: 75.00

Hospitalisation:

Age: 46

Onset Date: 01/05/2005

DOB: 18/08/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Incapacity/disability	Patient described Parkinsonian stiffness, with hypertonicity and cogwheel tremor, in all limbs.	Cessation of amisulpride

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Tablet	400.0 Milligram 2 times Oral
Batch:	Started: 01/04/2005 Stopped: 15/05/2005

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208063

Seq: 1

Gender: U

Reported: 20/05/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		The patient, who had been treated with Solian, experienced prolonged QT.	

Medicine Details:

AMPHOTERICIN (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason:		
	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At the time of the event, the patient was also commenced on amphotericin, and had low potassium. Interpretation of the QT interval may have been affected by the presence of U waves



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208261 **Seq:** 1 **Gender:** F
Reported: 30/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colitis ulcerative	Caused or prolonged inpatient hospitalisation	The patient experienced ulcerative colitis.	

Medicine Details:

SOLIAN (Suspected)	Reason:
1.0 Gram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208835	Seq: 1	Gender: M
Reported: 21/06/2005		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 20/05/2005		DOB: 06/04/1980
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		The patient experienced tachycardia (138 bpm), a low grade temperature (38.8 degrees C) and postural hypotension (83/50) approximately 3.5 weeks after commencing Clozaril.	Clozaril dose reduced to 200mg daily.
Neutropenia			
Orthostatic hypotension			
Pyrexia			

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 11/05/2005 Stopped: 14/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Blood pressure		11/05/2005	(sitting): 120/70	
21/06/2005	Blood pressure		13/05/2005	(sitting): 83/50	
21/06/2005	Blood pressure		27/05/2005	(sitting): 120/70	
21/06/2005	Blood pressure		02/07/2005	(sitting): 120/70	
21/06/2005	Neutrophils		14/06/2005	1.39	
21/06/2005	Neutrophils		15/06/2005	1.63	
21/06/2005	Neutrophils		20/06/2005	3.53	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208835
Reported: 21/06/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/05/2005
Outcome: Unknown

Age: 25
DOB: 06/04/1980
Causality: Causality probable

Reaction Details:

Medicine Details:

AMISULPRIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 11/05/2005	Stopped: 14/06/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Neutrophils		16/06/2005	2	
21/06/2005	Other data		11/05/2005	4	Pulse rate
21/06/2005	Other data		13/05/2005	111	Pulse rate
21/06/2005	Other data		27/05/2005	112	Pulse rate
21/06/2005	Other data		02/07/2005	100	Pulse rate
21/06/2005	Other data		11/05/2005	35.8 degrees	Body temperature
21/06/2005	Other data		13/05/2005	35.4 degrees	Body temperature

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208835
Reported: 21/06/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/05/2005
Outcome: Unknown

Age: 25
DOB: 06/04/1980
Causality: Causality probable

Reaction Details:

Medicine Details:

AMISULPRIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 11/05/2005	Stopped: 14/06/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Other data		27/05/2005	38.8 degrees	Body temperature
21/06/2005	Other data		02/07/2005	37.2 degrees	Body temperature

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208880	Seq: 1	Gender: M
Reported: 21/06/2005		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 31/05/2005		DOB: 18/01/1984
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis, decreased white blood cell count, neutrophil count and therapy regimen changed - Amisulpride increased from 200mg to 400mg.	Clozaril discontinued. Currently in haemtology ward for G-CVF and given IV antibiotics.
Leukopenia			
Neutropenia			
Therapy regimen changed			

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
HALOPERIDOL (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 08/09/2003
	Stopped: 31/05/2005
AMISULPRIDE (Suspected)	Reason:
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Neutrophils		31/05/2005	0.39	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10 ⁹ /L
21/06/2005	Neutrophils		31/05/2005	0.41	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10 ⁹ /L
21/06/2005	Neutrophils		01/06/2005	0.26	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10 ⁹ /L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208880

Seq: 1

Gender: M

Reported: 21/06/2005

Weight: 0.00

Hospitalisation:

Onset Date: 31/05/2005

Age: 21

DOB: 18/01/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped: 31/05/2005	
AMISULPRIDE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Neutrophils		03/06/2005	0.01	(08 Sep 2003-pre treatment) Neutrophil Cell Count $4.3 \times 10^9/L$
21/06/2005	Neutrophils		05/06/2005	0.00	(08 Sep 2003-pre treatment) Neutrophil Cell Count $4.3 \times 10^9/L$
21/06/2005	Neutrophils		04/06/2005	0.01	(08 Sep 2003-pre treatment) Neutrophil Cell Count $4.3 \times 10^9/L$

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208880 **Seq:** 1
Reported: 21/06/2005

