

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

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

Laboratory Investigations:

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Date	Туре	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 Reported: 17/06/2002 Hospitalisation: Admitted to hospi Onset Date: 06/06/2002 Outcome: Recovered Reaction Details:	Seq: 1			86.00
Medicine Details:				
SOLIAN (Suspected)	400.0 Milligram	Reason: Daily	Unspecified schizophrenia	
Batch:	Started: 09/05/2002	24,	Stopped: 06/06/200	2
Laboratory Investigations:				
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:
 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:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Breast enlargement			
	Breast pain			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	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.

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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: 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:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

R	(e	p	0	rt	D	e	ta	S	:

Gender: F Case Number: 177866 Seq: 1

Weight: 50.00 Reported: 08/08/2002 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

Daily

Batch: Started: 11/06/2002 Stopped: 25/07/2002

LAMICTAL (Suspected) Reason:

300.0 Milligram 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.

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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:
 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 schizophreni	a
	1.0 Gram	Daily	
Batch:	Started: 11/06/2002	Stopped: 25/07/200)2

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patients history - intellectual disability, aspergers syndrome.

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

Re	port	Deta	ails:
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 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:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	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

Re	po	rt	De	tai	ls:
	\sim		-	u	

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	Туре	Range	Date Tested	Result	Details

Additional Information:

Ecg normal when taken.

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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: 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
Fielened Teilii	Seventy	Report Description	Healineill
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	Туре	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.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 178996 Seq: 1 Gender: F Reported: 12/09/2002 Weight: spitalisation: Age: 30 Onset Date: 27/08/2002 DOB: 29/08/1971 Outcome: Recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment gitation hills Patient recovered 28/8/02. ceased seroquel. perhidrosis spomnia Patient recovered 28/8/02. ceased seroquel. Patient recovered 28/8/02. ceased seroquel. Seroquet (Suspected) Reason: Tablet 200.0 Milligram Daily Oral Batch: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Stopped: Started: Stopped: Stopped: Stopped: Stopped: Started: Stopped: Stop	Reported: 12/09/2002 pspitalisation: Onset Date: 27/08/2002 Outcome: Recovered paction Details: Preferred Term Severity Report Description gitation hills yperhidrosis psomnia Pacific Details: Preferred Term Preferred T	Age: 30 DOB: 29/08/1971 Causality: Causality possible Treatment Patient recovered 28/8/02.
onset Date: 27/08/2002 Outcome: Recovered action Details: Preferred Term Severity Report Description Treatment gitation hills Patient recovered 28/8/02. ceased seroquel. Patient recovered 28/8/02	Onset Date: 27/08/2002 Outcome: Recovered action Details: Preferred Term Severity Report Description gitation hills yperhidrosis asomnia Severity Report Description	Age: 30 DOB: 29/08/1971 Causality: Causality possible Treatment Patient recovered 28/8/02.
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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: 179322 Seq: 1 Gender: M

Reported: 23/09/2002 Weight: 71.00 Hospitalisation: Age: 69

Onset Date: 14/08/2002 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:		L TERM	Stopped:	
OMEPRAZOLE (Other drug)			Reason:	Other diseases of esophagus	
	20.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
SOLIAN (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	400.0	Milligram	Daily	Oral	
Batch:	Started: 07/	08/2002		Stopped: 26/08/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Reported: 25/09/2002 ospitalisation: Onset Date:				ender: F		
Onset Date:			Weight:			
				Age:		
				DOB:		
Outcome: Recovered			Caus	sality: Causality probable		
action Details:						
Preferred Term	Severity	Repo	ort Description	Treatment		
trapyramidal disorder						
omnolence				Was stared on solian 100mg then inceased to 200mg bd. dropped back to 100mg bd and increased weekly up to 600mg /day.		
edicine Details: IAZEPAM (Other drug)		Reas	son: Anxiety neurosis			
Oral application	5.0 Mi	lligram	As necessary Ora	al		
Batch:	Started: 04/07/	2002	Stopped:			
OLIAN (Suspected)		Reas	son:			
Tablet	400.0 Mi	lligram	Daily Ora	al		
Batch:	Started:		Stopped:			
	s:					
boratory Investigations Date Type F	Range Date Tested	Result		Details		



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

Re	po	rt	De	tai	ls:
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Case Number: 179410 Seq: 1 Gender: M

Reported: 26/09/2002 Weight: 80.00 Hospitalisation: Age: 26

Onset Date: DOB: 02/06/1976

Outcome: Recovered Causality: Causality possible

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	Sto	Stopped:		
ZOPICLONE (Suspected)		Reason:			
Tablet	105.0 Milligram	Total	Oral		
Batch:	Started: 17/07/2002	Sto	pped:		
CARBAMAZEPINE (Suspected)		Reason:			
Tablet	2.8 Gram	Total	Oral		
Batch:	Started: 17/07/2002	Sto	pped:		
MIRTAZAPINE (Suspected)		Reason:			
Tablet	210.0 Milligram	Total	Oral		
Batch:	Started:	Sto	pped:		

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: 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:

Cuotion 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 (Of	ther 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	Туре	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.

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

Report Details:	
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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		39.1 - 40.5 degrees celsius.	
Hemiparesis		Left sided weakness.	
Convulsion			
Dehydration			
Leukocytosis			
Respiratory disorder			
Tachycardia			
Urinary incontinence			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 (Otho	er 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	Туре	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

Re	po	rt	De	tai	ls:
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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:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			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	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 17 of 278



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

Panart Data	ilo					
Report Deta Case Numbe Reported		Seq: 1			Gender: F Weight:	
Hospitalisatior					Age : 28	
Onset Date			DOB : 01/09/1974			
	: Unknown			С	ausality: Causality probable	
eaction Det	ails: erred Term	Severity	Pon	ort Description	Treatment	
Visual disturba		Severity	Visual acivity de		Heatment	
Myopia			Tiodal dolliny do	o. 04004.	Ceased solian.	
Medicine De	etails:					
SOLIAN (Suspe			Rea	son: Unspecified ps	sychosis	
Tablet			Milligram	Oral		
Batch:		Started: 01	/08/2002	Stopped:	28/08/2002	
<u>Laboratory</u>						
Date	Туре	Range Date Tes	ted Result		Details	
		1	<u>'</u>			

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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: 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 dyskinetic movements mouth & tongue.	Patient required a visit to doctor.

Medicine Details:

FLUANXOL (Other drug)			Reason:	Unspecified schizo	phrenia
Injection	60.0	Milligram	Fortni	ightly Intra	amuscular
Batch:	Started: 07	/02/2002		Stopped:	
AKINETON (Other drug)			Reason:		
	2.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
VIBRA-TABS 50 (Other drug)			Reason:	Other acne of seba	ceous glands
	50.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	
TEMAZE (Other drug)			Reason:	Specific disorders	of sleep
	20.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Had similar reaction to seroquel 6/01.

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 19 of 278



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

Re	nn	rt	De	tail	ls:
176	μυ		$\mathbf{D}\mathbf{c}$	tai	ιο.

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:

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.

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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: 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	l
Bronchospasm	Severe		Date of recovery: 21/10/02.	l

Medicine Details:

SOLIAN (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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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Report Details:

Case Number: 180397

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

		Reported: 06/11/2002					Weight:			
Outcome: Not yet recove							Age:			
						DOB:				
nation Dataila:						y: Causality poss	ble			
action Details:	0	. I		nort Decer	tian I	Tagatas	1			
Preferred Term alactorrhoea	Severi		Re Discharge fron	port Descrip	DUON	Treatmen	l			
edicine Details:										
OLIAN (Suspected)			Re	eason:						
Tablet	6	0.00£	Milligram	Daily	Oral					
Batch:	Starte	d:		;	Stopped:					
EGRETOL (Suspected)			Re	eason:						
Tablet		1.0	Gram	Daily	Oral					
Batch:	Starte				Stopped:					
aboratory Investigations		te Teste	d Result		De	otails				
Date Type R					D(lans				



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

Re	po	rt	De	tai	ls:
	\sim		-	u	

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:

Medicine Details.			
CLOPIXOL (Other drug)		Reason:	
Injection	150.0 Milligram	Daily Intramusc	ular
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily Oral	
Batch:	Started: 01/09/2002	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also has hypothyroidism and diabetes.

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

Ren	ort	Deta	ils:
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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		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	Туре	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.

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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: 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)

Tablet

400.0 Milligram

Daily

Oral

Batch:

Started: 12/09/2002

Stopped:

Laboratory Investigations:

Euboratory investigations:							
Date	Туре	Range	Date Tested	Result	Details		

Additional Information:

No other exposure to other antipsychotic medicines.

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

Preferred Term Severity Report Description Treatment Urticaria urticarial rash - all body, erythema, not raised Wedicine Details: SOLIAN (Suspected) Reason: Tablet Oral Batch: Started: Stopped:		ails:						
Onset Date: 19/09/2002 Outcome: Recovered 30/09/2002 Causality: Causality probable action Details: Preferred Term Severity Report Description Treatment Urticarial urticarial rash - all body, erythema, not raised Medicine Details: SOLIAN (Suspected) Reason: Tablet Crail Batch: Started: Stopped:			Seq: 1					
Onset Date: 19/09/2002 Outcome: Recovered 30/09/2002 Causality: Causality probable action Details: Preferred Term Severity Report Description Treatment Urticaria urticarial rash - all body, erythema, not raised Erythema Medicine Details: SOLIAN (Suspected) Reason: Tablet Oral Batch: Started: Stopped:	-					_		
Outcome: Recovered solvesting the search of						=		
Preferred Term Severity Report Description Treatment Urticaria urticarial rash - all body, erythema, not raised Preferred Term Severity Urticarial rash - all body, erythema, not raised Prythema Medicine Details: SOLIAN (Suspected) Reason: Tablet Oral Batch: Started: Stopped:				30/09/2002				
Preferred Term Severity Report Description Treatment Urticaria urticarial rash - all body, erythema, not raised Medicine Details: SOLIAN (Suspected) Reason: Tablet Oral Batch: Started: Stopped:				00/00/2002	3 3.3.3	.)		
Urticaria urticarial rash - all body, erythema, not raised Medicine Details: SOLIAN (Suspected) Tablet Batch: Started: Started: Stopped: Aboratory Investigations:			Severity	Report D	escription	Treatment		
Medicine Details: SOLIAN (Suspected) Tablet Batch: Started: Stopped:	Jrticaria			urticarial rash - all bo	dy, erythema, not	Solian ceased.		
Medicine Details: SOLIAN (Suspected) Reason: Tablet Oral Batch: Started: Stopped:				raised				
Tablet Oral Batch: Started: Stopped: _aboratory Investigations:	Erythema							
Tablet Oral Batch: Started: Stopped: aboratory Investigations:								
Batch: Started: Stopped:		ected)		Reason:	0.1			
_aboratory Investigations:			Ctouto di					
				оторроч.				
	l aboratory	Investigation	s.					
				ed Result		Details		

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

Rep	oort	Deta	ils:
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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	Туре	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Benztropine and amisulpride.l

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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: 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		Developed a oculogyric crisis and mild laryngeal discomfort.	Treated with IM Benztropine.
	Pain			

Medicine Details:

Medicine Details.			
ZOLOFT (Other drug)		Reason: Depression	
Tablet	50.0 Milligram	Daily O	ral
Batch:	Started: 10/10/2002	Stopped:	
SOLIAN (Suspected)		Reason: Unspecified psyc	hosis
Tablet	200.0 Milligram	Daily O	ral
Batch:	Started: 10/10/2002	Stopped: 1	1/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 180900 Seq: 1 Gender: F

Reported: 20/12/2002 Weight: 0.00 Hospitalisation: Age: 29

Onset Date: 21/10/2002 **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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

	ber: 1812/8	Seq:	7			ender: ⊢
Repo	rted: 09/01/200	3			We	eight: 0.00
Hospitalisat	ion:					Age: 37
Onset D	Date:					DOB:
Outco	me: Recovere	d			Caus	sality: Causality probable
eaction D	etails:					
	eferred Term	Se	everity	Rep	ort Description	Treatment
Dystonia			Dy	stonia		
Medicine SOLIAN (Su	spected)			Rea	son:	al
Bate		9	tarted:		Stopped:	21
I aborato	ry Investigat	ions:				
Date	Туре	Range	Date Tested	Result		Details
		-				
Additiona	al Informatio	n:				
eport Run: 04/	/06/2007 04:08PM	l Database: p	usime02	A	ADRS004	Page 30 of 278

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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: 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)		Re	ason:	Other coagula	tion defects
Capsule			Daily		Oral
Batch:	Started:	L TERM	1	Stopped:	
LIPEX (Other drug)		Re	ason:	Othr&unspec r	metabolic diseases
Tablet	40.0	Milligram	Daily		Oral
Batch:	Started:	L TERM	1	Stopped:	
SOLIAN (Suspected)		Re	ason:		
Tablet	400.0	Milligram	Daily		Oral
Batch:	Started: 04/	10/2002		Stopped:	12/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Minax, Talohexal.

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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: 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
	Treated in outpatient department only		

Medicine Details:

ASTRIX 100 (Other drug)			Reason:	Other coagula	tion defects
Capsule			Daily		Oral
Batch:	Started:	L TE	ERM	Stopped:	
LIPEX (Other drug)			Reason:	Othr&unspec r	netabolic diseases
Tablet	40.0	Milligram	Daily		Oral
Batch:	Started:	L TE	ERM	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.

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

Report Deta						
Case Numbe Reported ospitalisation	d : 13/01/2003	Seq: 1			Gender: Weight: Age:	0.00
-	e: 07/12/2002				_	18/12/1956
	e: Unknown			С		Causality possible
eaction Det				J	uuouy.	caddanty possible
	erred Term	Severity	Report De	escription		Treatment
Extrapyramida		Caused or prolonged inpatient hospitalisation	Nausea, extrapyramid abdominal pain.			
Abdominal pai	n	Caused or prolonged inpatient hospitalisation				
Nausea		Caused or prolonged inpatient hospitalisation				
Medicine D	etails:					
AMISULPRIDE (Reason:			
Tablet		400.0	Milligram Daily		Oral	
			,			
Batch:		Started: 06/	-		07/12/2002	:
	Investigation		12/2002			
Laboratory		s:	12/2002		07/12/2002	

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 33 of 278



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, akathesia, parkinsonism and extrapyramidal disorder.	
Akathisia	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ı	SOLIAN (Suspected)	Reason:	Unspecified schizophrenia
	Tablet	400.0 Milligram Daily	Oral

Batch: Started: S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 34 of 278



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

Repor	t Detail	s:
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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:

todotion Dotailoi			
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.

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 35 of 278



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

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 181475 Seq: 1 Gender: M

Reported: 13/01/2003 Weight: 0.00 Hospitalisation: Age: 41

Onset Date: 20/11/2002 **DOB**: 13/12/1960

Outcome: Recovered 28/11/2002 Causality: Causality possible

Reaction Details:

caction betains.			
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:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Iron tablets.

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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: 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	Туре	Range	Date Tested	Result	Details

Additional Information:

At present patient is on 700mg/day Solian.

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

Case Number: 181697 Reported: 15/01/200 lospitalisation: Onset Date: Outcome: Recovere leaction Details: Preferred Term Parkinsonism Gait disturbance Tremor Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other data) Tablet Batch: SOLIAN (Suspected)	Severity	Parkinsonism - shuffling gait.		Weigl Aç DC Causali	er: M ht: 0.00 ge: 99U DB: ty: Causality possible Treatment Recovered 3 weeks after ceasing solian
Outcome: Recovered Recovered Rection Details: Preferred Term Parkinsonism Gait disturbance Fremor Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other of Tablet) Batch:	Severity 450.0	Parkinsonism - shuffling gait.	blunted focus,	Causali on	ty: Causality possible Treatment Recovered 3 weeks after
Preferred Term Parkinsonism Gait disturbance Tremor Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other drug) Tablet Batch:	Severity 450.0	Parkinsonism - shuffling gait.	blunted focus,	on	Treatment Recovered 3 weeks after
Preferred Term Parkinsonism Gait disturbance Tremor Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other drug) Tablet Batch:	450.0	Parkinsonism - shuffling gait.	blunted focus,		Recovered 3 weeks after
Parkinsonism Gait disturbance Tremor Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other drug) Tablet Batch:	450.0	Parkinsonism - shuffling gait.	blunted focus,		Recovered 3 weeks after
Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other drug) Tablet Batch:		shuffling gait.			
Medicine Details: EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other drug) Tablet Batch:					
EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other of Tablet) Batch:					
EFEXOR (Other drug) Tablet Batch: LITHIUM CARBONATE (Other of the state) Tablet Batch:					
Batch: LITHIUM CARBONATE (Other of Tablet Batch:) Milligram	ason:		
LITHIUM CARBONATE (Other of Tablet Batch:	Started:	o wiiiigiaiii	Daily	Oral	
Tablet Batch:		L TERN	l Sto	pped:	
Batch:			ason:		
) Milligram	Daily	Oral	
SULIAN (Suspected)	Started:	L TERN		pped:	
Tablet	800 (Re O Milligram	ason: Unspec Daily	ified schizophr Oral	enia
Batch:	Started:	o iviiligiam	-	pped:	
.aboratory Investigat		T		_	
Date Type	Range Date Te	ested Result		D	etails

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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:
 181699
 Seq: 1
 Gender:
 F

 Reported:
 15/01/2003
 Weight:
 0.00

Hospitalisation: Age: 60

Onset Date: DOB: 30/10/1942

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected) Reason: Depression

400.0 Milligram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 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:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Irritability			Currently reducing Solain dose in view of changing to Zyprexa.