Gender: M
Weight: 0.00
Age: 21
DOB: 18/01/1984
Causality: Causality possible

Hospitalisation:

Onset Date: 31/05/2005
Outcome: Not yet recovered

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped: 31/05/2005	
AMISULPRIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	Neutrophils		02/06/2005	0.02	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10 ⁹ /L
21/06/2005	White blood cells		31/05/2005	1.90	(08 Sep 2003- pre treatment) White Blood Cell count 7 x 10 ⁹ /L.
21/06/2005	White blood cells		31/05/2005	2.00	(08 Sep 2003- pre treatment) White Blood Cell count 7 x 10 ⁹ /L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208880

Seq: 1

Gender: M

Reported: 21/06/2005

Weight: 0.00

Hospitalisation:

Onset Date: 31/05/2005

Age: 21

Outcome: Not yet recovered

DOB: 18/01/1984

Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped: 31/05/2005	
AMISULPRIDE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	White blood cells		01/06/2005	2.00	(08 Sep 2003- pre treatment) White Blood Cell count $7 \times 10^9/L$.
21/06/2005	White blood cells		02/06/2005	1.00	(08 Sep 2003- pre treatment) White Blood Cell count $7 \times 10^9/L$.
21/06/2005	White blood cells		03/06/2005	0.3	(08 Sep 2003- pre treatment) White Blood Cell count $7 \times 10^9/L$.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 208880 **Seq:** 1

Gender: M

Reported: 21/06/2005

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 31/05/2005

DOB: 18/01/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped: 31/05/2005	
AMISULPRIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	White blood cells		04/06/2005	0.5	(08 Sep 2003- pre treatment) White Blood Cell count $7 \times 10^9/L$.
21/06/2005	White blood cells		05/06/2005	0.5	(08 Sep 2003- pre treatment) White Blood Cell count $7 \times 10^9/L$.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 209482 **Seq:** 1 **Gender:** M
Reported: 05/07/2005 **Weight:** 105.00
Hospitalisation: Required a visit to the doctor **Age:** 50
Onset Date: 01/04/2005 **DOB:** 13/08/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient experienced tardive dyskinesia and weight gain. He gained 16kg over 18 months - from 90kg to 106kg.	
Weight increased			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
800.0 Milligram	Daily
Oral	
Batch:	Started: 15/02/2004
	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 209774	Seq: 1	Gender: M
Reported: 12/07/2005		Weight: 85.00
Hospitalisation:		Age: 34
Onset Date: 31/05/2005		DOB: 16/03/1971
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Incapacity/disability	Jaw held open, neck sl extended looks like oculogyric type reaction although eye movement was okay He has been on Solian for some years but has lost 20kg weight	benztropine
Weight decreased	Incapacity/disability		

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	400.0 Milligram 2 times 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 209811
Reported: 13/07/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 27/05/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		The patient experienced hypertension and possible drug interaction whilst on Clopine treatment. Patient presented with high blood pressure of (140/105). Baseline blood pressure was (140/70).	

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason:	
Batch:	Started:	Stopped:
AMISULPRIDE (Suspected)	Reason:	Oral
Batch:	Started:	Stopped:
CLOPINE (Suspected)	Reason:	Oral
Tablet	50.0 Milligram	Daily
Batch:	Started: 08/06/2004	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 210546

Seq: 1

Gender: F

Reported: 09/08/2005

Weight: 0.00

Hospitalisation:

Onset Date: 15/06/2005

Age: 99U

Outcome: Recovered

DOB:

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Amenorrhoea Blood prolactin increased		Patient experienced galactorrhea, amenorrhoea, increased prolactin levels.	Ceased Solian.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason: Unspecified schizophrenia
900.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
OROXINE (Other drug)	Reason: Myxedema
50.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 23/05/2005 Stopped: 15/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 210941

Seq: 1

Gender: F

Reported: 19/08/2005

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date: 25/07/2005

DOB: 30/05/1989

Outcome: Recovered

15/08/2005

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Caused or prolonged inpatient hospitalisation	Raised serum prolactin level: 2300 mU/L. Previous serum prolactin level on 20/07/2005: 200mU/L	Solian was ceased

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	100.0 Milligram 3 times Oral
Batch:	Started: 18/07/2005 Stopped: 27/07/2005

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 211240
Reported: 31/08/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 25/07/2005
Outcome: Recovered

Age: 16
DOB: 30/05/1989
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Caused or prolonged inpatient hospitalisation	Raised serum prolactin level - 2300mU/L. Baseline serum prolactin level - 200mU/L. Normal serum prolactin level - < 420mU/L.	Solian was ceased.

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	100.0 Milligram	3 times	Oral
Batch:	Started: 18/07/2005	Stopped:	27/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/08/2005	Other data				Follow up serum prolactin levels were - 11/08/2005: 810mU/L, 15/08/2005: 470mU/L, 22/08/2005: 1100mU/L, 29/08/2005: 330mU/L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 211824

Seq: 1

Gender: M

Reported: 21/09/2005

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 09/09/2005

DOB: 15/05/1986

Outcome: Recovered

10/09/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Patient experienced leg cramps and dystonia.	Treated with Beztropine 2mg IMI.
Dystonia			

Medicine Details:

VALIUM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason: Depression		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 09/10/2004	Stopped: 10/10/2004	

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 212075

Seq: 1

Gender: M

Reported: 29/09/2005

Weight: 0.00

Hospitalisation:

Onset Date: 28/03/2005

Age: 69

Outcome: Recovered

DOB: 10/04/1935

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Rapid titration of Amisulpride 50 mg bd to 100 mg bd after 4 days, then 200 mg bd after 2 days, led to severe diarrhoea.	Amisulpride ceased.
Therapy regimen changed			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:	
Batch:	Started:	Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus	
Batch:	Started:	Stopped:
MICARDIS (Other drug)	Reason: Essential benign hypertension	
Batch:	Started:	Stopped:
TETRABENAZINE (Other drug)	Reason: Disturbance of coordination	
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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 212075

Seq: 1

Gender: M

Reported: 29/09/2005

Weight: 0.00

Hospitalisation:

Age: 69

Onset Date: 28/03/2005

DOB: 10/04/1935

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
400.0 Milligram	Daily
Oral	
Batch:	Started: 17/03/2005
	Stopped: 23/03/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 212457 **Seq:** 1 **Gender:** F
Reported: 12/10/2005 **Weight:** 0.00
Hospitalisation: Required a specialist consultation **Age:** 35
Onset Date: **DOB:** 25/11/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Incapacity/disability	The patient has a coarse tremor and ataxia.	Amisulpride ceased temporarily. Will recommence with dose kept below 600mg.
Coordination abnormal	Incapacity/disability		

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified neurosis
Tablet	1.2 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 212646	Seq: 1	Gender: F
Reported: 17/10/2005		Weight: 90.00
Hospitalisation:		Age: 30
Onset Date: 14/04/2004		DOB: 09/01/1974
Outcome: Recovered		Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema	Incapacity/disability	After initial and first evening dose patient experienced swelling of the toungue and an increase in difficulty in breathing. She was referred to A & E Dept. of Queanbeyn Hospital and admitted overnight with appropriate treatment. Discharged 15/04/2004	Given IMI/IV Phenergen plus Hydrocortisone IV plus Prednisolone oral as well as Ventolin 2 puffs; Responded well reported safe after 2-3hours.
Dyspnoea	Incapacity/disability		

Medicine Details:

SOLIAN (Suspected)	Reason:
Batch:	Started:
Stopped:	
SOLIAN (Suspected)	Reason:
Capsule	400.0 Milligram
1 time	Oral
Batch: ?	Started: 14/04/2004
Stopped: 14/04/2004	
SOLIAN (Suspected)	Reason:
Capsule	400.0 Milligram
1 time	Oral
Batch: ?	Started: 14/04/2004
Stopped: 14/04/2004	0
SOLIAN (Suspected)	Reason:
Capsule	400.0 Milligram
1 time	Oral
Batch: ?	Started: 14/04/2004
Stopped: 14/04/2004	0

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 213117

Seq: 1

Gender: F

Reported: 04/11/2005

Weight: 0.00

Hospitalisation:

Onset Date: 18/10/2005

Age: 38Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Caused or prolonged inpatient hospitalisation	The patient was lactating.	Amisulpride dose reduced.

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
CLONAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:
LACTULOSE (Other drug)	Reason:	
Batch:	Started:	Stopped:
SODIUM VALPROATE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/11/2005	Prolactin			4700	

Additional Information:

Patient also taking Parachoc.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 213117 **Seq:** 1

Gender: F

Reported: 04/11/2005

Weight: 0.00

Hospitalisation:

Age: 38Y

Onset Date: 18/10/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason:
Batch:	Started: Stopped:
ASCORBIC ACID (Other drug)	Reason:
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason:
	800.0 Milligram Daily Oral
Batch:	Started: 08/10/2005 Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Patient also taking Parachoc.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 213123 **Seq:** 1 **Gender:** U
Reported: 04/11/2005 **Weight:** 91.00
Hospitalisation: Required a visit to the doctor **Age:** 16
Onset Date: 15/03/2005 **DOB:** 01/01/1989
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain		The patient experienced a sore left breast with marked gynaecomastia.	
Gynaecomastia			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 15/04/2004 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 213725	Seq: 1	Gender: F
Reported: 23/11/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 48
Onset Date:		DOB: 02/05/1957
Outcome: Recovered	15/05/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colitis ulcerative	Caused or prolonged inpatient hospitalisation	Patient developed ulcerative colitis.	