Medicine Details:

ZYPREXA (Other drug)		Reason: Unspecifi	ed schizophrenia
	15.0 Milligram	Daily	
Batch:	Started: 11/06/2002	Stop	ped:
CITALOPRAM HYDROBROMIDE	(Other drug)	Reason: Depressi	on
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stop	ped:
SOLIAN (Suspected)		Reason: Unspecifi	ed schizophrenia
Tablet	400.0 Milligram	Reducing	Oral
Batch:	Started: 01/08/2002	Stopp	oed:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Had been treated for schizophrenia since June 1999 and never had manic features.

Reation 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.

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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: 181936 Seq: 1 Gender: F

Reported: 22/01/2003 Weight: 0.00 Hospitalisation: Age: 29

Onset Date: 03/01/2003 **DOB**: 12/11/1973

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
		Vomiting when dose of solian increased to 800mg/day. Some nausea on 600mg.	Reduced dose to 600mg.

Medicine Details:

SOLIAN (Suspected)Reason:Unspecified schizophreniaTablet800.0MilligramDailyOral

Batch: Started: 12/12/2002 **Stopped:** 03/01/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Report Details:

Case Number: 181945

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

	Sever		perventilation	ort Description	Age: 39 DOB: 25/05/1963 ausality: Causality possible Treatment Solian ceased. IM serenace given
Outcome: Recovered eaction Details: Preferred Term Dysarthria Hyperventilation Medicine Details: COGENTIN (Other drug) Batch:			perventilation	ort Description	Treatment Solian ceased. IM serenace
Preferred Term Dysarthria Hyperventilation Medicine Details: COGENTIN (Other drug) Batch:			perventilation	ort Description	Treatment Solian ceased. IM serenace
Preferred Term Dysarthria Hyperventilation Medicine Details: COGENTIN (Other drug) Batch:			perventilation	•	Solian ceased. IM serenace
Dysarthria Hyperventilation Medicine Details: COGENTIN (Other drug) Batch:			perventilation	•	Solian ceased. IM serenace
Medicine Details: COGENTIN (Other drug) Batch:	Starte	Ну		, dysarthria	
COGENTIN (Other drug) Batch:	Starte		Rea		giveri
Medicine Details: COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
COGENTIN (Other drug) Batch:	Starte		Rea		
Batch:	Starte		Rea		
Batch:	Starte			son:	
	Starte				
	Statte	d.		Stopped:	
EFEXOR (Other drug)		ou:			
			Rea	son:	
Batch:	Starte	ed:		Stopped:	
HALDOL DECANOATE (Other drug)			Rea	son:	
TIALBOL BLOANDATE (Other drug)			Rea	5011.	
Batch:	Starte	d:		Stopped:	
VALIUM (Other drug)			Rea	son:	
Batch:	Starte	d.		Stopped:	
Batcii.	Starte	u.		Stopped.	
Laboratory Investigations	e.				
	Range Da	te Tested	Result		Details
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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: 1819 Reported: 23/0 Hospitalisation: Onset Date: Outcome: Reco	1/2003		0.00
Medicine Details: SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
Laboratory Invest	tigations:		
Additional Inform	ation:		

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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: 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:

todotion Botano:								
Preferred Term	Severity	Report Description	Treatment					
Grand mal convulsion			Taken to emergency dept and given iv phenytoin, then stabilized on this.					

Medicine Details:

SOLIAN (Suspected)Reason:Unspecified schizophreniaTablet800.0 MilligramDailyOral

Batch: **Started**: 18/06/2002 **Stopped**: 19/07/2002

Laboratory Investigations:

Date	Туре	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.

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

Re	po	rt	De	tai	ls:
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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 schizophrer	nia
	2.0 Gram	Daily	
Batch:	Started:	Stopped:	Contin
SEROQUEL (Suspected)		Reason: Unspecified schizophrer	nia
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	Contin
SOLIAN (Suspected)		Reason: Unspecified schizophrer	nia
Tablet	200.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	Contin
LUVOX (Suspected)		Reason: Unspecified schizophrer	nia
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Туре	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

Re	po	rt	De	tai	ls:
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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:

100011011 D 0101101			1
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	Туре	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: 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:

towotion bottom						
	Preferred Term	Preferred Term Severity Report De		Treatment		
	Galactorrhoea	Required Visit Galactorrhoea to Doctor		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	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital at the time.

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

DOB:

Report Details:

Case Number: 182541 Seq: 1 Gender: M

 Reported:
 07/02/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 85Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

•	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Suicidal ideation	Life threatening	Suicidal ideation	

Medicine Details:

ZYPREXA (Other drug)			Reason:	Unspecified so	hizophrenia
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	Туре	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



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

Re	po	rt	De	tai	ls:
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 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: Unspeci	fied psychosis	
Injection	100.0 Milligram	Fortnightly	Intramuscular	
Batch:	Started: 19/08/2002	Stop	ped: 09/01/2003	
COGENTIN (Other drug)		Reason:		
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 05/04/2000	Stop	ped:	
SOLIAN (Suspected)		Reason: Unspeci	fied psychosis	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started: 26/11/2002	Stop	ped:	

Laboratory Investigations:

Date	Туре	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: 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 HYDROCHLOR	IDE (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

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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: 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
Neuroleptic malignant syndrome	threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given and GTN patch
Somnolence	threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Urinary retention	threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Vomiting	threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given

Medicine Details:

METOCLOPRAMIDE HYDROCHLOR	IDE (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

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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: 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:

touotion Dotumor			
Preferred Term	Severity	Report Description	Treatment
	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	Туре	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.

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

Re	po	rt	De	tai	ls:
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Case Number: 182909 Seq: 1 Gender: F

Reported: 14/02/2003 Weight: 0.00 Hospitalisation: Age: 67

Onset Date: 27/11/2002 **DOB**: 21/08/1935

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

Modifile Botalie:			
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:

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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: 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:

100000000000000000000000000000000000000			
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.

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

Re	po	rt	De	tai	ls:
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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.	Benztropine 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	Туре	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

Re	po	rt	De	tai	ls:
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Case Number: 183674 Seq: 1 Gender: F

Reported: 03/03/2003 Weight: 60.00 Hospitalisation: Age: 99u

Onset Date: 01/08/2002 DOB:

Outcome: Recovered 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 183682 Seq: 1 Gender: F

Reported: 04/03/2003 Weight: 0.00 Hospitalisation: Age: 54

Onset Date: 15/08/2002 **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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Report Details:	Re	po	rt	De	tai	ls:
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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	r drug)	Reason: Sc	hizo-affective type ps	sychos
Injection	200.0 Milligram	Fortnightl	у	
Batch:	Started:		Stopped:	Contin
CHLORPROMAZINE HYDROCHLOR	IDE (Other drug)	Reason: Sc	hizo-affective type ps	sychos
Tablet	2.5 Milligram	Daily	Oral	
Batch:	Started:		Stopped: 07/01/26	002
AMISULPRIDE (Suspected)		Reason: Sc	hizo-affective type ps	sychos
Tablet	400.0 Milligram	Daily	Oral	
Batch:	Started: 07/01/2002		Stopped: 08/01/20	002

Laboratory Investigations:

Date	Туре	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

Ren	ort	Deta	ils:
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 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:

<u> </u>			
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	Туре	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

Re	po	rt	De	ta	il	s:

Case Number:184497Seq: 1Gender:FReported:28/03/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 99U

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient hospitalised for 6 hours.

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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: 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:

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	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient developed a total of 3 episodes of complex partial seizure activity on amisulpride while carbamazepie 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.

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

Case Number: 184759 Reported: 08/04/2003 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1	Gender: M Weight: 0.00 Age: 99U DOB: Causality: Causality possible				
eaction Details: Preferred Term	Soverity	Papart Description	Treatment			
Rash pruritic	Severity	Report Description Itchy rash, nausea and vomiting.	Solian stopped because of			
·		nony raon, nadood and vorming.	vomiting.			
Nausea Vomiting						
ledicine Details: SOLIAN (Suspected)		Reason: Unspecified schi	zophrenia			
Tablet	600.0	Milligram Daily C	Oral			
_aboratory Investigation Date Type I	S: Range Date Teste	ed Result	Details			

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

eport Details:				
ase Number: 184760	Seq: 1		Gend	er: M
Reported: 08/04/2003			Weig	ht: 0.00
pitalisation:			Ag	ge: 99U
Onset Date:			DC	OB:
Outcome: Unknown			Causali	ity: Causality possible
ction Details:		_		
Preferred Term	Severity	Re	eport Description	Treatment
sh pruritic		Itchy rash		
edicine Details: OLIAN (Suspected)		R	eason: Unspecified schizophr	renia
Tablet	600.0	Milligram	Daily Oral	onia -
Batch:	Started:	g	Stopped:	Contin
boratory Investigatio	ns:			
Date Type	Range Date Tes	ted Result	С	etails
dditional Information:				
uullional illioillation.				
rt Run: 04/06/2007 04:08PM	Database: pusime02		ADRS004	Page 63 of 278



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

eport Details:				
ase Number: 184761	Seq: 1		Gender	F
Reported: 08/04/2003			Weight:	0.00
spitalisation:			Age:	99U
Onset Date:			DOB	
Outcome: Unknown			Causality:	Causality possible
action Details:				
Preferred Term	Severity	Rep	port Description	Treatment
onstipation		Constipation		
edicine Details:				
OLIAN (Suspected)			eason: Unspecified schizophrenia	a
Tablet		Milligram	Daily Oral	0 "
Batch:	Started:		Stopped:	Contin
aboratory Investigations				
aboratory Investigations: Date Type Ra	ange Date Test	ted Result	Deta	ils
dditional Information:				
dational information.				



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

Report Details:

Case Number:185100Seq: 1Gender:FReported:14/04/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 99U

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Hypercorticoidism		Patient experienced hypercortisolism and hyperprolactinemia.	Solian ceased.
	Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lamictal, Dothiepin, Yasmin and Immovane.

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Report Details:

Case Number: 185250

Reported: 29/04/2003

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Weight: 125.00

Hospitalisation:					Age: 24
Onset Date: 21/03/20	003				DOB : 14/12/1978
Outcome: Recover	ed			Cau	sality: Causality possible
eaction Details:					
Preferred Term	Sever	ity	Rep	ort Description	Treatment
Convulsive threshold lowe	ered Caused of prolonge inpatient hospitalis	d	vulsive thre	shold lowered	Diazepam administered. Da dose of amisulpride reduced 200mg and finally was cganged to risperidone Zuclopenthixol and sertralin were also reduced.
Medicine Details:					
CLOPIXOL (Other drug)			Rea	son:	
5	• .			0 /	
Batch:	Starte	ed:		Stopped:	
SOLIAN (Suspected)			Rea	son:	
Tablet					
Batch:	Starte	Started: 29/01/2003 Stopped:			
ZOLOFT (Suspected)			Rea	son:	
Batch:	Starte	ed:		Stopped:	
Laboratory Investiga	ations:				
Date Type		ite Tested	Result		Details
29/04/2003 Radiololgy					
Additional Information	on:				
eport Run: 04/06/2007 04:08F	PM Database: pusim	e02	Å	ADRS004	Page 66 of 278



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:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
	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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 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 Microgran	n 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 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:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Hypersensitivity nos, rash pruritic, wheezing and chest tightness	Given antihistamine, ventolin neb, topical menagement 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 Microgran	n 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.

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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:
 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:

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

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 TE	RM	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	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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

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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:
 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:

Neaction 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)		Reas	on:	Diabetes mellitus	
Tablet		Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
SOLIAN (Suspected)		Reas	on:	Schizophrenia	
Oral application	600.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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:186669Seq: 1Gender:FReported:06/06/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 73

Onset Date: 15/01/2003 DOB: 25/03/1929

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion botails.			
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)	Reas	son:	Diabetes mellitus	
Tablet		Dose Unspecified	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	
AMARYL (Other drug)		Reas	son:	Diabetes mellitus	
Tablet		Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
SOLIAN (Suspected)		Reas	son:	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.

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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: 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:

teaction 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)	Reas	on:	Diabetes mellitus	
Tablet		Dose Unspecified	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	
AMARYL (Other drug)		Reas	on:	Diabetes mellitus	
Tablet		Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
SOLIAN (Suspected)		Reas	on:	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.

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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: 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 maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Coordination abnormal		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Hyperhidrosis		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Hypertonia		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	

Medicine Details:

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

Laboratory Investigations:

Laborato	Euboratory invoctigations:							
Date	Туре	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.

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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: 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
Muscle rigidity		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Muscle spasms		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	
Neuroleptic malignant syndrome		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	Ceased Solian, given diazepam, Cogentin.
Tremor		Neuroleptic maliguant syndrome, rigidity, tremors, hypertonia, muscle spasm, creatine phosphokinase increased.	

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Patient was also taking Cipramil and Valium.

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

Report Details:	Re	po	rt	De	tai	ls:
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Gender: M Case Number: 186798 Seq: 1

Reported: 11/06/2003 Weight: 0.00 **Hospitalisation: Age:** 39

DOB: 06/07/1963 Onset Date: 30/05/2003

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botanor			
Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation		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	Туре	Range	Date Tested	Result	Details

Additional Information:

189532 is a duplicate.

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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:
 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
	Caused or prolonged inpatient hospitalisation		Admitted to Intensive Care unit.

Medicine Details:

Medicine Details.				
CLOZAPINE (Suspected)	Reason:			
Batch:	Started:	L TERM	Stopped:	
SOLIAN (Suspected)		Reason:		
Tablet	600.0 M	lilligram Daily	Oral	
Batch:	Started:	S TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 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:

teaction 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:

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	Туре	Range	Date Tested	Result	Details

Additional Information:

Poor compliance and medications.

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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: 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:

Cachon 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	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Nexium, Panadeine Forte, Efexor.

Report Run: 04/06/2007 04:08PM Database: pusime02 ADRS004 Page 79 of 278



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

Re	oa	rt	De	tai	ls:
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Gender: F **Case Number:** 187143 Seq: 1 Reported: 20/06/2003 **Weight: 86.00**

Hospitalisation: Age: 39 **DOB**: 26/10/1963

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 01/06/2003

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	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: 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	Туре	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.

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

Re	po	rt	De	tai	ls:
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Case Number: 187958 Seq: 1 Gender: M

Reported: 30/06/2003 Weight: 0.00 Hospitalisation: Age: 39

Onset Date: 19/01/2003 **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:

Medicine Details.				
MIRTAZAPINE (Other drug)		Reason:		
Tablet	30.0 Milligi	ram Daily	Oral	
Batch:	Started:	Stoppe	ed:	
AMISULPRIDE (Suspected)		Reason: Unspecifie	d psychosis	
Tablet	600.0 Milligi	ram Daily	Oral	
Batch:	Started:	Stopp	ed: 19/01/2003	

Laboratory Investigations:

Date	Туре	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

Repo	r4 I	Data	ila
Rebu) TLI	Jeta	IIIS.

 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	
·		Inability to walk unaided.	
Jaundice		Jaundice, sweating increased, muscle spasm.	It was recommended to stop amisulpride and valproate.
Muscle spasms	Severe	Severe muscle spasm	
Aphasia	Severe		
Hyperhidrosis			

Medicine Details:

EPILIM (Suspected)		Reason:		
Batch:	Started:	Stop	ped:	
SOLIAN (Suspected)		Reason:		
Tablet	1000.0 Milligram	Daily	Oral	
Batch:	Started:	Stop	oed:	
DOTHIEPIN HYDROCHLORIDE (S	uspected)	Reason:		
	150.0 Milligram	Daily		
Batch:	Started:	Stopp	ped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of Hepatitis B

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 83 of 278



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:

caction betails.									
Preferred Term Severity		Report Description	Treatment						
Psychotic disorder		, , , , , , , , , , , , , , , , , , , ,	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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Re	po	rt	De	tai	ls:
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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:

•	<u>toaotion Dotanoi</u>			
	Preferred Term	Severity	Report Description	Treatment
	Sleep disorder	Required Visit to Doctor	Insomia (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	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 85 of 278



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: Age: 26

Onset Date: 13/11/2002 **DOB:** 16/04/1976

Outcome: Unknown 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	Туре	Range	Date Tested	Result	Details
21/07/2003	Other data				

Additional Information:

Galactorrhoea two months throughout use of Amisulpride.