Medicine Details:

COGENTIN (Other drug)	Reason:
Tablet	Milligram
Batch:	Started: 30/06/2004 Stopped: 10/06/2005
TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
	Milligram Daily
Batch:	Started: 15/05/2005 Stopped: 15/08/2005
CELEBREX (Suspected)	Reason:
Capsule	1.0 Dose Unspecified
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
	1.0 Gram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug taken: Oestroderm. History of schizophrenia sometimes with suicidal thoughts and sharp pain headaches with sleeping difficulty.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214662

Seq: 1

Gender: F

Reported: 06/01/2006

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 01/04/2005

DOB: 09/12/1955

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Incapacity/disability	The patient experienced arthralgia whilst being treated with Amisulpride. She had painful joints - elbows, hips and knees. The reaction recurred on rechallenge.	Solian ceased, then re-introduced.

Medicine Details:

SOLIAN (Suspected)	Reason:
50.0 Milligram	Daily
Oral	
Batch:	Started: 15/03/2005
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214725

Seq: 1

Gender: F

Reported: 09/01/2006

Weight: 100.00

Hospitalisation:

Age: 23

Onset Date: 15/10/2004

DOB: 24/06/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Patient presented with 1 year amenorrhoea. Investigation revealed Prolactin increased.	Will use combined oral contraception pill to restore Citrogen and progestogen.
Blood prolactin increased			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:
Benztrop (Suspected)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2006	Magnetic				MRI shows no pituitary tumor.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214733	Seq: 1	Gender: F
Reported: 09/01/2006		Weight: 0.00
Hospitalisation: Required a visit to the doctor		Age: 60
Onset Date: 31/12/2005		DOB: 16/04/1945
Outcome: Recovered	11/09/2005	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness		The patient experienced muscle stiffness of all four limbs, progressing to painful nocturnal cramps of calves and feet for about three days. This was associated with restlessness. The stiffness and restlessness lasted approximately one week before the cramps.	Reduced Solian, restarted Olanzapine.
Muscle spasms			
Restlessness			

Medicine Details:

ZOLOFT (Other drug)	Reason:
100.0 Milligram	
Batch:	Started: 15/02/2000 Stopped:
LITHIUM CARBONATE (Other drug)	Reason: Unspecified schizophrenia
250.0 Milligram	Alternate days
Batch:	Started: L TERM Stopped:
QUILONUM SR (Other drug)	Reason: Unspecified schizophrenia
450.0 Milligram	Alternate days
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia
600.0 Milligram	Daily Oral
Batch:	Started: 26/08/2005 Stopped: 09/09/2005

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214905	Seq: 1	Gender: F
Reported: 12/01/2006		Weight: 87.00
Hospitalisation:		Age: 55
Onset Date: 17/02/2005		DOB: 26/11/1949
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient experienced flu-like symptoms of fever, clammy skin, shortness of breath, shivers, stiff neck and upper respiratory tract congestion. She had increased tone of upper limbs, cogwheel rigidity, decreased reflexes and diaphoresis. Her creatine kinase increased.	Amisulpride ceased. IV fluids given.
Blood creatine phosphokinase incr Cold sweat Dyspnoea Hyperhidrosis			

Medicine Details:

ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started:
Stopped:	
SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
Batch:	Started:
Stopped:	
FLUVOXAMINE MALEATE (Other drug)	Reason: Depression
Batch:	Started:
Stopped:	0
TRIMETHOPRIM (Other drug)	Reason: Othr diseases of urinary tract
Batch:	Started:
Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2006	Creatine				Creatine kinase - 1283.

Additional Information:

PMH: Schizophreniform disorder with somatic delusions, bipolar disorder, intellectual disability, anxiety/panic attacks & hypercholesterolaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214905
Reported: 12/01/2006

Seq: 1

Gender: F
Weight: 87.00

Hospitalisation:

Onset Date: 17/02/2005
Outcome: Recovered

Age: 55
DOB: 26/11/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia			
Hyporeflexia			
Influenza like illness			
Pyrexia			

Medicine Details:

MULTIVITAMINS (Other drug)	Reason:		
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Batch:	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia		
Batch:	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

PMH: Schizophreniform disorder with somatic delusions, bipolar disorder, intellectual disability, anxiety/panic attacks & hypercholesterolaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214915	Seq: 1	Gender: M
Reported: 12/01/2006		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 07/09/2005		DOB: 04/05/1957
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	The patient suffered general deterioration, incontinence of urine and faeces, feeling vague and tremor. He reported feeling unwell for the previous few days, had difficulty mobilising, was lethargic, febrile, had leg stiffness and SOBOE. He had a temperature of 39C, his white cell count was elevated and creatine kinase increased.	Ceased Amisulpride. Lorazepam given as muscle relaxant.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IRBESARTAN (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
COLCHICINE (Other drug)	Reason: Gout
Batch:	Started: Stopped: 0
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2006	C-Reactive Protein				CRP - 380.
12/01/2006	Creatine				Creatine Kinase - 1533.
12/01/2006	Creatinine				Baseline Cr - 0.185. Creatinine - 0.227.
12/01/2006	White blood cells				WCC - 19.9.