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 86 of 278



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:

todotion Botano.			T
Preferred Term	Severity	Report Description	Treatment
Autonomic nervous system imbala			
Delirium			
Hyperhidrosis			
Muscle rigidity			
Pyrexia			
Neuroleptic malignant syndrome		neuroleptic malignant syndrome, autonmic 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	Туре	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.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisation Onset Date	l: 22/07/200 : e: 14/07/200 : Recovere)3	1	14/07/2003				0.00	
	rred Term	Se	verity	Ren	ort Desci	rintion		Treatment	7
	ilea reiiii	36					. Po	nztropine and Midazolam.	-
Hypertonia			ta	ogwheel rigitit chycardia, hy	y, jaw pali per-reflexi	in, sweating a, clonus), De	nztropine and ivildazolam.	
Clonus									
Extrapyramidal	disorder								
Hyperhidrosis									
Hyperreflexia									
Pain in jaw									
Tachycardia									
Medicine De			300.0 Mi		ason: Daily		Oral		
Batch:		e.	tarted:	iligiaiii	Daily	Stannadi	Olai		
SOLIAN (Suspe	stad)	31	iarteu:	Por	ison:	Stopped:			1
Tablet	iteu)		300.0 Mi		Daily		Oral		}
Batch:		Si	tarted: 11/07/	_	Daily	Stopped:	14/07/2003	3]
Daten.			artea. 117077	2000		Otoppeu.	14/01/2000	,	I
Laboratory Date	I nvestigat Type	ions: Range	Date Tested	Result			Detai	ls	
Additional I	nformatio	n:							

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 88 of 278



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

Report Details:

Case Number: 189120 Seq: 1 Gender: F

Reported: 05/08/2003 Weight: 0.00 Hospitalisation: Age: 51

Onset Date: DOB: 23/07/1952

Outcome: Recovered 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:

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	Туре	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

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

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 189460 Seq: 1 Gender: F

Reported: 13/08/2003 Weight: 0.00 Hospitalisation: Age: 29

Onset Date: 01/07/2003 **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	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Thin discharge from breast 15 years before.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Reported: 20 Hospitalisation: Onset Date: Outcome: Nate: Reaction Details Preferred	0/08/2003	1				Gender:	IVI	
Onset Date: Outcome: Neaction Details Preferred						Weight:	0.00	
Outcome: N eaction Details Preferred						Age:	30	
eaction Details Preferred						DOB:	04/12/1972	
Preferred	lot yet rec	overed				Causality:	Causality possible	
Preferred):					_	• •	
		S	Severity	Rep	ort Descriptior	1	Treatment	
Bundle branch bloc	k left		L	eft anterior fas	icular block.			
Electrocardiogram	abnormal		L	eft anterior fas	icular block.			
QRS axis abnorma	I		L	eft anterior fas	icular block.			
Medicine Detai	ls:							
EPILIM (Suspected)				Rea	ason:			
Batch:		1	Started:		Stop	nadı		
SERZONE (Suspecte	nd)		Starteu.	Ra	ason:	peu.		
SENZONE (Suspecte	iu)			IX G	35011.			
Batch:		:	Started:		Stop	ped:		
SOLIAN (Suspected)				Rea	eason:			
Batch:		;	Started:		Stop	ped:		
CLOZARIL (Suspecte	ed)		050.0		ason:	0.1		
Tablet			350.0 M	_	Daily	Oral .		
Batch:			Started: 22/11	/2001	Stop	ped:	contin	
Laboratory Inve	estigatio	ons:						
	уре	Range	Date Tested	d Result		Detai	s	
20/08/2003 Electroca	ardiograph							

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

Report Details:	Re	po	rt	De	tai	ls:
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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:

٠,	todotion Dotailoi			
	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	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 92 of 278



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

Report Details:	Re	po	rt	De	tai	ls:
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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	Туре	Range	Date Tested	Result	Details
29/08/2003	Other data				

Additional Information:

Previously treated with olanzapine

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 93 of 278



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:
 Age: 75Y

Onset Date: 27/02/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			Reason:	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	Туре	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.

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

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Πt	: 131	JIL	De	ιai	15.

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:

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

Medicine Details:

SOLIAN (Suspected)Reason:SchizophreniaTablet200.0 MilligramDailyOral

Batch: Started: 05/11/2002 Stopped: contin

Laboratory Investigations:

Date	Туре	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

Re	po	rt	De	tai	ls	:
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 Case Number:
 190660
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2003
 Weight:
 59.00

Hospitalisation: Age: 18

Onset Date: 25/07/2003 **DOB**: 30/11/1984

Outcome: Recovered 02/09/2003 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		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:

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:

<u> Luboi atoi</u>	y ilivostiga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 96 of 278



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

Case Number: 190712 Reported: 22/09/2003 Hospitalisation: Onset Date: Outcome: Recovered Leaction Details: Preferred Term Oedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug) Tablet	Seq: 1 Severity Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati	Pe eye del ion	Reperipheral oede elids progressematitis.	ort Descri	iption na of face	Ag DC ausali	er: F nt: 0.00 ge: 26 DB: 27/02/1977 ty: Causality possible Treatment Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and derssings used.
Onset Date: Outcome: Recovered eaction Details: Preferred Term Dedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	iption na of face	Ag DC ausali	ge: 26 DB: 27/02/1977 ty: Causality possible Treatment Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Onset Date: Outcome: Recovered eaction Details: Preferred Term Dedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	iption na of face	DC ausali	ty: Causality possible Treatment Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Outcome: Recovered eaction Details: Preferred Term Dedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	iption na of face	ausali and	ty: Causality possible Treatment Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Preferred Term Dedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	iption na of face	and	Treatment Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Preferred Term Oedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	na of face		Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Oedema peripheral Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	Pe eye del ion	eripheral oede elids progress	ma, oeder	na of face		Withdrawal of carbamazepin then Solian. Prednisolone 50mg, promethazine and
Dermatitis exfoliative Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	prolonged inpatient hospitalisati Caused or prolonged inpatient hospitalisati Caused or prolonged inpatient	eye der ion	elids progress	ma, oeder sing to exf	na of face oliative		then Solian. Prednisolone 50mg, promethazine and
Eyelid oedema Medicine Details: CLONAZEPAM (Other drug)	prolonged inpatient hospitalisati Caused or prolonged inpatient						
Medicine Details: CLONAZEPAM (Other drug)	prolonged inpatient						
CLONAZEPAM (Other drug)		ion					
Tablet				ison:			
		2.0 Mill	•	As necess	•	Oral	
Batch:	Started:	01/07/2			Stopped:		
CHLORPROMAZINE HYDROCHLORID				ason:		0 1	
Tablet		0.0 Mill	-	As necess	•	Oral	
Batch: CARBAMAZEPINE (Suspected)	Started:	01/07/2			Stopped:		
, , ,	200) O M:II		ason: 2 times		Oral	
Tablet		0.0 Mill	Ü	2 times	Ctonnod	Oral	2002
Batch: SOLIAN (Suspected)	Started:	01/07/2		ason:	Stopped:	15/06/2	:003
SOLIAN (Suspected)	400) O Mill		2 times		Oral	
Batch:	Started:	0.0 Mill		2 (111165	Stopped:		2003
Daten.	Starteu.	01/01/2	2003		Stoppeu.	30/00/2	.003
<u> aboratory Investigations:</u>			I 5 "	1			
Date Type Rai	nge Date	Tested	Result			D	etails

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

Report Details	:	
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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
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:

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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:
 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 schizophreniaTablet400.0MilligramDailyOral

Batch:Started: 15/05/2003Stopped:Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Rep	ort	Det	ails:
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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	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient history incomplete.

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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: 191634 Seq: 1 Gender: M

Reported: 27/10/2003 Weight: 70.00 Hospitalisation: Age: 18

Onset Date: 23/08/2003 **DOB:** 09/07/1985

Outcome: Recovered 02/09/2003 Causality: Causality possible

Reaction Details:

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

Medicine Details:

AMISULPRIDE (Suspected) Reason:

Tablet 300.0 Milligram Daily Oral

Batch: **Started**: 21/08/2003 **Stopped**: 29/08/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Could not tolerate these and took self off medication.

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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:
 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	Туре	Range	Date Tested	Result	Details
10/11/2003	Other data				

Additional Information:

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

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

Re	po	rt	De	tai	ls	:
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 Case Number:
 192208
 Seq: 1
 Gender: M

 Reported:
 14/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 48

Onset Date: 02/11/2003 DOB: 05/11/1954

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction 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 Unspec	fied Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ſ	14/11/2003	Echocardiogram				

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:
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Case Number: 192237 Seq: 1 Gender: M
Reported: 14/11/2003 Weight: 0.00
Hospitalisation: Age: 24

Onset Date: 16/09/2003 **DOB**: 06/11/1978

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botanor										
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:	St	opped:	
CLOZARIL (Suspected)		Reason: Unspe	ecified schizophreni	a
Tablet	37.5 Milligram	Daily	Oral	
Batch:	Started: 02/06/1999	St	opped:	Contin
SOLIAN (Suspected)		Reason:		
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	

Laboratory Investigations:

Date	Туре	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

Re	po	rt	De	tai	ls:
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 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:

- de la	I		
Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation	Urinary incontinence.	

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Amisulpride was discontinued after ten days of treatment.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	12/12/2003 Unknown	Seq:	1		Ag DO	t: 0.00 e: 99U		
	ed Term	Se	verity	Repo	ort Description	Treatment		
Neuroleptic malig	ınant syndr	ome	Ne	uroleptic mali	gnant syndrome			
Medicine Deta	ails:							
SOLIAN (Suspecte	d)			Rea	son:			
Batch:		St	arted:					
Laboratory In			Date Tested	Pecult	De	taile		
Date	1 ypc	range	Date Tested	Nesull		uno .		
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

Re	po	rt	De	tai	ls:
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 Case Number:
 193475
 Seq: 1
 Gender:
 F

 Reported:
 22/12/2003
 Weight:
 0.00

Hospitalisation: Age: 44

Onset Date: 24/10/2003 DOB: 03/12/1958
Outcome: Recovered Causality: Causality possible

Reaction Details:

<u>toaction Botano.</u>			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Patient experienced galactorrhoea and amenorrhoea with hyperprolactinaemia, loss of libido.	
Amenorrhoea			
Galactorrhoea			
Loss of libido			

Medicine Details:

Medicine Details.				
AROPAX (Other drug)		Reason: Unspeci	fied schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 28/03/2002	Stopped:		Contin
SOLIAN (Suspected)		Reason: Unspecif	fied schizophrenia	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 10/10/2002	Stopped:		Contin

Laboratory Investigations:

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

Additional Information:

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Report Details:

Case Number: 193897

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Reported: 09/01/200	4	Weight: 0.00					
lospitalisation:		Age: 99U					
Onset Date:		DOB:					
Outcome: Unknown		Causality: Causality possible					
eaction Details:							
Preferred Term	Severity	Report Descr	ription	Treatment			
Tardive dyskinesia		Tardive dyskinesia, chror tremor	ic depression,	Was unsuccessfully treated with a number antidepressant trials. Solian was ceased, propranolol and tetrabenazine 12.5mg were given.			
Depression							
Tremor							
Medicine Details: SOLIAN (Suspected)		Reason:					
Batch:	Started:		Stopped:				
Laboratory Investigati	iono						
Laboratory Investigat Date Type	Range Date Te	sted Result		Details			
24.0	rtunge Date re	1.000.1		2 ottaile			
Additional Information	ո։						
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Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE, SOLIAN

Report	Details:
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 Case Number:
 194470
 Seq: 1
 Gender: U

 Reported:
 10/02/2004
 Weight:
 0.00

Hospitalisation: Age: 99U
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected) Reason: Schizophrenia

400.0 Milligram Daily

Batch: Started: Stopped: 15/09/2003

Laboratory Investigations:

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

Additional Information:

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

Re	po	rt	De	tai	ls:
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 Case Number:
 194471
 Seq: 1
 Gender:
 F

 Reported:
 10/02/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 40Y

Onset Date: DOB:

Outcome: Unknown 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

Dose Unspecified

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Rep	ort	Det	ails:
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 Case Number:
 194695
 Seq: 1
 Gender: M

 Reported:
 17/02/2004
 Weight:
 0.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

SOLIAN (Suspected) Reason: Unspecified schizophrenia

Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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: 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:

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	Туре	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).

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	194859	Seq: 1		Gender:	F
Reported:	24/02/2004			Weight:	0.00
spitalisation:				Age:	99U
Onset Date:				DOB	!
Outcome:	Unknown			Causality:	Causality possible
action Detai			ı		
Preferre		Severity	Rep	ort Description	Treatment
ardive dyskinesi	а		Tardive dyskine movements.	sia - involuntary tongue	
edicine Deta				ison:	
Tablet Batch:		400.0 Started:	Milligram	Daily Stopped:	
aboratory In			tod Dogult	Doto	ilo.
Date	Type F	Range Date Tes	ted Result	Deta	lis
dditional Inf	ormation:				
ort Run: 04/06/200	7 04:09PM Da	atabase: pusime02		ADRS004	Page 113 of 278



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 195074 Reported: 03/03/20 Hospitalisation: Onset Date: Outcome: Unknown Reaction Details:			DO	: 0.00 : 99U
Preferred Term	Severity	Report I	Description	Treatment
Breast cancer female				mastectomy was performed.
Medicine Details:				
PARACETAMOL (Other drug)		Reason	: Pain	
Batch:	Started:		Stopped:	
SOLIAN (Suspected)		Reason	: Unspecified schizophrer	ııa
Batch:	Started:		Stopped:	
Laboratory Investiga Date Type	tions: Range Date Test	ed Result	Def	ails
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:
 195919
 Seq: 1
 Gender: M

 Reported:
 24/03/2004
 Weight:
 0.00

Hospitalisation:
Onset Date:

Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion botailo:			1
	Preferred Term	Severity	Report Description	Treatment
	Convulsion		Patient experienced seizures.	
	Drug level increased			

Medicine Details:

Medicine Details.					
SOLIAN (Suspected)			Reason:		
Tablet	200.0	Milligram	Daily	Oral	
Batch:	Started:		s	topped:	
CLOZAPINE (Suspected)			Reason:		
Tablet	900.0	Milligram	Daily	Oral	
Batch:	Started:		S	topped:	

Laboratory Investigations:

Date	Туре	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.

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 115 of 278



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:

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

Medicine Details:

SOLIAN (Suspected)

Reason: Depression

800.0 Milligram Daily Oral

Batch: Started: 04/04/2003 Stopped:

Laboratory Investigations:

Date	Туре	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.

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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: 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:

Des Constant Tours	0	Descrit Description	Tourstonent
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	1
Capsule	450.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2003 L	TERM Stoppe	ed:
BUSPAR (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stoppe	ed:
SOLIAN (Suspected)		Reason: Depression	1
	200.0 Milligram	Daily	
Batch:	Started:	Stoppe	ed:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has emphysema secondary to chronic chest infection from childhood.

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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: 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
Dystonia	prolonged	Dystonic reaction, generalised muscle stiffness, neck tightness, difficulty breathing, tachycardia.	Benztropine 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Ren	ort	Deta	ils:
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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:

todotion Dotano.			
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.

Report Run: 04/06/2007 04:09PM Database: pusime02 ADRS004 Page 119 of 278



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:

•	todotion Botanoi			
	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	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had angioedema to chlorpromazine and metoclopramide.

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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: 196618 Seq: 1 Gender: M

Reported: 19/04/2004 Weight: 70.00 Hospitalisation: Age: 55Y

Onset Date: 01/01/2004 DOB:

Outcome: Recovered 09/01/2004 Causality: Causality probable

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
, ,	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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

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:

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

Medicine Details:

modifie Botanoi			
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	Туре	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: 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	Туре	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.

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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: 196948 Reported: 13/04/200 ospitalisation: Onset Date: 16/12/200 Outcome: Unknown	03		Gender: F Weight: 0.00 Age: 25 DOB: 18/10/1978 Causality: Causality possible	
eaction Details:			Caddanty: Caddanty possible	•
Preferred Term	Severity	Report Description	Treatment	
Orug ineffective	S	mptoms progressing.	Amisulpride ceased.	
Medicine Details: AMISULPRIDE (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Stoppe	ed:	
aboratory Investigat		I posti	Dataila	
Date Type	Range Date Tested	Result	Details	
Additional Informatio	n:			
eport Run: 04/06/2007	// Database: nusime02	ADRS004	Page 124 of	27º

Rep



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

DOB: 02/06/1926

Report Details:

 Case Number:
 196965
 Seq: 1
 Gender:
 U

 Reported:
 03/05/2004
 Weight:
 0.00

Hospitalisation: Age: 77

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date:

i todotion Botano.			
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 disord	ders of sleep	
	10.0 Milligram	Daily		Oral	
Batch:	Started: 01/12/2003		Stopped:		

Laboratory Investigations:

Date	Туре	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.

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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: 197153 Seq: 1 Gender: M

Reported: 10/05/2004 Weight: 0.00 Hospitalisation: Age: 47

Onset Date: 15/01/2004 **DOB:** 15/10/1956

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Urinary retention	

Medicine Details:

Medicine Details.				
SOLIAN (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	1.2 Gr	ram Daily	Oral	
Batch:	Started:		Stopped:	
COGENTIN (Suspected)		Reason:		
Tablet	4.0 Mi	illigram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

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

Additional Information:

Patient was also taking Thiordazine and Cephalexin.