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214915	Seq: 1	Gender: M
Reported: 12/01/2006		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 07/09/2005		DOB: 04/05/1957
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IRBESARTAN (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
COLCHICINE (Other drug)	Reason: Gout
Batch:	Started: Stopped: 0
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214915	Seq: 1	Gender: M
Reported: 12/01/2006		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 07/09/2005		DOB: 04/05/1957
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

IRBESARTAN (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
COLCHICINE (Other drug)	Reason: Gout
Batch:	Started: Stopped: 0
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 214915	Seq: 1	Gender: M
Reported: 12/01/2006		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 07/09/2005		DOB: 04/05/1957
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		
Urinary incontinence	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IRBESARTAN (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
COLCHICINE (Other drug)	Reason: Gout
Batch:	Started: Stopped: 0
AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia
	400.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 215018

Seq: 1

Gender: F

Reported: 17/01/2006

Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2005

Age: 46

Outcome: Unknown

DOB: 24/07/1959

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
International normalised ratio incre		Patient developed increased INR while she was treated with Solian , she had also experienced unintentional weight loss.	
Weight decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 215271 **Seq:** 1 **Gender:** M
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 20
Onset Date: 31/10/2005 **DOB:** 10/10/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonian gait		The patient developed a stiff gait, decreased arm swing and cogwheeling.	Benztropine given with little effect. Solian ceased, changed to Olanzapine.
Cogwheel rigidity			

Medicine Details:

TEMAZE (Other drug)	Reason:	
10.0 Milligram	Oral	
Batch:	Started:	Stopped:
SOLIAN (Suspected)	Reason: Unspecified schizophrenia	
600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 03/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 215746	Seq: 1	Gender: F
Reported: 10/02/2006		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date: 15/06/2005		DOB: 01/03/1975
Outcome: Recovered	15/10/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Oculogyration	benztropine

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2005	Stopped:	15/01/2006
EFEXOR (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 215978	Seq: 1	Gender: M
Reported: 19/02/2006		Weight: 80.00
Hospitalisation:		Age: 27Y
Onset Date: 01/08/2005		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Caused or prolonged inpatient hospitalisation	episodic severe trunk muscle spasm, dystonic reaction	benztropine, IMI intially, then oral
Dystonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 216999 **Seq:** 1 **Gender:** F
Reported: 04/04/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 21
Onset Date: 07/02/2006 **DOB:** 15/07/1984
Outcome: Recovered 12/03/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus	Caused or prolonged inpatient hospitalisation	Itchiness to both lower legs.	

Medicine Details:

SOLIAN (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/02/2006	Stopped: 11/03/2006	0

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 217783

Seq: 1

Gender: F

Reported: 01/05/2006

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Life threatening	Breast cancer	Mastectomy, chemotherapy

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: 15/06/2002
	Stopped: 0
	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 217788 **Seq:** 1 **Gender:** F
Reported: 01/05/2006 **Weight:** 73.00
Hospitalisation: Required a visit to the doctor **Age:** 40
Onset Date: 25/12/2005 **DOB:** 17/05/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased Amenorrhoea Depression Galactorrhoea Libido decreased Weight increased		Patient developed galactorrhoea. Also has lassitude, depression, weight gain, decreased libido and amenorrhoea.	Referred to endocrinologist.

Medicine Details:

SOLIAN (Suspected)	Reason:
100.0 Milligram	Daily
Oral	
Batch:	Started: 15/04/2005 Stopped: 11/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/05/2006	Prolactin				Prolactin 2802.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 217796 **Seq:** 1 **Gender:** M
Reported: 01/05/2006 **Weight:** 63.00
Hospitalisation: Required a visit to the doctor **Age:** 19
Onset Date: 08/04/2006 **DOB:** 18/03/1987
Outcome: Recovered 08/04/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness		Patient was noted to be experiencing neck stiffness and tilting head to the right. Arms were reported as being stiff.	Benztropine.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis
800.0 Milligram	Daily
	Oral
Batch:	Started: 05/04/2006 Stopped: 09/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Complained that his eyes were being "pulled back", into his head.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 217991 **Seq:** 1 **Gender:** F
Reported: 04/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: **DOB:** 15/07/1984
Outcome: Recovered 17/03/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Rash and itchiness leading to skin abrasion.	
Pruritus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)	Reason:	
Tablet	400.0 Milligram	Oral
Batch:	Started: 07/02/2006	Stopped: 11/03/2006

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 218502

Seq: 1

Gender: F

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 02/05/2006

Age: 14

Outcome: Unknown

DOB: 17/12/1991

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Pateint developed galactorrhea.	

Medicine Details:

CABERGOLINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	0
TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
Aripiprazole (Other drug)	Reason: Unspecified psychosis		
Batch:	Started:	Stopped:	0
SEROQUEL (Other drug)	Reason:		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 218503 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 218502

Seq: 1

Gender: F

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 14

Onset Date: 02/05/2006

DOB: 17/12/1991

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

QUETIAPINE (Other drug)	Reason: Unspecified psychosis	
Batch:	Started:	Stopped:
FLUTICASONE PROPIONATE (Other drug)	Reason: Asthma	
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)	Reason:	
Batch:	Started:	Stopped:
AMISULPRIDE (Suspected)	Reason:	
Batch:	Started:	Stopped: Oral

Laboratory Investigations:

Additional Information:

Report 218503 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 218834

Seq: 1

Gender: M

Reported: 01/06/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		QT prolongation	

Medicine Details:

KETOCONAZOLE (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
QUETIAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	1200.0 Milligram	Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 219030 **Seq:** 1 **Gender:** M
Reported: 07/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 55
Onset Date: 15/12/2005 **DOB:** 25/06/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinson's disease		Parkinson's disease	

Medicine Details:

EFEXOR (Other drug)	Reason: Depression		
150.0 Milligram			
Batch:	Started:	Stopped:	
KALMA (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 15/04/2006	0

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 219203

Seq: 1

Gender: F

Reported: 19/06/2006

Weight: 73.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 17/08/1965

Outcome: Recovered

25/05/2006

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Presented with rash. Developed amenorrhoea and galactorrhoea.	Solian was ceased. Treatment changed to Risperdal.
Amenorrhoea			
Galactorrhoea			

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified schizophrenia
Tablet	20.0 Milligram Daily Oral
Batch:	Started: 15/10/2005 Stopped: 11/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/06/2006	Prolactin		26/04/2006	385	Protactin - 2802.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 219520	Seq: 1	Gender: F
Reported: 27/06/2006		Weight: 0.00
Hospitalisation:		Age: 24Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Patient experienced a recent onset of galactorrhea and her serum prolactin level was found to be very high.	Taken off Solian.
Hyperprolactinaemia			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason:
450.0 Milligram	
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Tablet 500.0 Milligram	Oral
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Depression
100.0 Milligram	
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2006	Magnetic Resonance				Brain MRI with suprasellar views was ordered in order to exclude a prolactinoma of the pituitary gland. This came back unremarkable.

Additional Information:

Report 219521 is the second sequence to this report 219524 is the third sequence and 219525 is the fourth sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 219521
Reported: 27/06/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 24Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bipolar disorder		Patient was taken off Solian and she developed clear cut hypomanic symptoms. This was no doubt due to the Solian inadvertently exerting some sort of anti-manic effect which turned out to be a likely bipolar 11 disorder.	Ceased Solian.
Drug withdrawal syndrome			
Hypomania			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason:
450.0 Milligram	
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: Stopped:
SOLIAN (Suspected)	Reason: Depression
100.0 Milligram	
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 219520 is the first sequence to this report 219524 is the third sequence and 219525 is the fourth sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 219877

Seq: 1

Gender: M

Reported: 11/07/2006

Weight: 0.00

Hospitalisation:

Age: 31Y

Onset Date: 06/07/2006

DOB:

Outcome: Recovered

10/07/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous	Caused or prolonged inpatient hospitalisation	Solid erythematous rash around ankles on ankles and erythematous plaques on anterior thighs.	Amisulpride ceased

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 23/06/2006	Stopped: 07/07/2006	0

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 220345	Seq: 1	Gender: M
Reported: 25/07/2006		Weight: 90.00
Hospitalisation: Required a visit to the doctor		Age: 24
Onset Date: 22/06/2006		DOB: 28/06/1981
Outcome: Recovered	28/06/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Nausea Vomiting		Patient developed rash maculopapular type rash, confluent in areas especially groin, over trunk and upper thighs (not on face). Quite raised wheal like lesions, spread to inner arms. Nausea and vomiting.	Stopped Solian, treated with Phenergan.