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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: 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

•	ls:						
Case Number	197704	Seq: 1			G	ender:	F
	: 28/05/2004	· · · · · · · · · · · · · · · · · · ·					126.00
ospitalisation:						Age:	
Onset Date		4				_	: 03/01/1960
Outcome	Death				Cai	usality:	Causality possible
eaction Deta	ils:						
Prefer	red Term	Severity	Rep	ort Descri	otion		Treatment
Veight increase	ed		The patient weig mass index (BM morbidly obese.	ghed 126 k II) of 45, co	g with a boonsidered	dy	
Sudden death							
edicine De							
			Rea	nson:			
		Started:	Rea		Stopped:		
SOLIAN (Suspec Batch:	ted)	Started:			Stopped:		
SOLIAN (Suspec Batch:	ted))ral	
SOLIAN (Suspec Batch: CLOZARIL (Susp	ted)		Rea Milligram	ason: Daily)ral	
Batch: CLOZARIL (Susp Tablet Batch:	ected)	350.0 Started: 11	Rea Milligram	ason: Daily	C	Oral	
Batch: CLOZARIL (Susp	ected)	350.0 Started: 11	Rea Milligram /01/1996	ason: Daily	C	Dral Detai	ile

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 197788	Seq: 1		Gene	der: M
Reported: 04/03/2004			Weig	jht: 89.50
ospitalisation:				ge : 28Y
Onset Date:				OB:
Outcome: Unknown			Causa	lity: Causality certain
eaction Details:		T		T
Preferred Term	Severity	Report Descr		Treatment
Neuroleptic malignant syndro	me	December 2003 Neurolep syndrome.	otic malignant	Amisulpride ceased
Medicine Details: AMISULPRIDE (Suspected)		Reason:		
Batch:	Started:		Stopped:	
abaratam Invastigatio				
aboratory Investigation Date Type	Range Date Test	ted Result		Details
71				
Additional Information: Rechallenged twice with amisulp		n occurred.		
port Run: 04/06/2007 04:09PM	Database: pusime02	ADRS004		Page 129 of 27

Rep



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

Report Details	:						
Case Number: 7		Seq: 1		Gende Weight			
Hospitalisation: /		ital		_	e: 31		
Onset Date:	tarritted to rioop	itai			3 : 13/07/1972		
Outcome: F	Recovered				y: Causality possible		
Reaction Details				OddSanty	7. Causanty possible		
Preferred		Severity	Reno	rt Description	Treatment		
Drug level increas		-			rreatment		
Drug level ilicieas	eu	threatening	vomiting, diarrho and coma.	evels resulting in ea, acute renal failure			
Coma		Life threatening					
Diarrhoea		Life threatening					
Drug interaction		Life threatening					
Renal failure acute		Life threatening					
Medicine Deta AMISULPRIDE (Inte			Reas	· on·			
AWIGOLFRIDE (IIIte	raction)		Neas	oui.			
Batch:		Started:	Stopped:				
LITHIUM CARBONA	TE (Interaction)		Reas	son:			
Batch:		Started:		Stopped:			
Laboratory Inv		ge Date Test	ed Result	De	rails		
Buto	ype Run	ge Date rest	ed Result	50	iano -		
Date Type Range Date Tested Result Details Additional Information: Patient was also taking Serquel, Clopixal depot.							

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	197825	Seq: 1	Ge	nder: F
Reported:	03/06/2004		We	ight: 0.00
ospitalisation:	Admitted to hos	pital		Age: 31
Onset Date:				DOB : 13/07/1972
Outcome:	Recovered		Caus	ality: Causality possible
<u>eaction Detai</u>				
Preferre	d Term	Severity	Report Description	Treatment
Vomiting		Life threatening		
Medicine Deta AMISULPRIDE (Int			Reason:	
Batch:		Started:	Stopped:	
LITHIUM CARBON	ATE (Interaction)	- 2000 000	Reason:	
	, ,			
Batch:		Started:	Stopped:	
Laboratory In	vestigations	:		

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

D	ep	or	f D	lat.	ail	le:
К	eы	U	ιL	æι	all	15.

 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, htdration with eating.
Dry mouth	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IMIPRAMINE HYDROCHLORIDE (Suspected)		Reason:	Toxic diffuse g	joiter
Tablet	200.0	Milligram	Dail	/	Oral
Batch:	Started:	L	TERM	Stopped:	
AMISULPRIDE (Suspected)			Reason:	Depression	
Tablet	800.0	Milligram	Dail	/	Oral
Batch:	Started:	L	TERM	Stopped:	
THYROXINE SODIUM (Suspected)			Reason:		
Tablet	1.0	Dose Unspe	ecified Daily	/	Oral
Batch:	Started:	L	TERM	Stopped:	
LITHIUM CARBONATE (Suspected)			Reason:	Unspecified ps	sychosis
Tablet	750.0	Milligram	Dail	/	Oral
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 197974

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: U

Reported: 08/06/2004					Weigl	ht: 0.00
ospitalisation:					Αg	ge: 40
Onset Date: 09/03/2004					DC	DB : 03/04/1963
Outcome: Not yet recovered			C	ausali	ty: Causality possible	
eaction Details:		1				T
Preferred Term	Severity		Report De	escription		Treatment
	Caused or prolonged inpatient hospitalisatior	וו				
Medicine Details: OMEPRAZOLE (Suspected)			Reason:			
OMEFRAZOLE (Suspected)	40.0	Milligram	Daily	1		
Batch:	Started:		L TERM	Stopped:		
BENZTROPINE MESYLATE (Suspected)			Reason:	Otopped.		
Tablet		Milligram		I	Oral	
Batch:	Started:		L TERM	Stopped:	O I CI	
Laboratory Investigations:						
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: 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)

Tablet

Reason: Unspecified schizophrenia

Daily

Oral

Batch: Started: Stopped: 13/05/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 198055 Seq: 1 Gender: F

Reported: 11/06/2004 Weight: 70.00 Hospitalisation: Age: 26

Onset Date: 27/05/2004 **DOB**: 02/11/1977

Outcome: Recovered 02/06/2004 Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Report Details:

Case Number: 198123

Reported: 15/06/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight: 60.00

Hospitalisati					Age: 40)Y	
Onset D			DOB:				
	me: Unknown			Caus	sality: Ca	ausality possi	ble
<u>eaction D</u>		T	т _		ı		
	eferred Term	Severity		ort Description		Treatmen	t
Acne		Required Visit to Doctor	Pimples, breast extreme dizzines passed out).	milk, prolonged period, ss when walking (nearly	′		
Dizziness		Required Visit to Doctor					
Galactorrhoe	ea	Required Visit to Doctor					
Menorrhagia	l	Required Visit to Doctor					
Medicine SOLIAN (Sus	pected) et		Rea Milligram	Daily Or	al		
Batc	h:	Started:		Stopped:			
Laborator	y Investigatio	ons:					
Date	Туре	Range Date Test	ed Result		Details		
Additiona	I 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: 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
	Caused or prolonged inpatient hospitalisation		Amisulpride ceased.

Medicine Details:

SOLIAN (Suspected)
Reason:
1.2 Gram Daily Oral

Batch: Started: 23/02/2003 Stopped: 06/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking various concomitant medications.

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

Reported: 23/06/2004 spitalisation: Admitted to hosp Onset Date: 01/06/2004 Outcome: Not yet recovered				0.00
action Details:	J		Causanty.	Causality possible
Preferred Term	Severity	Report Descr	ription	Treatment
rug ineffective /eight increased		Lack of efficacy and weig	nt gain	
edicine Details:		Reason:		
Batch:	Started:	Dose Unspecified	Oral Stopped:	
	Data Too	And Donald	Data	
_aboratory Investigations:				
_aboratory Investigations: Date Type Ran	ge Date Tes	ted Result	Detai	S



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

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 198513 Seq: 1 Gender: M

Reported: 25/06/2004 Weight: 0.00
Hospitalisation: Age: 99u
Onset Date: DOB:

Outcome: Unknown 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Rep	oort	Deta	ils:
-----	------	------	------

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:

caction betails.									
Preferred Term	Severity	Report Description	Treatment						
	Required Visit to Doctor	Trismus and opisthotonos.							
- 1	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	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 199181	Seq: 1			Gender:	F	
Reported: 19/07/2004				Weight:		
spitalisation:				Age:		
Onset Date:				DOB:		
Outcome: Unknown			С	ausality:	Causality poss	ible
action Details:	0		and December in		T	. 1
Preferred Term	Severity		oort Description		Treatmer	nt .
vollen tongue	Life threatening	Swollen tongue	e, dyspnoea.	Ox	ygen	
/spnoea	Life threatening					
ledicine Details:						
OLIAN (Suspected)			ason:			
Tablet Batch:	100.0 Started:	Milligram	1 time Stopped:	Oral		
aboratory Investigation		ſ	_			
Date Type	Range Date Test	ed Result		Detai	S	
dditional Information:						



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

Re	po	rt	De	tai	ls:
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Case Number: 199263 Seq: 1 Gender: M

Reported: 21/07/2004 Weight: 92.00 Hospitalisation: Age: 44

Onset Date: 15/04/2004 **DOB**: 24/01/1960

Outcome: Recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	F 1	Dose of Luvox reduced to 100mg daily and Solian reduced to 100mg daily.

Medicine Details:

Modifile Botalie.			
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				
	Creatinine				
	Urea				

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:
 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		symptoms, parkinsonism symptoms along	Amisulpride discontinued and Quetiapine commenced 25mg/daily.
Depressive symptom			
Paranoia			
Parkinsonism			

Medicine Details:

AMISULPRIDE (Suspected)		Reason: Schize	ophrenia		
Tablet	400.0 Milligram	Daily	Oral		
Batch:	Started:	St	opped:	1 week	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

History: Chronic paranoid schizophrenia of about 15 years duration, 10 year history of poorly treated iabetes 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.

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

Re	port	: Det	tails:

 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

CLOPINE (Suspected) Reason: Schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: Started: 24/12/2002 Stopped: 07/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 199544

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Reported: 30/07/2004	4	Weight: 0.00						
- Hospitalisation: Admitted to		Age : 31Y						
Onset Date: 25/02/2003		DOB:						
Outcome: Recovered	İ	С	ausality: Causality possible					
eaction Details:								
Preferred Term	Severity	Report Description	Treatment					
Dystonia		Serious dystonias on 3 out of 6 clier	nts. Diazepam, observation and change to other antipsychotic.					
Medicine Details:								
SOLIAN (Suspected)		Reason:						
Batch:	Started:	Stopped:						
Laboratory Investigati	ons:							
Date Type	Range Date Tes	ted Result	Details					
Additional Information	n:							
eport Run: 04/06/2007 04:09PM	Database: pusime02	ADRS004	Page 145 of 278					



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

_aboratory Invest Date Type Additional Inform	Range	Date Tested	Result	Deta	ils
		Date Tested	Result	Deta	ils
		Toda Tadad	T. Danith	Data	
Batch:		Started:		Stopped:	
SOLIAN (Suspected) Tablet		200.0 Mi	Reason:	Oral	
Medicine Details:					
Dystonia		Se	erious dystonias.	Di ch	azepam, observation and ange to other antipsychotic
Preferred Te	erm S	Severity	Report Des		Treatment
					Causality possible
Outcome: Reco				DOB:	
	2/2003			Λαο:	45Y



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Repor Iospitalisat Onset D Outco	ber: 199546 ted: 30/07/2004 ion: Admitted to late: 25/02/2003 me: Recovered	hospital		Weig <i>A</i> D	der: M ght: 0.00 Age: 22Y OOB: lity: Causality possible
eaction D	etails: eferred Term	Severity	Ren	ort Description	Treatment
Dystonia	5161164 161111	Covonty	Serious dystonia	·	diazepam, observation and changed to other antipsycotic
M edicine					
SOLIAN (Sus			Rea	son:	
Table Batc		Started:		Oral Stopped:	
_aborator	ry Investigatio	ons:			
Date	Туре	Range Date Tes	sted Result		Details
Additiona	I Information	:			
eport Run: 04/	06/2007 04:09PM	Database: pusime02	ļ.	ADRS004	Page 147 of 278



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

Re	po	rt	De	tai	ls:
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 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		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:

L	Date	Type	Range	Date Tested	Result	Details
ſ	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:

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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

Case Number: 199760						
Ouse Humber: 100700	Seq: 1				Gender	: M
Reported: 06/08/2004					Weight:	0.00
lospitalisation:					Age:	51
Onset Date: 07/07/2004					DOB	: 01/10/1952
Outcome: Recovered				С	ausality	: Causality possible
eaction Details:						
Preferred Term	Severity		Report De	scription		Treatment
Muscle rigidity						
Psychotic disorder						
Pyrexia						
Tremor						
Medicine Details:						
CLONAZEPAM (Other drug)			Reason:			
Injection	0.5	Milligram	1 time	:		
Injection Batch:	0.5 Started :	Milligram	1 time	Stopped:		
•		Milligram	1 time			
Batch:	Started:	Milligram Milligram	Reason:			
Batch:	Started:		Reason:	Stopped:		
Batch: DIAZEPAM (Other drug)	Started:		Reason:	Stopped:		
Batch: DIAZEPAM (Other drug) Batch:	Started: 0.3 Started:		Reason: As ne	Stopped:		
Batch: DIAZEPAM (Other drug) Batch:	Started: 0.3 Started:	Milligram	Reason: As ne	Stopped:		
Batch: DIAZEPAM (Other drug) Batch: DIAZEPAM (Other drug)	Started: 0.3 Started: 0.5	Milligram	Reason: As ne	Stopped: cessary Stopped:	chizophreni	а
Batch: DIAZEPAM (Other drug) Batch: DIAZEPAM (Other drug) Batch:	Started: 0.3 Started: 0.5 Started:	Milligram	Reason: As ne Reason: Daily	Stopped: cessary Stopped:	chizophreni Oral	a

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

Re	po	rt	De	tai	ls:
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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:

•	todotion Botanor			
	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	Туре	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

Re	port	Detail	ls:
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Gender: F Case Number: 199898 Seq: 1

Weight: 0.00 Reported: 11/08/2004 **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)

	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:			

Reason:

Gastroenteritis and colitis

100.0 Milligram Tablet Oral Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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

Re	po	rt	De	tai	ls	:
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Case Number:200025Seq: 1Gender:MReported:16/08/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 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	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	Туре	Range	Date Tested	Result	Details
16/08/2004	Creatine				Creatinine kinase at 9,000-10,000.

Additional Information:

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Case Number: 200025

Reported: 16/08/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

Weight: 0.00

Hospitalisation: Admitted to h	nospital	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 Mi		Oral		
Batch:	Started:	Stopped			
Laboratory Investigation	ns:				
Additional Information:					
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Date Range: 1 Jan 1960 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AMISULPRIDE, SOLIAN

Ren	ort	Deta	ils:
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Case Number:200034Seq:1Gender:FReported:23/06/2004Weight:0.00Hospitalisation:Admitted to hospitalAge:37

Onset Date: 03/06/2004 DOB: 09/04/1967

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

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		

Laboratory Investigations:

Date	Туре	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 diability.

One week prior to admission the patien was using phentermine resin and herbalife for weight loss and the patient said phentermine resin " makes me feel good".

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

Report Details:	ort Details:
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 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 diability.

One week prior to admission the patien was using phentermine resin and herbalife for weight loss and the patient said phentermine resin " makes me feel good".

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

D	ep	or	f D	lat.	ail	le:
К	eы	U	ιL	æι	all	15.

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:

odotion Botano.							
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	S
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 06/04/2004	Stopped:	10/08/2004

Laboratory Investigations:

Date	Туре	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: 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:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Dystonia.	Ceased Solian.

Medicine Details:

CLOZAPINE (Other drug)			Reason:	Unspecified so	chizophrenia	
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 disease	s 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	Туре	Range	Date Tested	Result	Details

Additional Information:

Attempt to switch to Solain from Clozaril.

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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: 200106 Reported: 18/08/2004 Hospitalisation: Onset Date: 15/07/2004 Outcome: Recovered Reaction Details:	Seq: 1	Ag DO	er: M nt: 139.50 e: 40 eB: 10/12/1963 ty: Causality probable
Medicine Details:			
SOLIAN (Suspected)		Reason:	
Tablet Batch:	500.0 Milligram Started:	Daily Oral Stopped:	0
Laboratory Investigations	:		
Additional Information: Attempt to switch to Solain from Cloz	zaril.		

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

Case Number: 200124 Reported: 18/08/2004	Seq: 1			_	_
	-			Gender:	
				Weight:	
ospitalisation:				Age:	
Onset Date:				DOB:	
Outcome: Unknown			C	ausality:	Causality possible
eaction Details:		т			
Preferred Term	Severity		t Description		Treatment
Blood prolactin increased		Prolactinoma-Blo	od prolactin increas	sed.	
Galactorrhoea					
Pituitary tumour benign					
Prolactinoma		1			
ledicine Details:					
Lexapro (Other drug)		Reas	on:		
Lexapro (Other drug)	10.0	Reas Milligram	on:		
Lexapro (Other drug) Batch:	10.0 Started:	Reas Milligram	on: Stopped:		
			Stopped:	is	
Batch:	Started:	Milligram Reas	Stopped:	is	
Batch:	Started:	Milligram Reas Milligram	Stopped: on: Anxiety neuros Daily	is 31/08/2004	. 0
Batch: SOLIAN (Suspected) Batch:	Started: 50.0 Started: 01/	Milligram Reas Milligram 03/2004	Stopped: on: Anxiety neuros Daily	31/08/2004	
Batch: SOLIAN (Suspected) Batch:	Started: 50.0 Started: 01/	Milligram Reas Milligram 03/2004	Stopped: on: Anxiety neuros Daily	31/08/2004 Detail	s

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

Re	po	rt	De	tai	ls:
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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:

Neaction Details.	caction betails.							
Preferred Term	Severity	Report Description	Treatment					
Fatigue	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 so	chizophrenia	
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	Туре	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

Re	po	rt	De	tai	ls:
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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	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 200429

Reported: 30/08/2004 **Hospitalisation:** Admitted to hospital

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

Weight: 0.00

Age: 21

Onset Date:				DC	B:		
Outcome: Unknown				Causali	ty: Causa	ality possible	
eaction Details:							
Preferred Term	Severity	Rep	ort Descrip	tion		Treatment	
Hypotension	Caused or prolonged inpatient hospitalisation	Experienced hy her to fall.	potension w	hich caused			
Fall	Caused or prolonged inpatient hospitalisation						
Medicine Details: SOLIAN (Suspected)		Rea	son:				
Databa	Otanta di			A annad.			
Batch: Abilify (Suspected)	Started:	Pos	ison:	topped:			
Tablet	15.0	Milligram	Daily	Oral			
Batch:	Started:	Willigram	-	topped:	0		
Laboratory Investigati	ons:						
Date Type	Range Date Test	ted Result		D	etails		
Additional Information	1:						
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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:
 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	prolonged	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	Туре	Range	Date Tested	Result	Details
02/09/2004	Creatine	0-195	27/07/2004	655	

Additional Information:

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

Re	po	rt	De	tai	ls:
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Case Number:200506Seq: 1Gender:MReported:02/09/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 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:

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

Re	po	rt	De	tai	ls	:
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Case Number:200506Seq: 1Gender:MReported:02/09/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 30

Onset Date: 27/07/2004 **DOB**: 24/02/1974

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction 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:

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

Repo	rt D	etai	ls:
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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	neuroleptic malignant syndrome and myocarditis. Electrocardiogram abnormal -	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 M	illigram Daily	Oral	
Batch:	Started:		Stopped:	0
SOLIAN (Suspected)		Reason:	Unspecified schizophrenia	
	800.0 Mi	illigram Daily	Oral	
Batch:	Started:		Stopped:	0
SEROQUEL (Suspected)		Reason:		
Tablet	600.0 Mi	illigram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
07/09/20	04 Other data				

Additional Information:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 166 of 278



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

Report Do	etails:
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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:

touction Dotailor			
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:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	200713	Seq: 1		Ger	nder: U
Reported:	10/09/2004			Wei	ght: 0.00
Hospitalisation:					Age : 99U
Onset Date:					OOB:
Outcome:	Unknown			Causa	ality: Causality possible
Reaction Detai	ls:				
	ed Term	Severity	Rep	ort Description	Treatment
Gastrointestinal I	naemorrhage	Э	Patient experier haemorrhage.	ced a gastrointestinal	
Medicine Det			Rea	son:	
Tablet	,			Oral	
Batch:		Started:		Stopped:	
Laboratory In	vestigatio	ons:			
Date	Type	Range Date Tes	ted Result		Details
Additional Inf	formation				
eport Run: 04/06/200	07 04:10PM	Database: pusime02		ADRS004	Page 168 of 278



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:

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

Medicine Details:

SOLIAN (Suspected)	F	leason:			
Tablet	600.0 Milligram	Daily	Oral		
Batch:	Started: 15/09/2003	Sto	opped:	0	

Laboratory Investigations:

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

Additional Information:

Patient stopped taking Solian 2/12 ago.

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

Rei	port	Deta	ils:
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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:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 201436

Reported: 05/10/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight: 0.00

lospitalisat							e : 69	
Onset D							B : 28/06/1935	
Outco	me: Unknown					Causalit	y: Causality poss	ible
eaction D								
Pro	eferred Term	Se	verity	Repo	ort Description	n	Treatmen	t
Angioedema	a		An	igioneurotic oe spnoea, rash,	edema, swolle	en tongue,		
.			ay	spnoea, rasn,	neadache, in	somnia.		
Dyspnoea								
Headache Insomnia								
Rash								
Swollen tong	THE							
Medicine								
SOLIAN (Sus				Rea				
Table			50.0 Mill	ligram	1 time	Oral		
Bato	:h:	St	arted:		Sto	pped:		
l abayatay								
Date	ry Investigati	Range	Date Tested	Result		Do	etails	
Date	Туре	Kange	Date Testeu	Result		De	taiis	
Additiona	ıl Information	1:						
eport Run: 04/	06/2007 04:10PM	Database: pu	sime02	Д	DRS004		Page 171	of 278



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

Re	po	rt	De	tai	ls	:
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Case Number:201565Seq: 1Gender:FReported:08/10/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 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	Туре	Range	Date Tested	Result	Details
08/10/2004	Magnetic				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. MRI SPINE Report: There is moderate expansion of the cervical cord with moderate hyperintensity on T2 weighted sequences in the central two thrids of the cervical cord and also slight hyperintensity in the central thoracic cord

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.

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:201565Seq: 1Gender:FReported:08/10/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 20Y

Onset Date: DOB:
Outcome: Recovered Causality: Causality possible

prolonged inpatient hospitalisation

Outcome: Recovered
Reaction Details:

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		

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
					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.
08/10/2004	Other data				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.

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.

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Hospitalisation:

Case Number: 201638

Reported: 11/10/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

Weight: 0.00

Age: 40

	ate: 15/08/200			DOB:					
Outcome: Not yet recovered				Causality: Causality possible					
action D			., 1						
	eferred Term	Se	everity		ort Description		Treatment		
Convulsion				vements for tack	ed involuntary leg he past few month ned. Patient also evulsion and episo chest area.		Amisulpride ceased.		
/skinesia									
perhidrosi	is								
edicine LOPIXOL (II				Rea	son: Unspecified	psychosis			
Batc	h:	s	tarted: Stopped:						
TELAZINE (Interaction)			Rea	son:				
						Oral			
Batc		S	tarted:		Stopped	:			
OLIAN (Inte			900 0 M/:II		son: Depression				
Table Batc		9	800.0 Mill	ıyıdılı	Daily	Oral : 25/09/2	2004 0		
	IOL (Other drug)			Rea	son:	0,00/2	· v		
						Oral			
Batc	h:	S	tarted:		Stopped				
horator	y Investigat	ions:							
Date	Type	Range	Date Tested	Result			atalla.		
			Date Tested	. toodit		D	etails		



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

Re	port	Deta	ails:
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 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	threatening	The patient developed confusion, agitation, incontinence, muscle rigidity, hyperreflexia, hyperthermia at 38.5 degrees Celsius and elevated CPK at 515. The diagnosis of neuroleptic malignant syndrome was made.	Amisulpride ceased.
Agitation	Life threatening		
Confusional state	Life threatening		
Hyperreflexia	Life threatening		

Medicine Details:

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

Laboratory Investigations:

Date	Туре	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: 201895	Seq: 1			G	ender: 1	M
Reported: 21/10/2004	•			w	eight: 7	72.00
Hospitalisation:					Age: 7	75
Onset Date: 27/09/2004					DOB:	19/02/1929
Outcome: Recovered		06/10/2	004	Cau	sality: (Causality possible
Reaction Details:						
Preferred Term	Severity		Report De	scription		Treatment
Incontinence	Life threatening					
Muscle rigidity	Life threatening					
Pyrexia	Life threatening					
Medicine Details:			D	11	h *-	
RISPERDAL (Suspected)			Reason:	Unspecified psycl		
5		Milligram	Daily		ral	
Batch:	Started: 22/0	19/2004	Decem	Stopped: 22		
SERENACE (Suspected)	500.0	Microgram	Reason: Daily	Unspecified psycl	nosis	
Batch:	Started: 26/0	-	Dally	Stopped: 26	3/08/2004	
Laboratory Investigations	: :					
Additional Information:						

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Hospitalisation:

Case Number: 202017

Reported: 26/10/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

Weight: 0.00

Age: 17

Onset Dat	t e: 10/09/200)4				DOB:			
Outcom	e: Unknown				С	ausality: (Causality possi	ble	
ction De	tails:								
Prefe	erred Term	Se	verity	Repo	ort Description		Treatmen	t	
lydactyly			va ar in is in	aginally deliver oproximately 4 fant was born no corrective fant is otherwis	er 2004 the mother ed a full term infant 0 weeks gestation. with an extra digit. Treatment planned as healthy. The motino delivery complicion.	The There nd the her is			
edicine D	etails:								
PREXA (Sus	pected)			Rea	son: Unspecified so				
					Oral				
Batch:			tarted:		Stopped:				
ANNABIS PRI	EPARATION (Su	ispected)		Rea	son:				
Batch:		Si	arted: Stopped:						
IISULPRIDE	(Suspected)		Reason:						
						Oral			
Batch:		St	tarted:		Stopped:				
aboratory Date	Investigat Type	ions: Range	Date Tested	Result		Details			
dditional	Informatio	n:							
t Run : 04/06	/2007 04:10PN	1 Database: pu	usime02	P	ADRS004		Page 177	of 278	



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

Re	po	rt	De	tai	ls:
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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
			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	Туре	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

Re	port	Detail	ls:
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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:

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	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	202390	Seq: 1		Gende	r: F
	09/11/2004	-		Weight	
lospitalisation:					: 99u
Onset Date:				DOE	
Outcome:	Unknown			Causality	: Causality possible
eaction Deta	ils:				• •
	ed Term	Severity	Rep	ort Description	Treatment
Electrocardiogra	m QT prolonged		Patient experien	ced QT prolonged.	
Medicine Det			Rea	son:	
				Oral	
Batch:		Started:		Stopped:	0
Laboratory li	nvestigations:				
Date	Type Ra	nge Date Teste	ed Result	Det	ails
Additional In	formation:				
eport Run: 04/06/20	07 04:10PM Data	abase: pusime02		ADRS004	Page 180 of 278



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

Case Number: 202418 Reported: 09/11/2004 ospitalisation: Onset Date:	Seq: 1		Gender: Weight: Age: DOB:	0.00 99U
Outcome: Death, maybe dru	ng		Causality:	Causality possible
eaction Details:				
Preferred Term Overdose	Severity	Report Descriverdose.	ription	Treatment
Medicine Details: SOLIAN (Suspected)	800.0 Mi	Reason: illigram Daily	Oral	
Batch:	Started:		Stopped:	
	no. Data Tantad	Dowlf	Dotoi	lo.
Laboratory Investigations: Date Type Ranger 199/11/2004 Serum drug level	ge Date Tested		Detai de blood level at 5.6mg/l	

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 181 of 278



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:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Oro-facial involuntary dyskinetic 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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Repor Hospitalisati Onset D	ate: me: Not yet re					Age DO	er: F t: 51.00 e: 25 B: 07/05/1979 y: Causality possible
	eferred Term	Sever	tv	Repo	ort Description		Treatment
Amenorrhoe			Pat		ced amenorrhea and	d S	Switched to Olanzapine and then Abilify.
Galactorrhoe	ea						,
Medicine	Dotails:						
	E (Other drug)			Rea	son:		
Bato	h:	Starte	d: 01/05/20	004	Stopped:	08/07/20	004 0
HALOPERID	OL (Other drug)			Rea	son:		
Batc	h:	Starte	d: 01/08/20	004	Stopped:		0
ALPRAZOLA	M (Other drug)			Rea	son:		
Bato	h:	Starte	d: 01/05/20	004	Stopped:	15/05/20	004 0
AMISULPRID	E (Suspected)			Rea	son:	Oral	
Batc	h:	Starte	d:		Stopped:		
Laborator	y Investigat	ions:					
Date	Туре		e Tested	Result		De	etails
Additiona	l Informatio	n:					

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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: 203119	Seq: 1				Gender:	F	
Reported: 29/11/2004					Weight:	51.00	
Hospitalisation:					Age:	25	
Onset Date:						07/05/1979	
Outcome: Not yet recovered	d					Causality possible	
Reaction Details:					•	, , , , , , , , , , , , , , , , , , ,	
Medicine Details:							
EFEXOR-XR (Suspected)			Reason:	Depression			
Capsule, modified release		75.0 Milligram	Daily		Oral		
Batch:	Starte	ed: 07/01/2004	·	Stopped		Contin	
Laboratory Investigations:							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
Laboratory investigations.							
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:
 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:

<u> </u>			
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:

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

Laboratory Investigations:

Date	Туре	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:

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

d to hospital d to hospital O04 DOB: 03/06/1963 red Severity Report Description Treatment Caused or prolonged inpatient hospitalisation	Case Num							
d to hospital Odd Odd DOB: 03/06/1963 Causality: Causality possible Severity Report Description Treatment Caused or prolonged inpatient hospitalisation Reason: Started: Stopped:		ber: 203166	Seq	j: 1			Gene	der: M
red Severity Report Description Treatment Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Reason: Reason: Started: Stopped:	Repo	rted: 01/12/200)4				Weig	jht: 0.00
Severity Report Description Treatment Caused or prolonged inpatient hospitalisation Reason: Started: Stopped:	ospitalisat	ion: Admitted	to hospital				Α	ge : 41
Severity Report Description Treatment Caused or prolonged inpatient hospitalisation nase incr Caused or prolonged inpatient hospitalisation Caused or Reason: Started: Stopped:	Onset D	Date: 09/11/200)4				D	OB : 03/06/1963
Caused or prolonged inpatient hospitalisation nase incr Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Reason: Reason: Started: Stopped:	Outco	me: Recovere	d				Causa	lity: Causality possible
Caused or prolonged inpatient hospitalisation nase incr Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Started: Reason: Started: Stopped:	eaction E	etails:						
prolonged inpatient hospitalisation nase incr Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Reason: Reason: Started: Stopped: Stopped: Started: Stopped: Stopped:	Pr	eferred Term	S	everity	Rep	ort Descripti	on	Treatment
prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Reason: Started: Stopped: Started: Stopped:	Psychotic d	isorder	prolo inpat	onged exa tient tac	acerbation of chycardia, hy	psychotic syr pertension, ra	mptoms, ised CK	Clozaril ceased.
prolonged inpatient hospitalisation Reason: Started: Stopped: Reason: Started: Stopped:	Blood creati	ne phosphokina	prolo inpat	onged tient				
Started: Stopped: Reason: Started: Stopped:	Delirium		prolo inpat	onged tient				
Reason: Started: Stopped:								
Started: Stopped:		Details: AM (Other drug)			Rea	ason:		
		AM (Other drug)		Started:	Rea		opped:	
	CLONAZEPA	AM (Other drug) ch:	;	Started:	_	Sto	opped:	
Reason:	CLONAZEPA Bate	AM (Other drug) ch:	•	Started:	_	Sto	opped:	
	CLONAZEPA Bato DIAZEPAM (Bato	AM (Other drug) ch: Other drug) ch:			_	Sto		
Started: Stopped:	CLONAZEPA Bato DIAZEPAM (AM (Other drug) ch: Other drug) ch:			Rea	Sto ason: Sto		
Reason:	CLONAZEPA Bate DIAZEPAM (AM (Other drug) ch: Other drug) ch: ner drug)	:	Started:	Rea	Stonson:	opped:	
25.0 Milliarom Doily Oral	Bate DIAZEPAM (Bate SOMAC (Oth	AM (Other drug) ch: Ch: ener drug)	:	Started:	Rea Rea	Sto ason: Sto ason:	opped:	
·	Bate Bate SOMAC (Oth	AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected)	:	Started: Started:	Rea Rea Rea	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (AM (Other drug) ch: ch: ner drug) ch: Suspected)	•	Started: Started: 25.0 Milli	Rea Rea igram	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	/2004 0
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (Tabl	AM (Other drug) ch: ch: ner drug) ch: Suspected) et ch:	· · · · · · · · · · · · · · · · · · ·	Started: Started: 25.0 Milli	Rea Rea igram	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	/2004 0
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (Tabl	AM (Other drug) ch: ch: ner drug) ch: Suspected)	ions:	Started: Started: 25.0 Milli Started: 16/12/1	Rea Rea igram 994	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate Bate SOMAC (Oth Bate CLOZARIL (: Tabl Bate Date 01/12/2004	AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected) et ch: ry Investigat Type Creatine	i ons: Range	Started: 25.0 Milli Started: 16/12/1 Date Tested	Rea Rea igram 994 Result	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	
Started: 16/12/1994 Stopped: 14/11/2004 0 ations: Range Date Tested Result Details <200 09/11/2004 665 <200 10/11/2004 1920	Bate DIAZEPAM (Bate SOMAC (Othe Bate CLOZARIL (Table Bate Date 01/12/2004 01/12/2004	AM (Other drug) ch: Other drug) ch: er drug) ch: Suspected) et ch: Type Creatine Creatine	ions: Range <200	Started: 25.0 Milli Started: 16/12/1 Date Tested 09/11/2004 10/11/2004	Rea Rea igram 994 Result 665 1920	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	
Reason:	Bate DIAZEPAM (AM (Other drug) ch: Other drug)			_	Sto		
25.0 Milliarom Doily Oral	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected)	:	Started: Started:	Rea Rea Rea	Storason: Storason:	opped:	
·	Bate Bate SOMAC (Oth Bate CLOZARIL (:	AM (Other drug) ch: ch: ner drug) ch: Suspected)	•	Started: Started: 25.0 Milli	Rea Rea igram	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	/2004 0
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (Tabl	AM (Other drug) ch: ch: ner drug) ch: Suspected) et ch:	· · · · · · · · · · · · · · · · · · ·	Started: Started: 25.0 Milli	Rea Rea igram	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	/2004 0
Started: 16/12/1994 Stopped: 14/11/2004 0	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (Tabl	AM (Other drug) ch: ch: ner drug) ch: Suspected) et ch:	· · · · · · · · · · · · · · · · · · ·	Started: Started: 25.0 Milli	Rea Rea igram	Stores Stores Stores Stores Stores Stores Daily	opped: opped: Oral	/2004 0
Started: 16/12/1994 Stopped: 14/11/2004 0 ations: Range Date Tested Result Details	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (: Tabl Bate Aborato Date	AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected) et ch: ry Investigat Type	i ons: Range	Started: 25.0 Milli Started: 16/12/1 Date Tested	Rea Rea igram 994 Result	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	
Started: 16/12/1994 Stopped: 14/11/2004 0 ations: Range Date Tested Result Details <200 09/11/2004 665	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (Tabl Bate -aborato Date 01/12/2004	AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected) et ch: ry Investigat Type Creatine	ions: Range <200	Started: 25.0 Milli Started: 16/12/1 Date Tested 09/11/2004	Rea Rea igram 994 Result 665	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	
Started: 16/12/1994 Stopped: 14/11/2004 0 ations: Range Date Tested Result Details <200 09/11/2004 665 <200 10/11/2004 1920	Bate DIAZEPAM (Bate SOMAC (Oth Bate CLOZARIL (: Tabl Bate Date 01/12/2004 01/12/2004	AM (Other drug) ch: Other drug) ch: ner drug) ch: Suspected) et ch: ry Investigat Type Creatine	ions: Range <200	Started: 25.0 Milli Started: 16/12/1 Date Tested 09/11/2004 10/11/2004	Rea Rea igram 994 Result 665 1920	Stores Stores Stores Stores Stores Stores Daily	opped: Oral opped: 14/11	

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Case Number: 203166

Reported: 01/12/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

Weight: 0.00

Hospitalisation: Admitted to h	nospital		Age: 41
Onset Date: 09/11/2004			DOB : 03/06/1963
Outcome: Recovered		Caus	ality: 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:	
	600.0 M	illigram Daily	
Batch:	Started: 01/09	/2004 Stopped:	
Laboratory Investigation	าร:		
Additional Information:			
Report Run: 04/06/2007 04:10PM	Database: pusime02	ADRS004	Page 187 of 278



Case Number: 203187

Reported: 01/12/2004

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight: 0.00

ospitalisation:						Αç	je: 99U	
Onset Date:							DB:	
Outcome:						Causali	ty: Causality poss	ible
<u>action Detai</u>							<u> </u>	
Preferre	ed Term	Se	verity		ort Desc		Treatmer	
asculitic rash			Pa an	tient experier d an ankle oe	iced a va: dema.	sculitis-type rash	Referred to a derma	itologist.
edema periphe	al							
Medicine Deta				Pee				
HALOPERIDOL (O	mer arug)			Кеа	son:			
Batch:		St	tarted:			Stopped:		
SOLIAN (Suspecte	d)			Rea	son:			
Tablet			1.0 Gra	am	Daily	Oral		
Batch:		St	tarted:			Stopped:		
_aboratory In	vestigatio	O ns: Range	Date Tested	Result		D	etails	
Additional Inf	ormation	:						
port Run: 04/06/200	7 04:10PM	Database: pu	usime02		ADRS004		Page 188	of 278



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

	s:				
Report Detail Case Number:		Seq: 1		Gend	er: F
	04/01/2005	ocq.			nt: 0.00
ospitalisation:	04/01/2003			_	je: 49
Onset Date:				DC	
	Not yet recovered	d			ty: Causality possible
eaction Deta		u		Causan	ty. Causality possible
	ed Term	Severity	Report De	scription	Treatment
ardive dyskines			Patient developed tard		Solian discontinued.
Medicine Det			Reason:	Schizo-affective type p	sychos
	,	1.0	Gram Daily	Oral	-,
Batch:		Started:	S TERM	Stopped:	
.aboratory Ir	nvestigations:				
_aboratory Ir	nvestigations: Type Ran	ge Date Test	ed Result	D	etails
		ge Date Test	ed Result	D	etails

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

Re	po	rt	De	tai	ls	:
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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:

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 TE	ERM Stopped:

Laboratory Investigations:

<u> Luboi atoi</u>	y ilivostiga				
Date	Туре	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

Repo	ort D	etail	s:
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Case Number: 204194 Seq: 1 Gender: M

Reported: 13/01/2005 Weight: 0.00 Hospitalisation: Age: 19

Onset Date: 22/12/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

AMISULPRIDE (Suspected) Reason: Unspecified psychosis

600.0 Milligram Daily Oral

Batch: Started: 21/12/2004 Stopped: 22/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 191 of 278



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

Report Details:

Case Number:204253Seq: 1Gender: MReported:14/01/2005Weight:80.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: DOB: 11/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	prolonged	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		Ora	al	
Batch:	Started:		L TERM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecified schize	phrenia	
	400.0	Milligram	Daily	Ora	al	
Batch:	Started:		STERM	Stopped:	0	
OLANZAPINE (Suspected)			Reason:			
	20.0	Milligram	Daily			
Batch:	Started:		L TERM	Stopped:	0	

Laboratory Investigations:

Date	Туре	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. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

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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:204253Seq: 1Gender: MReported:14/01/2005Weight:80.00Hospitalisation:Admitted to hospitalAge: 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		Oı	al	
Batch:	Started:	L TE	RM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecified schiz	ophrenia	
	400.0	Milligram	Daily	Oi	al	
Batch:	Started:	STE	ERM	Stopped:	0	
OLANZAPINE (Suspected)			Reason:			
	20.0	Milligram	Daily			
Batch:	Started:	L TE	RM	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. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 193 of 278



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

Report Details:

Case Number: 204253 Gender: M Seq: 1 Reported: 14/01/2005 Weight: 80.00

Hospitalisation: Admitted to hospital Age: 29

DOB: 11/09/1975 Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
	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 schizop	hrenia	
	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. Literautre Report: Brakoulias V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal pf Psychiatry. August 2005;39(8) 738

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

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Rei	oori	: De	taı	IS:

Case Number:204323Seq: 1Gender: MReported:18/01/2005Weight: 70.00Hospitalisation:Admitted to hospitalAge: 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:

McGicilic Details.				
AROPAX (Suspected)		Reason: D	epression epression	
			Oral	
Batch:	Started:		Stopped:	
SOLIAN (Suspected)		Reason: D	Depression	
			Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

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

Additional Information:

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

Re	po	rt	De	tai	ls	:
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Case Number:204818Seq: 1Gender:MReported:02/02/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 53

Onset Date: 12/08/2004 **DOB**: 18/11/1950

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		arrest.	Cessation of suspected offending agents.
	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 7	TERM Stopped : 20/08/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 205195

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Repor	tea: 11/02/2005	1		vveignt: 0.00				
lospitalisati	ion:				Αç	ge: 16		
Onset D	ate:				DC	OB:		
Outco	me: Unknown				Causali	ity: Causality possible		
eaction D	etails:							
	eferred Term	Se	everity	Repo	rt Description	Treatment		
Vision blurre	ed				rienced blurred vision for taking Amisulpride.			
Medicine								
DIAZEPAM (DIAZEPAM (Other drug)			Reas	son:			
Bato	Batch: Started:				Stopped:			
SOLIAN (Sus	pected)			Reas	on: Unspecified schizophr	renia		
					Oral			
Bato	h:	S	tarted:	Stopped:				
	y Investigatio		Data Tarkad	D# [2.4.9.		
Date	Туре	Range	Date Tested	Result	D	Details		
Additiona	I Information	:						
eport Run: 04/0	06/2007 04:10PM	Database: pu	usime02	Al	DRS004	Page 197 of 278		



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

Report	: Details:
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Case Number:205392Seq: 1Gender:MReported:17/02/2005Weight:57.00Hospitalisation:Admitted to hospitalAge: 58

Onset Date: DOB: 29/08/1946

Outcome: Recovered 13/01/2005 Causality: Causality probable

Reaction Details:

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

Medicine Details:

NORVASC (Other drug)			Reason:	Essential benign hypertension	
	10.0	Milligram	Daily		
Batch:	Started:	L TE	ERM	Stopped:	
DUCENE (Other drug)			Reason:	Anxiety neurosis	
	4.0	Milligram	Daily		
Batch:	Started:	L TE	ERM	Stopped:	
CARTIA (Other drug)			Reason:	Acute,ill-def cerebrovascular disease w/o hyperte	
	100.0	Milligram	Daily		
Batch:	Started:	L TE	ERM	Stopped:	
Mirtazon (Other drug)			Reason:	Depression	
	60.0	Milligram	Daily		
Batch:	Started:	L TE	-DM	Stopped:	

Laboratory Investigations:

Laboratory investigations.						
	Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	205392	Seq: 1					Gender:	M	
Reported:	17/02/2005						Weight:	57.00	
Hospitalisation:	Admitted to hospit	al					Age:	58	
Onset Date:							DOB:	29/08/1946	
Outcome:	Recovered		13/0	1/2005		С	ausality:	Causality prob	able
Reaction Detai	ls:								
Medicine Det	ails:								
	OTINE PATCHES 14M	G (Other drug)		Reas	on:	Smoker			
		14.0	Milligram		Daily				
Batch:		Started:		L TERM		Stopped:			
SOLIAN (Suspecte	ed)			Reas	on:	Unspecified so	hizophrenia		
Tablet		500.0	Milligram		Daily		Oral		
Batch:		Started:		L TERM		Stopped:	09/01/2005	5	
Laboratory In	vestigations:								
Additional Inf	formation:								
	·-								
eport Run: 04/06/200	07 04:10PM Databa	ase: pusime02		Al	DRS00	04		Page 199	of 278



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	205432	Seq: 1		Ger	nder: U	
Reported:	22/02/2005			Wei	ight: 0.00	
lospitalisation:				,	Age: 99u	
Onset Date:				Γ	DOB:	
Outcome:	Unknown			Causa	ality: Causality possible	
eaction Detai						
	ed Term	Severity		ort Description	Treatment	
Tardive dyskines	ia		The patient deve dyskinesia.	eloped a tardive		
Medicine Det SOLIAN (Suspecte			Rea	son:		
				Oral		
Batch:		Started:		Stopped:		
Laboratory In	vestigatio	ons:				
Date	Туре	Range Date Te	ested Result		Details	
Additional Information:						
eport Run: 04/06/20	07 04:10PM	Database: pusime02	,	ADRS004	Page 200 of 278	



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:

Castion Betailer			
Preferred Term	Severity	Report Description	Treatment
	to Doctor		Ceased Solian and resumed Zyprexa.

Medicine Details:

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 Milligrar	m Daily	Oral	
Batch:	Started: 15/09/2004		Stopped: 15/12/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has schizoaffective illness with residual symptoms of chronic condition.

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

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	Туре	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: 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:

<u> </u>			
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	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:206365Seq: 1Gender:UReported:31/03/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 45Y

Onset Date: DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Suicide attempt		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	Туре	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 Detail	s:
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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:

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

Medicine Details:

Medicine Details.					
CLOZAPINE (Other drug)		Reason:			
Batch:	Started:	Stop	ped:		
SODIUM VALPROATE (Other drug)		Reason:			
Batch:	Started:	Stop	ped:		
SOLIAN (Suspected)		Reason:			
Tablet	800.0 Milligram	Daily	Oral		
Batch:	Started: 01/05/2004	Stop	ped:	0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
31/03/2005	Radiololgy				anuerysm of right anterior cerebral artey

Additional Information:

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 206904
 Seq: 1
 Gender:
 F

 Reported:
 11/04/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 24

Onset Date: 15/03/2003 **DOB**: 22/02/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

1 Seq: 1		Gend					
2005		Weigh	nt: 0.00				
		Age: 99u					
		DOB:					
wn		Causali	ty: Causality possible				
n Severity	Repor	Description	Treatment				
			Cabergoline - but no response				
	Reaso	n:					
Started:		Stopped:					
gations:							
Range Date Teste	ed Result	De	etails				
	wn Severity Started: Range Date Teste	wn Severity Report Reaso Started: Range Date Tested Result	Weight Ag DO Causalition Severity Report Description Reason: Started: Stopped:				

ADRS004

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

Re	po	rt	De	tai	ls:
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 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:

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

Medicine Details:

CLOPINE (Suspected)		Reason:	Unspecified so	hizophrenia	
Tablet	350.0 Milligra	am Daily		Oral	
Batch:	Started: 30/04/2004	1	Stopped:	02/04/2005	0
FLUOXETINE HYDROCHLORIDE (Se	uspected)	Reason:	Depression		
	20.0 Milligra	am Daily		Oral	
Batch:	Started:	L TERM	Stopped:		0
AMISULPRIDE (Suspected)		Reason:	Schizophrenia		
Tablet	300.0 Milligra	am Daily		Oral	
Batch:	Started: 30/10/2002	2	Stopped:		

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

Re	po	rt	De	tai	ls:
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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:

	<u> </u>				
Preferred Term		Severity	Report Description	Treatment	
	Parkinsonism	ability	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	Туре	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

 Case Number:
 208063
 Seq: 1
 Gender: U

 Reported:
 20/05/2005
 Weight: 0.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	208261	Seq: 1			Gender:	F	
Reported:	30/05/2005				Weight:	0.00	
spitalisation:	Admitted to h	nospital			Age:	99u	
Onset Date:					DOB:		
Outcome:	Unknown				Causality:	Causality poss	ible
action Detai	ls:						
Preferre	ed Term	Severity	Re	port Description		Treatmer	nt
olitis ulcerative		Caused or prolonged inpatient hospitalisation		perienced ulcerati	ive colitis.		
edicine Det			R	eason:			
		1.0	Gram	Daily	Oral		
Batch:		Started:		Stopp	ed:		
aboratory In	vestigatio	ns:					
Date	Туре	Range Date Test	ed Result		Deta	ils	
	,,						
dditional Inf	formation:						
ort Run: 04/06/200	07 04:10PM	Database: pusime02		ADRS004		Page 211	of 278



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:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Tachycardia		- F	Clozaril dose reduced to 200mg daily.
Neutropenia Orthostatic hypotension Pyrexia			

Medicine 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	Туре	Range	Date Tested	Result	Details
21/06/2005	Blood pressure		11/05/2005	(sitting):	
21/06/2005	Blood pressure		13/05/2005	(sitting): 83/50	
21/06/2005	Blood pressure		27/05/2005	(sitting):	
21/06/2005	Blood pressure		02/07/2005	(sitting):	
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:

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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: 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:

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	Туре	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		Body temperature
21/06/2005	Other data		13/05/2005	35.4 degrees	Body temperature

Additional Information:

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

Onset Date: 20/05/2005 Outcome: Unknown	Seq: 1		Gender: M Weight: 0.00 Age: 25 DOB: 06/04/1980 Causality: Causality probable
spitalisation: Onset Date: 20/05/2005 Outcome: Unknown			Age : 25 DOB : 06/04/1980
Outcome: Unknown			DOB : 06/04/1980
Outcome: Unknown			
Outcome: Unknown action Details:			Causality: Causality probable
action Details:			
edicine Details:		Reason:	
Detale:			
Batch:	Started:		Stopped:
CLOZARIL (Suspected)			Unspecified schizophrenia
	Started: 225.0 Millio Started: 11/05/20	gram Daily	
Tablet Batch: Batch:	225.0 Millig Started: 11/05/20	gram Daily 005	Unspecified schizophrenia Oral Stopped: 14/06/2005 0
Tablet Batch: Batch:	225.0 Millig Started: 11/05/20	gram Daily	Unspecified schizophrenia Oral Stopped: 14/06/2005 0

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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:
 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:

todotion Dotano			
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:	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	Туре	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:

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

 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:

١	V	e	di	Cİ	n	e C)e	tai	IS
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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	Туре	Range	Date Tested	Result	Details
21/06/2005	Neutrophils		03/06/2005	0.01	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10^9/L
21/06/2005	Neutrophils		05/06/2005	0.00	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10^9/L
21/06/2005	Neutrophils		04/06/2005	0.01	(08 Sep 2003-pre treatment) Neutrophil Cell Count 4.3 x 10^9/L

Additional Information:

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

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Report Details:		
Case Number: 208880	Seq: 1	Gender

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 Detai	IIS:
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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	Туре	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:

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

Ran	ort	Deta	ile:
Reb	DIL	Deta	115.

 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 Deta	ails:
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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	Туре	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 x 10^9/L.
21/06/2005	White blood cells		02/06/2005	1.00	(08 Sep 2003- pre treatment) White Blood Cell count 7 x 10^9/L.
21/06/2005	White blood cells		03/06/2005	0.3	(08 Sep 2003- pre treatment) White Blood Cell count 7 x 10^9/L.

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 D	etails:						
Repo ospitalisat Onset I Outco	Date: 31/05/200 ome: Not yet re)5	1		С		0.00
eaction D	Details:						
Medicine DIAZEPAM (Ro	ason:		
DIAZLI ANI (Other drug)			Ne	u3011.		
Bate		St	tarted:	5.	Stopped:		
HALOPERID	OL (Other drug)			Ke	ason:		
Bate	ch:	Si	tarted:		Stopped:		
CLOZARIL (Suspected)			Re	ason:		
Tabl	et		500.0 Milli	gram	Daily	Oral	
Bate	ch:	St	tarted: 08/09/2	003	Stopped:	31/05/2005	5
	DE (Suspected)				ason:		
Tabl	et		200.0 Milli	gram	Daily	Oral	
Bate	ch:	Si	tarted:		Stopped:		
aborato	ry Investigat	tions:					
Date	Туре	Range	Date Tested	Result		Detai	ls
21/06/2005	White blood cells		04/06/2005	0.5	(08 Sep 2003- pre trea	tment) Whi	te Blood Cell count 7 x 10^9/L.
21/06/2005	White blood cells		05/06/2005	0.5	(08 Sep 2003- pre trea	atment) Whi	te Blood Cell count 7 x 10^9/L.
	•				•		
N dditions	al Informatio	n:					
Auditiona	ii iiiioriiialio	11.					

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 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:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 220 of 278



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

Report	Details:
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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		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/dis ability		

Medicine Details:

SOLIAN (Suspected)			Reason:	
Tablet	400.0	Milligram	2 times	Oral
Batch:	Started:		Stopped	:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Hospitalisation:

Case Number: 209811

Reported: 13/07/2005

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

Weight: 0.00

Age: 29

Onset Date:		DOB : 27/05/1976				
Outcome: Unknown				Causality:	Causality poss	ible
eaction Details:						
Preferred Term	Severity	Rep	ort Description	on	Treatmer	nt
lypertension		The patient exp possible drug in treatment. Patie blood pressure blood pressure				
ledicine Details:						
VENLAFAXINE HYDROCHLOR	IDE (Suspected)	Rea	ison:			
Batch:	Started:		Sto	pped:		
AMISULPRIDE (Suspected)		Rea	ison:			
				Oral		
Batch:	Started:		Sto	pped:		
CLOPINE (Suspected)			ison:			
Tablet		Milligram	Daily	Oral		
Batch:	Started: 08	/06/2004	Sto	pped:		
.aboratory Investigat Date Type	ions: Range Date Tes	sted Result		Details		
additional Informatio	n:					
ort Run: 04/06/2007 04:10PM	1 Database: pusime02		ADRS004		Page 222	of 278



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

Ren	ort	Deta	ils:
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Case Number: 210546 Seq: 1 Gender: F

 Reported:
 09/08/2005
 Weight:
 0.00

 Hospitalisation:
 Age:
 99U

Onset Date: 15/06/2005 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Patient experienced galactorrhea, amenorrhoea, increased prolactin levels.	Ceased Solian.
Amenorrhoea			
Blood prolactin increased			

Medicine Details:

LITHIUM CARBONATE (Other drug)			Reason:	Unspecified schizophrenia	
	900.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	
OROXINE (Other drug)			Reason:	Myxedema	
	50.0	Microgram	Daily		
Batch:	Started:	1	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	Туре	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

Re	po	rt	De	tai	ls:
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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:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	prolonged	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:

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

Re	po	rt	De	tai	ls	:
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Case Number: 211240 Seq: 1 Gender: F

Reported: 31/08/2005 Weight: 0.00 Hospitalisation: Age: 16

Onset Date: 25/07/2005 **DOB**: 30/05/1989

Outcome: Recovered Causality: Causality probable

Reaction Details:

100.00.00.			
Preferred Term	Severity	Report Description	Treatment
	prolonged	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	Туре	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:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisatio Onset Da	d: 21/09/200 n: te: 09/09/200 e: Recovere)5	1	10/09/2005		c		0.00
	erred Term	Se	verity	Repo	ort Des	scription		Treatment
Muscle spasm				tient experien			I Tr	eated with Beztropine 2mg
			dy	stonia.		, ,	IM	I.
Dystonia								
Medicine D	etails:							
VALIUM (Other				Rea	son:			
Batch:		St	arted:			Stopped:		
SOLIAN (Susp	ected)			Rea	son:	Depression		
Tablet			400.0 Mil	ligram	Daily	_		
Batch:		St	Started: 09/10/2004 Stopped: 10/10/				10/10/200	4
Laboratory Date	Investigat Type	i ons: Range	Date Tested	Result			Deta	ils
Additional	Informatio	n:						

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Report Details:

Case Number: 212075

Reported: 29/09/2005

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Weight: 0.00

lospitalisati	on:					Ag	je : 69		
Onset Da	ate: 28/03/200)5		DOB : 10/04/1935					
Outcor	ne: Recovere	:d				Causali	ty: Causality probable		
action D	etails:								
Pre	eferred Term	Se	everity	Rep	ort De	escription	Treatment		
iarrhoea			1	00 mg bd after	4 day	sulpride 50 mg bd to vs, then 200 mg bd vere diarrhoea.	Amisulpride ceased.		
herapy regi	men changed								
ledicine l		-		D.					
SODIUM VAL	PROATE (Other of	ırug)		Rea	son:				
Batcl	h:	s	Started:			Stopped:			
METFORMIN	HYDROCHLORIC	E (Other drug)		Rea	son:	Diabetes mellitus			
Patal		c	Norted.			Stannadi			
Batcl MICARDIS (O			Started:	Rea	son:	Stopped: Essential benign hyper	rtension		
	g,								
Batcl	h:	S	Started:			Stopped:			
TETRABENA:	ZINE (Other drug)		Rea	son:	Disturbance of coordin	ation		
Batcl	h·	¢	Started:			Stopped:			
			otarteu.			оторрец.			
aborator Date	y Investigat Type	tions: Range	Date Tested	d Result		D	etails		
Date	Турс	range	Date Tester	a result			Ctans		
dditiona	l Informatio	n:							
ort Run : 04/0	06/2007 04:10PM	M Database: p	usime02	,	ADRS0	004	Page 227 of 278		



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

Report Details:				
Case Number: 212075 Reported: 29/09/2005 Hospitalisation: Onset Date: 28/03/2005 Outcome: Recovered Reaction Details:	Seq: 1			0.00
Medicine Details:				
AMISULPRIDE (Suspected)	400 O Milliana		pecified psychosis	
Batch:	400.0 Milligram Started: 17/03/2005	Daily S	Oral Stopped: 23/03/2005	0
Laboratory Investigations:				
Additional Information:				

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

Re	po	rt	De	tai	ls:
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Case Number:212457Seq: 1Gender:FReported:12/10/2005Weight:0.00Hospitalisation:Required a specialist consultationAge: 35

Onset Date: DOB: 25/11/1969

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Tremor		ataxia.	Amisulpride ceased temporarily. Will recommence with dose kept below 600mg.
Coordination abnormal	Incapacity/dis ability		

Medicine Details:

SOLIAN (Suspected)		Reason: Unspec	cified neurosis
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Sto	pped:

Laboratory Investigations:

Date	Туре	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	Detail	ls:
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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:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Tongue oedema	ability	experienced swelling of the tounge and an increase in difficulty in breathing. She was reffered to A & E Dept. of Queanbeyn	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/dis ability		

Medicine Details:

SOLIAN (Suspected)		Reason:		
Batch:	Started:	Sto	pped:	
SOLIAN (Suspected)		Reason:		
Capsule	400.0 Milligram	1 time	Oral	
Batch: ?	Started: 14/04/2004	Sto	pped: 14/04/2004	
SOLIAN (Suspected)	ı	Reason:		
Capsule	400.0 Milligram	1 time	Oral	
Batch: ?	Started: 14/04/2004	Sto	pped: 14/04/2004	0
SOLIAN (Suspected)	ı	Reason:		
Capsule	400.0 Milligram	1 time	Oral	
Batch: ?	Started: 14/04/2004	Sto	pped: 14/04/2004	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

spitalisation:	: 213117	Seq:	1			Gender: F
•	: 04/11/2005					Weight: 0.00
Onset Date	:					Age : 38Y
Onset Date	: 18/10/2005					DOB:
	: Not yet reco	overed			C	ausality: Causality possible
action Deta						
	red Term		verity		ort Description	Treatment
alactorrhoea		Cause prolono inpatie hospita	ged	The patient was	lactating.	Amisulpride dose reduced.
ledicine De	taile:					
CLOMIPRAMINE		IDE (Other drug	g)	Rea	ason:	
Batch:		Sta	arted:		Stopped:	
CLONAZEPAM (C	Other drug)			Rea	ison:	
Batch:		Sta	arted:		Stopped:	
ACTULOSE (Otl	her drug)			Rea	ison:	
Batch:		St:	arted:		Stopped:	
SODIUM VALPRO	OATE (Other dru		ii tou.	Rea	ason:	
	27 ti = (0 tillot tillo	-9/				
Batch:		Sta	arted:		Stopped:	
	41 41					
aboratory I	nvestigatio _{Type}		Date Teste	d Result	1	Details
Dute	actin	range	Date Tester	d Result	4700	Details



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

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	d			Causality:	Causality possible
Reaction Detail	ils:					
Medicine Det	aile:					
	ENNA (Other drug)			Reason:		
	ζ,					
Batch:		Started:			Stopped:	
ASCORBIC ACID	(Other drug)			Reason:		
Batch:		Started:			Stopped:	
SOLIAN (Suspecte	ed)			Reason:		
		800.0 M	illigram	Daily	Oral	
Batch:		Started: 08/10/	/2005		Stopped:	
CLOZAPINE (Susp	pected)			Reason:		
Tablet		400.0 M	illigram	Daily	Oral	
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
Laboratory	ivestigations.					
Additional Int						
Patient also taking	raraciioc.					

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 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:

Neaction 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	Туре	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: 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:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	Patient developed ulcerative colitis.	

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	Milligram	Oral	
Batch:	Started: 30/06/2004	Stopped: 10/06/2005	
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
	Milligram	Daily Oral	
Batch:	Started: 15/05/2005	Stopped: 15/08/2005	
CELEBREX (Suspected)		Reason:	
Capsule	1.0 Dose Unspec	ecified Oral	
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Gram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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

Re	po	rt	De	tai	ls	:
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Case Number: 214662 Seq: 1 Gender: F

Reported: 06/01/2006 Weight: 0.00 Hospitalisation: Age: 49

Onset Date: 01/04/2005

Outcome: Recovered

DOB: 09/12/1955

Causality: Causality certain

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Arthralgia	ability		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	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.

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Report Details:

Case Number: 214725 Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

ospitalisation:			weight: 100.00		
			Age : 23		
Onset Date: 15/10/2004	,	DOB : 24/06/1981			
Outcome: Not yet reco	overed	Causality: Causality possible			
eaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Amenorrhoea		Patient presented with 1 year amenorrhoea. Investigation reveal Prolactin increased.	Will use combined oral contraception pill to restore Citrogen and progestogen.		
Blood prolactin increased		<u> </u>			
Medicine Details:					
SOLIAN (Suspected)		Reason: Unspecified	d schizophrenia		
Batch:	Started:	Stoppe	ed:		
Benztrop (Suspected)		Reason:			
Batch:	Started:	Stoppe	ed:		
		THE PART I	Date		
_aboratory Investigation Date Type 09/01/2006 Magnetic	Ons: Range Date Tes	sted Result MRI shows no pitu	Details itary tumor.		
	Range Date Tes	otou i toouit	2010110		



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

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

 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

Outcome: Recovered

11/09/2005

DOB: 16/04/1945

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Musculoskeletal stiffness	Coverny	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.		
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:

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

Report Detail	s:
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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 metaboli	c diseases
Batch:	Started:		Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	Unspecifid affective ps	sychosis
Batch:	Started:		Stopped:	
FLUVOXAMINE MALEATE (Other drug)		Reason:	Depression	
Batch:	Started:		Stopped:	0
TRIMETHOPRIM (Other drug)		Reason:	Othr diseases of urina	ry tract
Batch:	Started:		Stopped:	0

Laboratory Investigations:

Date	Туре	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.

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

Re	po	rt	De	tai	ls:
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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:

Nouvilla Details.						
	Preferred Term	Severity	Report Description	Treatment		
	Hypertonia					
	Hyporeflexia					
	Influenza like illness					
	Pyrexia					

Medicine Details:

MULTIVITAMINS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)		Reason: Unspecified schizophrenia	
	800.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

PMH: Schizophreniform disorder with somatic delusions, bipolar disorder, intellectual disability, anxiety/panic attacks & hypercholesterolaemia.

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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:
 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
	inpatient hospitalisation	incontinence of urine and faeces, feeling	Ceased Amisulpride. Lorazepam given as muscle relaxant.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IRBESARTAN (Other drug)		Reason:	Essential benign hypertensio	n
Batch:	Started:		Stopped:	
ATENOLOL (Other drug)		Reason:	Essential benign hypertensio	n
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	Туре	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.

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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: 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.

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

Rep	ort	Detail	ls:
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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 hyperten	sion
Batch:	Started:		Stopped:	
ATENOLOL (Other drug)		Reason:	Essential benign hyperten	sion
Batch:	Started:		Stopped:	
COLCHICINE (Other drug)		Reason:	Gout	
Batch:	Started:		Stopped:	0
AMISULPRIDE (Suspected)		Reason:	Unspecified schizophrenia	ì
	400.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 242 of 278



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

Re	po	rt	De	tai	ls:
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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 hyperten	sion
Batch:	Started:		Stopped:	
ATENOLOL (Other drug)		Reason:	Essential benign hyperten	sion
Batch:	Started:		Stopped:	
COLCHICINE (Other drug)		Reason:	Gout	
Batch:	Started:		Stopped:	0
AMISULPRIDE (Suspected)		Reason:	Unspecified schizophrenia	ì
	400.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

PMH: HTN, diet controlled type 2 DM, gout, renal impairment and schizophrenia.

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 243 of 278



Report Details:

Case Number: 215018

Reported: 17/01/2006

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight: 0.00

lospitalisat	ion:				Ag	e : 46
Onset D	ate: 15/12/2005				_	B : 24/07/1959
Outco	me: Unknown				Causali	ty: Causality possible
eaction D	etails:					
Pr	eferred Term	Se	verity	Report Desc	ription	Treatment
Internationa	normalised ratio	incre	s	ratient developed increa he was treated with Soli xperienced unintentiona	an , she had also	
Weight decr	eased					
Medicine	Details:					
SOLIAN (Sus	spected)			Reason:		
Bato	h:	St	arted:		Stopped:	
	<u>y Investigațio</u>			ı		
Date	Туре	Range	Date Tested	Result	De	etails
Additiona	I Information					
eport Run: 04/	06/2007 04:10PM	Database: pu	ısime02	ADRS004		Page 244 of 278



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

Re	oa	rt	De	tai	ls:
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Case Number:215271Seq: 1Gender:MReported:24/01/2006Weight:0.00Hospitalisation:Required a visit to the doctorAge: 20

Onset Date: 31/10/2005 **DOB:** 10/10/1985

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Parkinsonian gait		decreased arm swing and cogwheeling.	Benztropine given with little effect. Solian ceased, changed to Olanzapine.
Cogwheel rigidity			

Medicine Details:

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	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 245 of 278



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

Report Details:	Re	po	rt	De	tai	ls:
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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:

•	todotion Botanoi				
	Preferred Term	Severity	Report Description	Treatment	
	Oculogyration		Oculogyration	benztropine	

Medicine Details:

nealence 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	Туре	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

Ren	ort	Deta	ils:
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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:

Veaction Details.			
Preferred Term	Severity	Report Description	Treatment
Muscle spasms		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	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 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
	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	Туре	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: 217783 Reported: 01/05/20 Iospitalisation: Onset Date: Outcome: Unknown			DOE	: 0.00 : 48Y		
eaction Details: Preferred Term	Severity	Reno	ort Description	Treatment		
Breast cancer female	Life threatening	Breast cancer	·	astectomy, chemotherapy		
Medicine Details:						
SOLIAN (Suspected)		Reason: Unspecified schizophrenia				
Batch:	Started: 15	/06/2002	Oral Stopped:	0		
Laboratory Investiga	ations: Range Date Tes	ted Result	Deta	ails		

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 249 of 278



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

Report Details:	Re	po	rt	De	tai	ls:
-----------------	----	----	----	----	-----	-----

 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:

<u>teaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		Patient developed galactorrhoea. Also has lassitude, depression, weight gain, decreased libido and amenorrhoea.	Referred to endocrinologist.
Amenorrhoea			
Depression			
Galactorrhoea			
Libido decreased			
Weight increased			

Medicine Details:

SOLIAN (Suspected)

Reason:

100.0 Milligram Daily Oral

Batch: Started: 15/04/2005 Stopped: 11/04/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
01/05/2006	Prolactin				Prolactin 2802.

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:
 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:

Caction Dotaile			
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.	

Medicine Details:

AMISULPRIDE (Suspected) Reason: Unspecified psychosis

800.0 Milligram Daily Oral

Batch: Started: 05/04/2006 Stopped: 09/04/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Complained that his eyes were being "pulled back", into his head.

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

Ran	ort	Deta	ile:
Reb	DIL	Deta	115.

Case Number:217991Seq: 1Gender:FReported:04/05/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 21

Onset Date: DOB: 15/07/1984

Outcome: Recovered 17/03/2006 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		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	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 252 of 278



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

006 vn Se	everity Par	Repo teint develope	Causa ort Description	Age: 14 DOB: 17/12/1991 ality: Causality possible Treatment
'n			Causa ort Description	ality: Causality possible
			ort Description	
Se			•	Treatment
			•	
l				
		Reas	son:	
			Stopped:	0
CHLORIDE (Other	r drug)	Reas	son:	
S	Started:		Stopped:	
		Reas	son: Unspecified psychol	sis
S	Started:		Stopped:	0
		Reas	son:	
S	Started:		Stopped:	
ations:				
Range	Date Tested	Result		Details
	CHLORIDE (Othe	Started: CHLORIDE (Other drug) Started: Started: Started:	Started: CHLORIDE (Other drug) Reas Started: Reas Started: Reas Started:	Started: Stopped: CHLORIDE (Other drug) Reason: Started: Stopped: Reason: Unspecified psychol Started: Stopped: Reason: Started: Stopped:

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 253 of 278



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	19/05/2006 02/05/2006 Unknown	Seq: 1			0.00
Medicine Deta	ails:				
QUETIAPINE (Other			Reason:	Unspecified psychosis	
Batch:		Started:		Stopped:	
FLUTICASONE PR	OPIONATE (Other dr	ug)	Reason:	Asthma	
Batch:		Started:		Stopped:	
RISPERIDONE (Su	spected)		Reason:		
Batch:		Started:		Stopped:	
AMISULPRIDE (Su	spected)		Reason:	Oral	
Batch:		Started:		Oral Stopped:	
Laboratory In	vestigations:				
Additional Inf Report 218503 is t	Formation: he second sequence	e to this report.			

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 254 of 278



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Severity	Report Description	Weight: Age: DOB: Causality:	99u	
Severity		DOB:		
Severity				
Severity		Causality:	Causality possible	
			- ·	
olonged			Treatment	
	QT prolongation			
1g)	Reason:			
Started:	Stoppe	d:	0	
	Reason:			
Started:	Stoppe	d:		
	Reason:			
1200.0	Milligram	Oral	ıl	
Started:	Stoppe	d:	0	
	ted Result	Detai	is	
	Started: 1200.0 Started:	Started: Stoppe Reason: Started: Stoppe Reason: 1200.0 Milligram Started: Stoppe	Started: Stopped: Reason: Started: Stopped: Reason: 1200.0 Milligram Oral Started: Stopped:	

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 255 of 278



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

_			_		
Re	no	rt	De	ate.	ils:

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	Туре	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

Re	po	rt	De	tai	ls:
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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:

duction Botano.			
Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased			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	Туре	Range	Date Tested	Result	Details
19/06/2006	Prolactin		26/04/2006	385	Protactin - 2802.

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:
 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:

todotion Botano.			
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:

<u>wiedicine Details:</u>							
VENLAFAXINE HYDROCHLORIDE (Other	er 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	Туре	Range	Date Tested	Result	Details
27/06/2006	Magnetic				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.

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

Re	po	rt	De	ta	il	s:

 Case Number:
 219521
 Seq: 1
 Gender:
 F

 Reported:
 27/06/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 24Y

 Onset Date:
 DOB:

Outcome: Unknown 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 (Oth	ner 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	Туре	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.

Report Run: 04/06/2007 04:10PM Database: pusime02 ADRS004 Page 259 of 278



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

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

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:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
, ,	prolonged	Solid erythematous rash around ankles on ankles and erythematous plaques on anterior thighs.	Amisulpride ceased

Medicine Details:

AMISULPRIDE (Suspected)
Tablet 700.0 Milligram Daily Oral

Batch: Started: 23/06/2006 **Stopped:** 07/07/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 04:11PM Database: pusime02 ADRS004 Page 260 of 278



Case Number: 220345

Reported: 25/07/2006

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Weight: 90.00

e: 22/06/2006 e: Recovered ails: rred Term apular	Se	everity	28/06/2006		OOB: 28/06/1981 Ality: Causality possible			
ails: rred Term	Se	everity		Causa	inty: Causanty possible			
rred Term	Se	verity						
	36		Dong	ort Description	Treatment			
Rash maculo-papular			Report Description Treatment 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. Treatment Stopped Solian, treated verification phenergan.					
			Rea	son: Otr spec symp psyc	nopathol nec			
	Si	tarted:		Stopped:				
her drug)			Reason: Depression					
	_							
oz (Other drug)	St	tarted:	Rea		sleen			
z (Othor drug)			Rou	Son. Openino disordero of	Sicop			
	St	tarted:	Stopped:					
MESYLATE (Othe	r drug)		Rea	son:				
	Si	tarted:		Stopped:				
Investigatio	ns:							
Туре	Range	Date Tested	Result		Details			
nformation:								
	Investigatio Type	other drug) Scher drug) Scoz (Other drug)	Started: Ther drug) Started: Started: Started: Started: MESYLATE (Other drug) Started: Investigations: Type Range Date Tested	Started: Started: Started: Started: Started: Started: MESYLATE (Other drug) Started: Investigations: Type Range Date Tested Result	Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: Started: Stopped: MESYLATE (Other drug) Started: Stopped: Started: Stopped: Started: Stopped:			

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Case Number: 220345

Reported: 25/07/2006

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M Weight: 90.00

lospitalisation:	Required a visit to the	ne doctor				Age:	24	
Onset Date:	22/06/2006					DOB:	28/06/1981	
Outcome:	Recovered		28/06/2	2006	C	ausality:	Causality possible	Э
action Detai	ls:							
Medicine Det	ails:							
RISPERIDONE (Ot	her drug)			Reason:				
Databa		Ctoutoul.			Ctannad.			
Batch: SOLIAN (Suspecte	od)	Started:		Reason:	Stopped:			
Tablet	u)	800.0	Milligram	Daily		Oral		
Batch:		Started: 15		Daily	Stonned:	22/06/2006	i	
CLOPIXOL-ACUPI	IASE (Suspected)	Otarica: 10	700/2000	Reason:	оторреи.	22/00/2000		
	(212)	3.0	Dose Unspe					
Batch:		Started:	·	ĺ	Stopped:			
aboratory in	vestigations:							
Additional Inf	ormation:							
 								

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 221146	Seq: 1		Gend	ler: F		
Reported: 29/08/2006			Weig	ht: 0.00		
spitalisation:			A	ge: 36Y		
Onset Date:			DO	OB:		
Outcome: Unknown			Causal	lity: Causality possible		
action Details:				_		
Preferred Term	Severity	Report	Description	Treatment	t	
wollen tongue		Tongue and lip swe	elling diagnosed as			
p swelling		allergic reaction.				
ledicine Details: SOLIAN (Suspected)		Reason				
Tablet		Milligram Da	aily Oral			
Batch:	Started:		Stopped:			
.aboratory Investigation	ons: Range Date Teste	ed Result		Details		
Additional Information	ı :					
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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisa Onset I	nber: 222082 rted: 29/09/2006 tion: Admitted to 1 Date: 06/06/2006 ome: Unknown Details:	Seq: 1		V		0.00	
	referred Term	Severity	Rep	ort Description		Treatment	
Akathisia		Caused or prolonged inpatient hospitalisation	Severe tremor a	·	Am red	isulpride was being uced.	
Tremor		Caused or prolonged inpatient hospitalisation	olonged patient				
<u>Medicine</u>	Details:						
AMISULPRI	DE (Suspected)		Rea	ison:			
Tabl	let			(Oral		
Bat	ch:	Started:		Stopped:			
	ry Investigatio						
	Туре	Range Date Test	ed Result		Detail	S	
Date 29/09/2006	Other data			Clozaril level = 1200, Cl			

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

Re	po	rt	De	tai	ls:
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Case Number: 222418 Seq: 1 Gender: F

Reported: 12/10/2006 Weight: 0.00 Hospitalisation: Age: 51

Onset Date: 27/09/2006 **DOB**: 04/03/1955

Outcome: Unknown 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 Mi	lligram Daily		Oral
Batch:	Started:	L TERM	Stopped:	
AMISULPRIDE (Suspected)		Reason:		
Tablet	150.0 Mi	lligram Daily		Oral
Batch:	Started: 15/03/2	2004	Stopped:	0
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	500.0 Mi	lligram Daily		Oral
Batch:	Started: 15/09/2	2001	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Severity E			Weight: Age: DOB: ausality:	
		ort Description	DOB:	Causality possible
		ort Description		
		ort Description	ausality:	
				Treatment
				Treatment
I	Electrocardiogra	ım QT prolonged, terval.		
<u> </u>	moreaseu QT III	to vai.		
			I	
	Rea			
Ctanta di			Oral	0
Started:	D			0
	Rea	son:		
Started:		Stopped:		
	Rea			
			Oral	
Started:		Stopped:		
	Rea	son: Unspecified ps	ychosis	
50.0 N	Milligram	Daily	Oral	
Started: 01/06	6/2006	Stopped:		0
e Date Teste	d Result		Details	 3
		Increased QT interval.		
	Started: 50.0 N Started: 01/00	Started: Rea Started: Rea Started: Rea 50.0 Milligram Started: 01/06/2006	Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped: Reason: Unspecified ps 50.0 Milligram Daily Started: 01/06/2006 Stopped:	Started: Stopped:

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

eport Details:					
ase Number: 22501	18 Seq	: 1		Gende	er: F
Reported: 22/01	/2007			Weigh	nt: 0.00
spitalisation: Requi	ired a visit to the	doctor		Ag	e : 57
Onset Date:				DO	B : 10/06/1949
Outcome: Recov	vered			Causalit	ty: Causality possible
action Details:					
Preferred Terr	m S	everity		ort Description	Treatment
lopecia		На	irloss		ceased Amisulpiride.
ledicine Details:					
AMISULPRIDE (Suspected	d)		Reas	son: Unspecified psychosis	
Tablet		400.0 Milli		Daily Oral	
Batch:	5	Started:		Stopped:	
aboratory Investi	igations:				
.aboratory Investi	i gations: Range	Date Tested	Result	De	etails

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

Report D	etails:							
Case Num	nber: 225075	Seq: 1		Gene	der: F			
Repo	rted: 24/01/200)7	Weight: 0.00					
lospitalisa	tion:			A	.ge: 27			
-	Date: 07/08/200	06			OB : 28/04/1979			
Outco	me: Recovere	d		Causa	lity: Causality possible			
eaction [Details:				,			
	referred Term	Severity	Repo	ort Description	Treatment			
Vision blurr	ed	prolonged	stiffness, fall in b under arm rash.	l, blurred vision, muscle athtub, viral infection,	Amisulpride, anti-viral medication and antibiotics.			
Fall		Caused or prolonged inpatient hospitalisation						
Musculoske	eletal stiffness	Caused or prolonged inpatient hospitalisation						
<u>Medicine</u>	Details:							
SOLIAN (Su	spected)		Rea	son:				
Bat	ch:	Started:		Stopped:				
	ry Investigat		ad Pasult		Dotaile			
Date 24/01/2007	Type Neutrophils	Range Date Testo 09/08/200			Details			
24/01/2007	Neutrophils	07/06/200						
24/01/2007	White blood cells	11/08/200						
24/01/2007	White blood cells	09/08/200						
Additional Information:								

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Case Number: 225075

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Reported: 24/01/2007		Weight: 0.00				
Hospitalisation:			Age : 27			
Onset Date: 07/08/2006		DOB : 28/04/1979				
Outcome: Recovered		Caus	ality: Causality possible			
Reaction Details:	T 0 " T					
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					
Madiaina Dataila:			_			
Medicine Details: SOLIAN (Suspected)		Reason:				
GOLIAN (Guspoticu)		Nouson.				
Batch:	Started:	Stopped:				
Laboratory Investigations	:					
Additional Information:						
oport Pun : 04/06/2007 - 04:11PM - Da	tabasa: pusima02	ADDS004	David 200 of 270			

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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: 225161 Reported: 29/01/2007 Hospitalisation: Onset Date: 02/01/2007 Outcome: Recovered	Seq: 1	02/01/2007	Ag DC	er: M nt: 90.00 ge: 19 DB: 27/03/1987 ty: Causality probable
Reaction Details: Preferred Term	Severity	Report De	ecription	Treatment
Priapism		Priapism	•	Required treatment in ED.
Medicine Details: AMISULPRIDE (Suspected)	200.0	Reason:	Unspecified schizophro	enia
Tablet Batch:	Started:	Milligram Daily	Oral Stopped:	
Laboratory Investigation				
Date Type	Range Date Test	ed Result	D	etails
	<u> </u>			

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

02/2007 quired a visit to the 01/2007 t yet recovered	q: 1		Age	:: 95.00 : : 21
quired a visit to the 01/2007 t yet recovered	doctor		Age	: 21
/01/2007 t yet recovered	doctor			
t yet recovered			DOI	
·				3: 18/11/1985
·			Causality	: Causality possible
erm S	Severity	Repo	rt Description	Treatment
	lov	v grade. Grade	low- noticed by patient &	
: :				
		Reas	on:	
	Started:		Stopped:	
cted)		Reas	on:	
	Started:		Stopped:	0
		Reas		
	15.0 Mil	ligram		
		3	,	
stigations:				
	Date Tested	Result	De	ails
	stigations:	S: cted) Started: cted) Started: 15.0 Mil Started:	Started: Started: Reas Started: Reas 15.0 Milligram Started: Started:	Started: Stopped: Cted) Reason: Started: Stopped: Started: Stopped: Reason: Othr&unspec metabolic 15.0 Milligram Daily Oral Started: Stopped:

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

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:225533Seq: 1Gender: MReported:07/02/2007Weight: 85.00Hospitalisation:Required a visit to the doctorAge: 48

Onset Date: 02/11/2006 Age: 48

DOB: 23/06/1958

Outcome: Recovered 21/11/2006 Causality: Causality possible

Reaction Details:

teaction betails.								
Preferred Term	Severity	Report Description	Treatment					
Oedema peripheral		Patient had swollen lower legs with red itchy skin within a week of using Solian.	Drug ceased.					
Erythema								
Pruritus								

Medicine Details:

Medicine Details:						
SODIUM VALPROATE (Other drug)			Reason:	Unspecifid affe	ective psychosis	
	1.5	Gram	Daily			
Batch:	Started:		L TERM	Stopped:		
SOLIAN (Suspected)			Reason:	Unspecifid affe	ective psychosis	
Tablet	200.0	Milligram	Daily		Oral	
Batch:	Started: 02/	11/2006		Stopped:	09/11/2006	

Laboratory Investigations:

Date	Туре	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:
 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:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain (40kg in 4 months), prolactin increased, appetite increased, amenorrhoea.	
Amenorrhoea			
Blood prolactin increased			
Increased appetite			

Medicine Details:

SOLIAN (Suspected)		Reason:	Unspecified psychosis
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2006		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Magnetic				Pituitary gland enlarged on MRI.
	Prolactin	<300			Prolactin 3,000, normal

Additional Information:

Patient was started on 400mg Solian, then reduced to 200mg and then 100mg.

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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:
 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	Туре	Range	Date Tested	Result	Details
22/02/2007	Creatine kinase				CK "very high"

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: 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:

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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: 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:

Cuction Betails.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		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.
Choking			
Dyspnoea			
Laryngospasm			
Salivary hypersecretion			

Medicine Details:

VENLAFAXINE HYDROCHLORID	E (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	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous accute dystonic reaction to amisulpride 09/06 suspected.

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

eport Details: case Number: 226808	Seq: 1		Gender:	F	
	о е ц. ∣				
Reported: 21/03/2007 spitalisation:			Weight:		
Onset Date:			Age: DOB:		
Outcome: Unknown			Causanty:	Causality possible	
action Details:	Coverity	Danart F) a comination	Tractment	
Preferred Term achycardia	Severity		Description	Treatment	
CityCardia		atient experienced	tacriycardia.		
edicine Details: OLIAN (Suspected)		Reason:			
Tablet	30.0 Mil	ligram	Oral		
Batch:	Started:		Stopped:	0	
		Pagult	Detai	s	
.aboratory Investigatio	P INS: Range Date Tested	Result	Detai	S	



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

Report Details:

Case Number:226923Seq: 1Gender: MReported:23/03/2007Weight: 56.00Hospitalisation:Admitted to hospitalAge: 13

Onset Date: DOB: 24/01/1994

Outcome: Unknown Causality: Causality possible

Reaction Details:

t todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		ago, have noticed consistently higher platelets.	Incidental finding, no treatment required. NB Solian (amisulpride induced higher prolactin level.)
Hyperprolactinaemia Platelet count increased			

Medicine Details:

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	Туре	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:

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