Medicine Details:

LORAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
Batch:	Started:
Stopped:	
EFEXOR-XR (Other drug)	Reason: Depression
Batch:	Started:
Stopped:	
Zolpidem Sandoz (Other drug)	Reason: Specific disorders of sleep
Batch:	Started:
Stopped:	
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 220345 **Seq:** 1 **Gender:** M
Reported: 25/07/2006 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 24
Onset Date: 22/06/2006 **DOB:** 28/06/1981
Outcome: Recovered 28/06/2006 **Causality:** Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SOLIAN (Suspected)	Reason:		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2006	Stopped: 22/06/2006	
CLOPIXOL-ACUPHASE (Suspected)	Reason:		
	3.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 221146	Seq: 1	Gender: F
Reported: 29/08/2006		Weight: 0.00
Hospitalisation:		Age: 36Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		Tongue and lip swelling diagnosed as allergic reaction.	
Lip swelling			

Medicine Details:

SOLIAN (Suspected)		Reason:	
Tablet	200.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 222082 **Seq:** 1 **Gender:** M
Reported: 29/09/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 06/06/2006 **DOB:** 09/06/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	Severe tremor and akathisia.	Amisulpride was being reduced.
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/09/2006	Other data				Clozaril level = 1200, CK: = 3000

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 222418

Seq: 1

Gender: F

Reported: 12/10/2006

Weight: 0.00

Hospitalisation:

Onset Date: 27/09/2006

Age: 51

Outcome: Unknown

DOB: 04/03/1955

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes	Commenced on Diaformin.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
AMISULPRIDE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 15/03/2004 Stopped: 0
LITHIUM CARBONATE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 15/09/2001 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 223304	Seq: 1	Gender: F
Reported: 17/11/2006		Weight: 0.00
Hospitalisation:		Age: 30Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Electrocardiogram QT prolonged, Increased QT interval.	
Electrocardiogram QT prolonged			

Medicine Details:

SOLIAN (Suspected)	Reason:
Batch:	Oral
Started:	Stopped: 0
EPILIM (Suspected)	Reason:
Batch:	Stopped:
EFEXOR (Suspected)	Reason:
Batch:	Oral
Started:	Stopped:
LAMICTAL (Suspected)	Reason: Unspecified psychosis
	50.0 Milligram Daily Oral
Batch:	Started: 01/06/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2006	QT interval				Increased QT interval.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225018 **Seq:** 1 **Gender:** F
Reported: 22/01/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 57
Onset Date: **DOB:** 10/06/1949
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Hairloss	ceased Amisulpiride.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225075
Reported: 24/01/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 07/08/2006
Outcome: Recovered

Age: 27
DOB: 28/04/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Caused or prolonged inpatient hospitalisation	Physically unwell, blurred vision, muscle stiffness, fall in bathtub, viral infection, under arm rash.	Amisulpride, anti-viral medication and antibiotics.
Fall	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Neutrophils		09/08/2006	1.50 x 10 ⁹ /L	
24/01/2007	Neutrophils		07/06/2007	3.10 x 10 ⁹ /L	
24/01/2007	White blood cells		11/08/2006	3.90 x 10 ⁹ /L	
24/01/2007	White blood cells		09/08/2006	2.90 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225075

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 07/08/2006

DOB: 28/04/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paranoia	Caused or prolonged inpatient hospitalisation		
Rash	Caused or prolonged inpatient hospitalisation		
Viral infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225161

Seq: 1

Gender: M

Reported: 29/01/2007

Weight: 90.00

Hospitalisation:

Age: 19

Onset Date: 02/01/2007

DOB: 27/03/1987

Outcome: Recovered

02/01/2007

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism	Caused or prolonged inpatient hospitalisation	Priapism	Required treatment in ED.

Medicine Details:

AMISULPRIDE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225382 **Seq:** 1 **Gender:** M
Reported: 02/02/2007 **Weight:** 95.00
Hospitalisation: Required a visit to the doctor **Age:** 21
Onset Date: 04/01/2007 **DOB:** 18/11/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Development of oro- buccal dyskinesia- low grade. Grade low- noticed by patient & girlfriend release phenoma present.	

Medicine Details:

RISPERIDONE (Suspected)	Reason:		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason:		
Batch:	Started:	Stopped: 0	
Abilify (Suspected)	Reason: Othr&unspec metabolic diseases		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past exposure to other antipsychotics-risperidone, amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225533 **Seq:** 1 **Gender:** M
Reported: 07/02/2007 **Weight:** 85.00
Hospitalisation: Required a visit to the doctor **Age:** 48
Onset Date: 02/11/2006 **DOB:** 23/06/1958
Outcome: Recovered 21/11/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral Erythema Pruritus		Patient had swollen lower legs with red itchy skin within a week of using Solian.	Drug ceased.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
1.5 Gram	Daily
Batch:	Started: L TERM Stopped:
SOLIAN (Suspected)	Reason: Unspecifid affective psychosis
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 02/11/2006 Stopped: 09/11/2006

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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 225645

Seq: 1

Gender: F

Reported: 08/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 29/07/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Amenorrhoea Blood prolactin increased Increased appetite		Weight gain (40kg in 4 months), prolactin increased, appetite increased, amenorrhoea.	

Medicine Details:

SOLIAN (Suspected)	Reason: Unspecified psychosis		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/02/2007	Magnetic				Pituitary gland enlarged on MRI.
08/02/2007	Prolactin	<300			Prolactin 3,000, normal

Additional Information:

Patient was started on 400mg Solian, then reduced to 200mg and then 100mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 226045	Seq: 1	Gender: U
Reported: 22/02/2007		Weight: 116.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 29/01/2007		DOB: 06/02/1984
Outcome: Death		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heat stroke	Life threatening	Heat stroke:Severe Heat stroke,leading to multi-organ failure with rhabdomyolysis, coagulopathy and hepatic dysfunction.	
Blood creatine phosphokinase incr	Life threatening		
Circulatory collapse	Life threatening		
Coagulopathy	Life threatening		
Hepatic function abnormal	Life threatening		

Medicine Details:

CLOZAPINE (Other drug)		Reason: No reason given	
Batch:	Started: 11/12/2001	Stopped: 10/01/2007	0
CLOPINE (Suspected)		Reason: No reason given	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2007	Stopped: 30/01/2007	0
EFEXOR-XR (Suspected)		Reason: No reason given	
Capsule	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2006	Stopped: 08/02/2007	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/02/2007	Creatine kinase				CK "very high"

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 226045	Seq: 1	Gender: U
Reported: 22/02/2007		Weight: 116.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 29/01/2007		DOB: 06/02/1984
Outcome: Death		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Life threatening		
Loss of consciousness	Life threatening		
Multi-organ failure	Life threatening		
Rhabdomyolysis	Life threatening		
Sepsis	Life threatening		

Medicine Details:

CLOZAPINE (Other drug)		Reason: No reason given
Batch:	Started: 11/12/2001	Stopped: 10/01/2007 0
CLOPINE (Suspected)		Reason: No reason given
Tablet	500.0 Milligram	Daily Oral
Batch:	Started: 10/01/2007	Stopped: 30/01/2007 0
EFEXOR-XR (Suspected)		Reason: No reason given
Capsule	225.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 0
SOLIAN (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 01/01/2006	Stopped: 08/02/2007 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 226551 **Seq:** 1 **Gender:** F
Reported: 13/03/2007 **Weight:** 71.00
Hospitalisation: Required a visit to the doctor **Age:** 36
Onset Date: 27/02/2007 **DOB:** 27/03/1970
Outcome: Recovered 27/02/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Choking Dyspnoea Laryngospasm Salivary hypersecretion		Patient experienced acute dystonic reaction and laryngospasm - choking, difficulty breathing, hypersalivating and thick tongue. Experienced 2 episodes in 4 hours.	Treated with benztropine, promethazine and salbutamol.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Depression	
225.0 Milligram	Daily	
Batch:	Started:	Stopped: 27/02/2007
SOLIAN (Suspected)	Reason: Unspecified psychosis	
800.0 Gram	Daily	Oral
Batch:	Started: 26/02/2007	Stopped: 27/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous accute dystonic reaction to amisulpride 09/06 suspected.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 226808

Seq: 1

Gender: F

Reported: 21/03/2007

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	30.0 Milligram
Batch:	Started:
	Stopped: 0
	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 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE,SOLIAN

Report Details:

Case Number: 226923	Seq: 1	Gender: M
Reported: 23/03/2007		Weight: 56.00
Hospitalisation: Admitted to hospital		Age: 13
Onset Date:		DOB: 24/01/1994
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		Patient started taking these drugs 2 years ago, have noticed consistently higher platelets.	Incidental finding, no treatment required. NB Solian (amisulpride induced higher prolactin level.)
Hyperprolactinaemia Platelet count increased			

Medicine Details:

SOLIAN (Suspected)	Reason:
400.0 Milligram	Daily
Batch:	Started: Stopped:
QUILONUM SR (Suspected)	Reason:
900.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2007	Platelets		31/03/2005	620	pt 175-415
23/03/2007	Platelets		15/04/2005	597	pt 175-415
23/03/2007	Platelets		06/07/2005	635	pt 175-415
23/03/2007	Platelets		18/08/2005	679	pt 175-415
23/03/2007	Platelets		21/11/2005	659	pt 175-415
23/03/2007	Prolactin		24/11/2006	984	(40-318)
23/03/2007	Prolactin		23/02/2007	677	(40-318)

Additional Information: